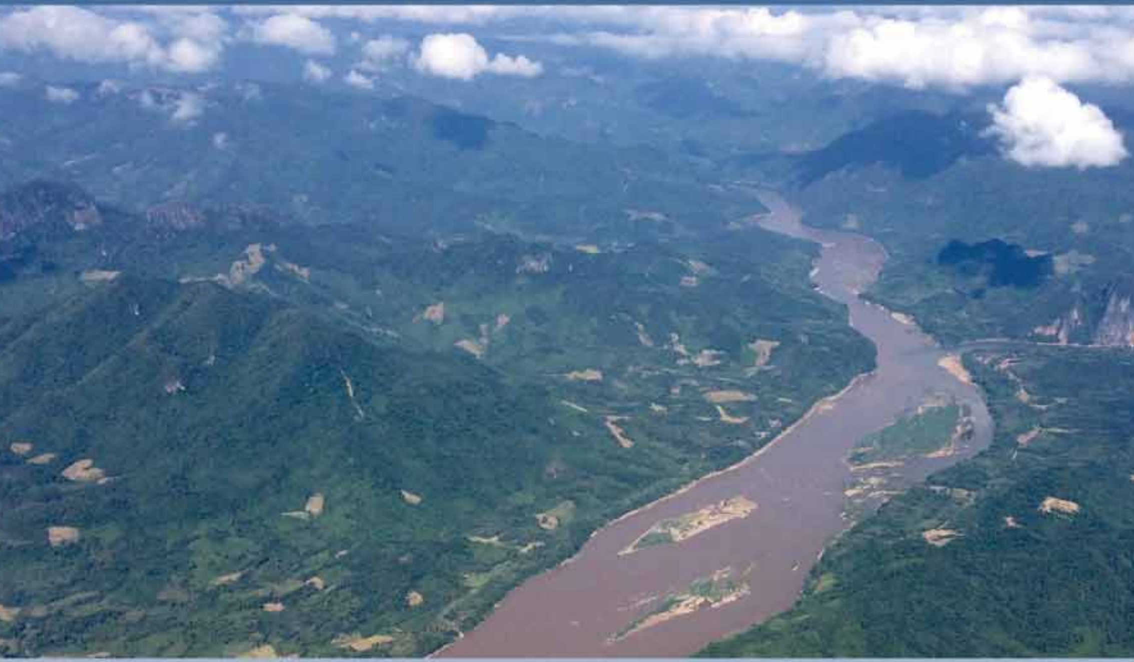
Ethical Research Committee
of the University of Health Sciences of Laos
IRD Advisory Committee on Deontology and Ethics



# The Paths of Ethics in Research in Laos and the Mekong Countries

French National Research
Institute for Sustainable
Development

Institut de Recherche
pour le Développement
FRANCE

# THE PATHS OF ETHICS IN RESEARCH IN LAOS AND THE MEKONG COUNTRIES

This book may be cited as:

Moulin A.M., Oupathana B., Souphanthong M., Taverne B. (Eds.) 2018. *The Paths of Ethics in Research in Laos and the Mekong Countries–Health. Environment, Societies*. Ethical Research Committee of the University of Health Sciences of Laos, IRD Advisory Committee on Deontology and Ethics. Marseille et Dakar, Éditions de l'IRD and L'Harmattan-Sénégal, 178 p.

# The Paths of Ethics in Research in Laos and the Mekong Countries

## Health, Environment, Societies

*Edited by Anne Marie MOULIN,*
*Bansa OUPATHANA, Manivanh SOUPHANTHONG,*
*and Bernard TAVERNE*

This volume developed out of the colloquium
“Ethics in Research for International Development:
Health, Environment, Societies”
held in Vientiane on 26 and 27 October 2015.

It is published under a joint initiative
of the Ethical Research Committee of the University
of Health Sciences of Laos and
the Advisory Committee on Deontology and Ethics of the French
National Research Institute for Sustainable Development (IRD)

2018

French National Research Institute for Sustainable Development
IRD
Institut de Recherche pour le Développement
FRANCE

*Editorial coordination:*

Marie BAUDRY de VAUX and Bernard TAVERNE

*Translation into English and French:*

Sharon CALANDRA, Michèle HANSEN, and Jean-Marc POISSON

*Layout and typesetting:*

Charles BECKER

*Cover illustration*

Photograph: © Louis Gabaude

This volume is also published by L'Harmattan-Sénégal in French

under the title:

*Les voies de l'éthique de la recherche au Laos et dans les pays du Mékong*

10 VDN, Sicap Amitié 3, lot. Cité Police
Dakar, Sénégal
http://harmattansenegal.com
senharmattan@gmail.com

ISBN : 978-2-343-14165-7
EAN : 9782343141657

44 Bd de Dunkerque
13572 Marseille Cedex 02
http://www.ird.fr
editions@ird.fr

ISBN : 978-2-7099-2624-9

# Contents

# Acknowledgments

We would like to express our thanks to all those who helped make this book a reality:

- The participants in “Ethics in Research for International Development: Health, Environment, Societies, in the Countries of the Greater Mekong Region,” an international colloquium held in Vientiane, Laos on 26–27 October, 2015.

- The institutions that organized the colloquium: the Ethical Research Committee for the University of Health Sciences of Laos and the Advisory Committee on Deontology and Ethics at the French Institut de Recherche pour le Développement

- The institutions that supported the symposium: the University of Health Sciences of Laos, the Agence universitaire de la Francophonie, the Service de Coopération et d’Action Culturelle of the French Embassy in Laos, IRD’s SELTAR regional pilot program (“Risks to soil, water, coastal waters, and societies in South and Southeast Asia”), and the Institut de Recherche pour le Développement.

- Marie Baudry de Vaux, Chargée de Mission, Advisory Committee on Deontology and Ethics at the French Institut de Recherche pour le Développement from 2012 to 2018, for the courage, talent, and unflagging devotion she brought to the Committee and this book project.

- Sharon Calandra and Charles Becker, for their ability to translate and prepare this book for publication under a tight deadline without losing their patience or good humor.

* * *

# *Preface*
# Ethics: A Cultural Revolution or an Excuse for Conformity?

## Didier SICARD*

Holding a colloquium in the Lao People’s Democratic Republic on the ethics of clinical and environmental research seemed as necessary as it was revolutionary. But aren’t there more pressing priorities for economic and health development than reflecting on ethical issues? Is it all that important?

Paradoxically, not only is it very important, but the “ethics weapon” is the best key to sustainable development and health. The Institut de Recherche pour le Développement (IRD) and the University of Health Sciences of Laos understood this before the rest of the world by conceiving of this topic for an international colloquium. Clearly, the West offers no lessons in this area because of its endless insistence on relegating ethical issues behind power and performance strategies!

Herein lies the importance of this original colloquium, addressing these issues head-on from the Southeast Asian, and especially Lao, perspective.

In a way, I embody these contradictions in research ethics as they arise in the Lao People’s Democratic Republic. In the 1970s, when little attention was paid to ethics, it seemed perfectly natural to me to conduct studies on hemoglobin by asking nurses to take blood samples for epidemiological purposes to differentiate the various forms of hemoglobinopathies. This enabled me to conduct a survey that, while not exhaustive, at the very least discovered that Laos was among the world’s countries most affected by alpha-thalassemia, which was a heavy burden. No patient consent was requested, no explanations were given. The samples were sent to Paris for direct delivery via the Air France pilots. What another time! The results arrived a few days later, and I gave the name *Wat Sisaket* to a hitherto unknown, new form of G6PD (glucose-6-phosphate dehydrogenase) deficiency[1] and shared its discovery at an international conference in Japan.

---

* Professor of Medicine at Paris Descartes University, former President of the National Consultative Ethics Committee (CCNE) for health and life sciences in France.

[1] An enzymatic deficiency of red blood cells.

Upon returning to France, I became aware of my cavalier attitude, and with deeper reflection I began to teach ethics at a time when it was not part of the curriculum.

In 1999, President Jacques Chirac appointed me president of the National Consultative Ethics Committee of France, and since then ethical reflection has been at the heart of my scientific and medical pursuits. In the 2000s, I returned to Laos as a member of the Board of Directors of the Institut Pasteur and met the Director, Paul Brey, who fully shares this vision and puts it into practice, which is rare! I participated in epidemiological studies conducted before and after the filling of the Nam Theun dam. A problem arose when obtaining consent from individuals before taking samples, even though sampling was minimally or non-invasive. Could the village head or the head of household substitute their approval for individual consent from each family member? The Lao culture seems adapted to this. However, ultimately international regulatory documents governing ethics have declared that each individual should be addressed. We made three successive requests to the inhabitants for consent: head of the village, heads of household, and individuals. And it is true that the individual consent form is by far the most common means for collecting assent from all participants. The situation caused by this experiment was the topic of a letter in the journal *Nature*.[2]

Thus, I discovered what would be my ethics “road to Damascus” in Laos, the site of my conversion.[3] It was in Laos that I began applying ethics to real-life situations but also taking the risk that an ethical stance might overreach, exposing indifference to the study’s social and environmental conditions. This embodies the importance of the colloquium and this manual, which reports on key findings. For perhaps the first time, a colloquium has made an in-depth and lucid inquiry into the problems surrounding ethical reflection in a country in the global South.

It is not a natural coincidence that 90% of the world’s patients are in the global South and 90% of medicines are in the North or that 80% of the North’s waste is dumped the South. It is because of economic inequalities. The issue of money is indeed fundamental. How do we ask patients or their families to cover the costs of an extra day in the hospital for a clinical study? How do we ignore ritual practices that leave science in contested territory? How do we refuse a proposal for a therapeutic trial that will only benefit the North but that subsidizes researchers in the South? How do we avoid losing the freedom of consent when the study provides a drug that is usually inaccessible? How do we broach fair and honest information about a disease

---

2. Guerrier G., Sicard D., & Brey P.T. (2012). Informed Consent: Cultural Differences, *Nature*, *483*(7387): 36–36.
3. An allusion to the illumination of Saint Paul, persecutor of Christians (editors’ note).

that is considered dishonorable (HIV, leprosy, or tuberculosis)? How do we establish a biobank for epidemiological purposes while maintaining confidentiallity? How do we ensure that research that considers the interests of those who donate their bodies is properly valued? How do we study the harmful effects of pesticides when the economy depends on them? All of these questions have been stripped down to their essence and explored in the following chapters.

Several conclusions can be drawn from these reflections. The first is that despite universal imperatives, ethics is above all local. The second is that ethics must be able to confront economic issues that do not tolerate even a hint of ethical thinking. In a nutshell, research must construct its own local integrity on a solid foundation of ethics rather than using ethics as window dressing—or worse, as an excuse for conformity.

* * *

# Pathways through Ethics in Laos and the Mekong Region

## Manivanh SOUPHANTHONG,[*] Anne Marie MOULIN[**]

This book is the product of an encounter that took place in Vientiane in 2015 between the Ethics Committee of the Institut de Recherche pour le Développement (IRD) and the University of Health Sciences of Laos (UHS) at the first ever colloquium on ethics in Laos. In his opening remarks, the President of the University called this a remarkable event. Researchers and students from the Upper Mekong, Thailand, Vietnam, and Laos gathered together with their counterparts from France, Switzerland, and Brazil. The countries of the Mekong Delta represent an extremely dynamic region in which research and academic activity has grown exponentially in recent years.

Research in the areas of health, the environment, and the social sciences always raises questions, particularly with regard to the imbalance of knowledge and power between scientists and research subjects. Such questions are broadly philosophical: they touch on the source of knowledge, through formal training and personal experience; the goals of scientific experimentation; and how to ensure that the benefits of science will be equally distributed. They cover respect for individuals, especially those who are sick, and how to maintain balance in the living world and in the communities that form it. The fact of human suffering underlies our most basic contemplation of the way of the world and how it should be viewed: Unjust? Evil? Should we adapt? Resist? Seek to improve it?

Health sciences, an area of study at the UHS in Vientiane, encompasses research on much more than medicine alone, to include the natural and built environment, resources for life and survival, and the domestic and wild animals that share these environments with humans. We have adopted this broad view in this text, to cover ethics in clinical and public health research as well as in environmental and social science research.

---

[*] Physician, President of the University of Health Sciences' Ethical Research Committee, Lao PDR.

[**] Philosopher, Physician, Director Emeritus of Research at the CNRS (UMR SPHERE), Chair of the IRD Advisory Committee on Deontology and Ethics, France.

Throughout the world, humans face moral issues about their work. Reflection is not the prerogative of the wealthy alone: Epictetus, a sage of Ancient Greece, was born a slave. Yet in the twentieth century this issue has increasingly fallen to the professional category dubbed “researchers.” That century also witnessed drifts and diversions away from core activities, especially in health and clinical research, i.e., research performed on the bodies of patients. Various tragic events have roused public opinion over the years, exposing the fallibility or moral indifference of those scholars who seek to advance understanding, a pursuit they feel is a higher common good and, as such, bestows them with the authority to engage in certain behaviors, such as using human beings as mere means for exploring the laws of nature. A school of thought developed in the West specifically devoted to the ethical challenges of medical research, in which human experiments have often been conducted on those incapable of giving consent, especially in certain social groups and poor countries. A host of texts have been developed to address this issue, from the 1979 Belmont Report in the United States to the World Medical Association’s Declaration of Helsinki in 1964 and its numerous subsequent revisions, which in recent years have been more broadly applied to Africa and Asia.

Scientific research ethics is contemporary with modern research, from atomic physics to chemistry, microbiology to genetics, and more recently ecology and environmental science. Ethics issues have thus expanded to include aspects of research beyond the purely medical, which is why we decided to include the topics you find herein.

One does not spontaneously “turn to ethics.” Ethical reflection requires an inward-looking effort, a kind of conversation with oneself. It is an inquiring, open attitude that must be acquired over time. It bears repeating that science is an ethical process in and of itself: working to advance knowledge that may benefit everyone is, after all, a laudable exercise. There are several proverbs in the Muslim world urging us to seek knowledge “from cradle to grave” and “even unto China,” long viewed as the edge of the world. There are myriad names among the various languages of the Mekong region for learned people who transmit knowledge and put it into practice. We met in Vientiane to reflect on how science can be incorporated into materializing and appreciating the beauty, bounty, and balance of the world here in Southeast Asia.

In Laos, medicine is a prestigious profession and medical knowledge is glorified. Those with medical degrees receive the title “Doctor” or in Lao, *Thane mor*. This distinguished title is also expected to reflect physicians’ moral qualities and devotion to human life, qualities that elevate them above common mortals. In practice, the choice of the medical profession is often dictated by family tradition but may also reflect the desire for wealth and privileged status.

The ethics of scientific research have significantly evolved in the past 50 years. The current trend, especially in the United States, is to view ethics as a matter for an entire bureaucracy of specialists. A vast literature is available, composed of the founding texts and glosses thereof that set out procedures and codes of conduct. Our event in Vientiane was intended to be an opportunity for colleagues from Laos and the Mekong region and the West to exchange ideas and experiences born from their shared scientific backgrounds on urgent issues that cannot be resolved by mechanically applying a code of conduct. More than a specialization or an add-on to optional training, ethics is above all the lifelong work of personal contemplation rooted in practice.

Didier Sicard, the former Chairman of the National Consultative Ethics Committee in France with extensive personal experience in Laos, opens this volume. He reminds us that no informed consent form, regardless of how detailed it might be, releases researchers from their obligation to inform prospective participants. We must always keep in mind that a true exchange is needed, and must take whatever time is necessary to adapt to others' points of view and speak in a language they understand. This is a far cry from administering a quick questionnaire, which could be poorly translated and not well understood. The mechanical application of a form or ethical "recipe" is a useful exercise, but must always incorporate an element of deeper reflection. Progress in ethics is not the simple accumulation of formulas; it is a deeper understanding of a state of mind, an original culture of exchanging and critically examining knowledge.

In Laos, the recent organization of ethics committees and the advent of specialized training might lead us to believe this is the birth of bioethics, if we did not already know that there is no radical beginning here. These developments mirror those elsewhere in the region of millennial thinking on the morality and harmony of human behavior and the world as a whole.

Like academic institutions everywhere, the Laos UHS strives to further ethical thinking among its student population to create an "ethical reflex" early in the training of future health professionals. Such a culture of ethics is increasingly important, and the UHS would like to highlight the importance of the course entitled "Revolutionary Moral Merit" (in Lao, *Khunsombat silatham pativat Koonsombat sila dhamma pativad*). The UHS established a new committee in 2014 specifically focused on the area of medical ethics as a subset of research ethics. The Ethics Committee for university research is responsible for analyzing the ethical aspects of university research projects on the basis of their reference guidelines, following up on their achievements, and disseminating their findings. It is the only body with this responsibility within the UHS; as of this writing, it has reviewed over 80 student-led projects. To strengthen the ethical evaluation of research, the university's strategic plan includes a plan to introduce training activities and teaching modules on ethics and to adopt a common internal reference framework of guidelines.

Familiarity with current international codes of conduct is only one element in training young researchers. They are embarking on a lifetime of learning about situation-based ethical intention, and thus will continually question themselves about their professional activities and how those activities affect the people around them. There has been much discussion about the distance between so-called pure science in the laboratory and applied science in the field. Louis Pasteur, our bodhisattva, cut to the heart of this issue when he said “there is no such thing as science and applied science; there is only one science, which is applied in different contexts.”

A culture of ethics requires a relationship with other disciplines: a form of opening to the Other. Interdisciplinarity involves active exchanges between people from different educational backgrounds and openness to all facets of issues raised by research. In the practice of medicine in Laos, for example, a physician must consider any manner of issues concerning the natural and social environment as well as material or psychological problems patients may face.

One central question in medical ethics is how much health professionals are paid. Ancient Greeks and Romans debated the legitimacy of remuneration for physicians and the immorality of having a patient pay, since patients are by definition in a situation of hardship. Physicians to Western royalty and aristocracy provided free treatment to the poor to counterbalance their privileged status. Medicine later came to be the domain of the bourgeois or of landowners with sources of revenue that allowed them to not charge their clients. Treating the poor for free was an obligation. In Laos, authorities encourage physicians and teachers to spend time working in rural, remote, and underserved areas. These professionals are civil servants and as such receive a salary, but this is often not enough to cover their personal needs. Administrative authorities and local populations offer them recompense in the form of money, goods (rice, meat, vegetables, fruits), or services (domestic help). Rural patients pay doctors with the products of their own labor.

Transmission and communication are required both to teach and to be taught. Science cannot be the exclusive domain of a minority. It is by definition a “public good” to be protected and shared, with the understanding that such sharing will not harm recipients.

Traditional knowledge and the use of plants and other natural substances is one source of therapy. Laos and other countries in the Mekong region are home to many such healers, some of whom specialize in certain conditions. Where does this knowledge fit in the health system? Are there links between traditional healers and a university setting? Because patients often spontaneously associate hospitals with *kru* (traditional

Cambodian medicine) and mediums, how do the various professionals divide or share their rights and obligations? Should they communicate with one another, or should it be up to patients to connect them in their search to alleviate their suffering? This is a central question in Laos and many other countries in the Mekong region, in light of the effect of rituals on patients' mental state and the diversity of natural remedies used by traditional healers. Remedies provided by autochthonous plants are a veritable national heritage to be explored, especially in tribal regions, as long as exploration does not become harmful exploitation. The experiences of neighboring countries like India, with its Ayurvedic medicine, provide good illustrations of the many potential legal and economic pitfalls: wild plants may disappear, leading to impoverishment of available resources; traditional know-how is not recognized as protected by intellectual property rights; commercialization may see an associated circulation of counterfeit products; and so forth.

Science is not the only public good that must not be monopolized by a handful of people. Nature—water, air, sunlight, earth—must also be available to everyone. Jonas Salk, inventor of the polio vaccine in 1954, refused to patent his discovery, with the memorable statement "could you patent the sun?" Yet for many years water has no longer been a public good. The hoarding of water resources by the largest landowners in the world is a well-known legal situation; one sociologist of desert countries calls water "the friend of the powerful." The science that enables optimal sharing of useable water such as in the Mekong Delta could be applied internationally to resolve conflicts between countries sharing water borders in what is known as "scientific diplomacy." Air pollution has long been a literal and figurative black cloud hanging over the planet that affects us all. Preserving plant and animal diversity is another urgent issue that requires us to examine how we modulate and transform the genomes of the living world.

Once we agree that science is a public good, we realize there is an obligation to give back the knowledge that is gained from those who provide the information—patients, subject-objects of observation or experimentation, and authorities and decision-makers. Emerging diseases are combatted using information gleaned from the communities affected by them, such as those experiencing environmental upheaval from the major construction projects planned along the Mekong River.

Progress in science and new technologies has created even more specific questions. Many of the issues raised during the colloquium concerned dysfunctions in the healthcare market and the consumer-driven, mercantile direction of the medical arts. Progress can widen health divides by increasing the costs of treatment, as Mayfong Mayxay and Bansa Oupathana note. The image of Buddha and his teachings on renunciation can fuel a debate about the choices to be made in this area.

A tragic period in Laos' history occurred during the Indochina Wars, when it declared neutrality but was not able to escape the jaws of the warring parties that surrounded it. Today the country could represent an oasis of research. Its lands are home to an array of assets, especially in their biodiversity, which extend beyond the flora used in therapies that are currently being inventoried. Laos harbors an untapped wealth of observations of bacterial and viral species that remain virtually unknown, in a unique social context that Paul Brey, Director of the Vientiane Institut Pasteur, described as an urban habitat bordering wilderness, with city and countryside intermingling. Laos is also home to multiple cultures and languages that are ceaselessly evolving, so cataloging them is a continual work in progress (see the work of Yves Goudineau, IRD-EFEO and Grégoire Schlemmer, IRD), and of course we cannot forget the richness of the secular rituals associated with daily life (described in Louis Gabaude's chapter on Theravada Buddhism).

The Vientiane colloquium naturally addressed the issue of a true dialogue between the "Asian" and "Western" views of the countries in the region (e.g., Laos, Vietnam, Thailand, Myanmar, and Cambodia on the one hand and England, France, etc. on the other) to broadly recognize the common nature of all of the problems involved in applying science to the fields of health and the environment, and researching references and possible responses in the cultures of the region. During the colloquium we were only able to sketch out a comparison between various research ethics situations in the countries of the Upper Mekong. An overview of the development of ethics committees in the three ASEAN countries (Laos, Thailand, and Vietnam) provided a glimpse of the structural framework for such thinking at the institution, university, and country levels. A newsletter about research ethics in the region could broaden and sustain the passionate debates held during the conference.

Ethics is more than just a procedural safeguard. It is a critical thought process innate to us all, using a formula created and tested in each country, drawing original elements from local philosophies and cultures to explore and share. We must seek and find the often narrow, perilous path, yet recognize there is more than just a single path. Louis Gabaude reminds us of Buddha's teaching saying that, like a musician, we must discover the proper amount of tension in the strings of our instrument—neither too tight nor too loose—for it to hit the right notes.

This volume does not capture the full range of discussions at the colloquium, nor does it claim to be exhaustive. Its three sections present the principles that guide research ethics in three selected areas, illustrated using concrete cases presented by specialists. The international reference texts are found at the end of each chapter and at the end of the book. Our hope is that this book will be used as a day-to-day guide in scientific research practice, offering a range of situations completed with commentary by the authors, who focus on issues they themselves have faced.

This guide will be translated into Lao and, we hope, other languages of the Mekong region. Readers should adapt it to the situations in which they find themselves, and make notes in its margins for their own use. Experience has shown that the readers of today and tomorrow who come across this book in libraries or at book vendors will discover new problems and original solutions tested by real experience. A single stone tossed into the Mekong River will create a ripple effect that extends across the water.

May the memory of this conference resonate powerfully for years to come!

* * *

# Elements of Ethical Practices for Scientific Research Conducted in Resource-Limited Countries

**Bernard TAVERNE**[*]

Until the 1980s, scientific research conducted in resource-limited countries (RLCs) was mainly applied research, sometimes called "research for development." Its primary goal was to solve local problems to help improve people's living conditions in these countries, particularly by promoting or strengthening the capacity to meet their basic needs (such as health, education, food, and infrastructure), although this research was usually defined by foreign teams.

Since then, the landscape of scientific research in RLCs has changed considerably. In Southeast Asia, despite wide disparities between countries, some common trends embody the general direction of science policies, international collaboration, and researchers' mobility. Research is now characterized by: (i) the relationships and dependence of all countries, to varying degrees, on the science systems of the global Triad, composed of the United States/Europe/Japan; (ii) the increased mobility of scientific personnel (researchers, engineers, and technicians) and competition to attract them, as countries seek to train, attract, and retain increasingly more scientific professionals; (iii) expanding international collaborations in science and technology, global competition that has pushed countries to create networks and promote transnational research projects; and (iv) the incorporation of science policy into national development policy in nearly all countries.[1]

This shift in RLC-based scientific research towards the Global Scientific System has had consequences, however. Biological resources (plants, animals, humans) and research itself (clinical trials, GMOs) have become commodities. When research data are circulated around the globe, questions may be raised about who exactly owns the various biological collections and databases. Research has become privatized, and thus subject to competitive strategies (both individual and collective), forcing foreign institutions to

---

[*] Anthropologist, Physician, IRD UMI 233, Inserm U 1175, University of Montpellier, France.

[1] Turpin, T., Woolley, R., Intarakumnerd, P., & Amaradasa, W. (2010). Southeast Asia and Oceania. In S. Schneegans (Ed.), *UNESCO science report 2010: the current status of science around the world* (pp. 437-463). Paris: UNESCO.

choose between selecting the highest bidder or promoting local establishments. Funding and evaluations are based on global scientific criteria (publications, patents, and economic profitability). Lastly, research teams are transnational, composed of a scientific diaspora.

"Development" is obviously a priority in the Millennium Development Goals (MDGs) and the Sustainable Development Goals (SDGs) for RLCs. Scientific research is viewed as a lever for economic and social development for these countries. Yet, the priority objectives for scientific research obviously also respond to many other economic (or political) issues that may influence how research objectives with high economic potential for their sponsors are defined without directly targeting development in the country where this research is taking place.

Inequalities in decision-making power between countries, institutions, and researchers involved in transnational research in RLCs mean ethics must be at the forefront when conducting scientific research in these countries. Several generations of researchers at the Institut de Recherche pour le Développement (IRD), from a broad range of disciplines, have reflected on the ethics of scientific research practices for decades.[2,3,4] Their reflection led to the development of a Guide on Good Research Practices that specifies the main ethical principles for scientific research in RLCs.[5]

From a general perspective, research should respect the following principles as a minimum: (i) social justice and equity; (ii) compatibility with local needs; (iii) an acceptable cost/benefit ratio for individuals and communities; and (iv) scientific relevance and quality.

Application of these principles should result in: (i) a fair and equitable partnership; (ii) relevant research objectives (of high scientific quality); (iii) participation of the populations concerned; and (iv) equitable distribution of benefits (including ownership of acquired collections and data). Let us briefly review these four points.

## 1. A fair scientific partnership

For transnational teams, the economic and human resource gap between teams, the differences in researchers' status in their respective countries, and varying levels of participation in global research networks produce asymmetric power relationships that hamper the decision-making

---

[2] Waast, R. (Ed.). (1996). *20th century sciences: beyond the metropolis: The keynote speeches*. Marseille: ORSTOM.

[3] Bonnet, D. (Ed.). (2003). *L'éthique médicale dans les pays en développement. Autrepart*, (28). Paris: Éditions de L'Aube/IRD.

[4] Vidal, L. (Ed.). (2014). Expériences du partenariat au Sud : Le regard des sciences sociales. Marseille: IRD Éditions. doi:10.4000/books.irdeditions.9213

[5] CCDE. (2012). *Guide des bonnes pratiques de la recherche pour le développement*. Marseille: IRD.

power of RLC teams. These teams then might appear to be merely involved in implementing programs that were decided upon elsewhere.

A fair scientific partnership assumes (i) collaboration of researchers and national and foreign institutions when deciding on goals, priorities, and choices for scientific programming; (ii) pooling of human, material, and financial resources to conduct research through joint efforts; and (iii) strengthening of local scientific communities through training, especially to promote local researchers' inclusion in international research networks.[6]

## 2. Relevant research objectives

Research objectives must be relevant to the country where the research is carried out. In other words, research must respond to issues directly related to the needs of the country where it is conducted, leading to crucial questions. Specifically, who defines the research topics and which arguments underlie their selection? Is this based on the interests of the research sponsor? On foreign or national investigators' interests? On national development priorities?

These questions arise, for example, when clinical trials involve diseases that would not be considered a public health issue in that county, suggesting that these trials amount to off-shored experimentation—or in blunt terms, patient exploitation.[7]

Research objectives should be relevant for a given country. Topics should be defined with the input of representatives from the RLC(s) involved and approval from government authorities, which may create difficulties when these officials lack interest in a disease that has a genuine impact on people's well-being (which is sometimes the case for HIV/AIDS, leprosy, or diseases that are rare but serious or that affect marginalized groups). The research must clearly support the needs of the country where it is conducted (again, this obviously means knowing who defines the objectives and if the influence of various lobbies outweighs public input. Research should also take into account the state of global scientific knowledge; and, lastly, the quality of this research must meet international criteria (Good Clinical Practice).

## 3. Local community participation in the research process

For a long time, individuals and populations have been viewed as mere "study objects" for research. Consequently, they have been poorly or uninformed about the research objectives, goals, and methods. This lack of

---

[6] CCDE. (2012). *Éthique du partenariat dans la recherche scientifique à l'IRD*. Marseille: IRD.

[7] Shah, S. (2006). *The body hunters. Testing new drugs on the world's poorest patients*. New York: New Press.

participation fostered misunderstandings between research teams and communities, which in turn led to distrust and even rejection of research teams. Participation of the population being studied is extremely important, and requires serious thought and specific approaches.

Local communities' participation in the research process assumes: (i) fostering the communication and flow of information between research teams and the study population; (ii) clarifying the goals and methods of the research; and (iii) promoting the population's participation in the research process, which proves challenging when this population must focus on other pressing concerns. Theoretically, it boils down to: working *with* and *for* the people.

In the early 1990s, in Western countries, people living with HIV united to set up patient associations. These associations campaigned to address the needs of AIDS patients, accelerate the search for new treatments, improve the conditions of care for medical research participants, and increase access to new drugs. People gained knowledge and expertise inside these associations that approached or equaled that of health professionals and scientists. These "expert patients" have become contacts for scientists and public officials,[8,9] while associations played and still play an intermediary role between the research teams and the study population or specific social groups within the population. The patient-association model advocating for patient rights and consideration of their needs has gradually become widespread in most of the world's countries, especially in Asia, while also evolving for other diseases. These associations play an indispensable role in the implementation of health research. Similarly, associations representing neighborhoods, villages, regions, users of a specific service, and others are key contacts in all aspects of the research process in any field. Of course, the involvement of these experts from the general public, their role, their activities, and how accurately they represent public opinion varies greatly and must be detailed country by country.[10]

Recognition of endogenous knowledge is a form of participation by the population that can test research teams' capacity for listening and adapting to the local context.

## 4. Equitable distribution of research benefits

Who ultimately benefits from the research? Or more specifically, who receives a benefit and what is it? There is no easy answer because the

---

[8] Lestrade, D. (2000). *Act-up, une histoire*. Paris: Denoël.

[9] Dodier, N. (2003). *Leçons politiques de l'épidémie de sida*. Paris: Éditions de l'École des Hautes Études en Sciences Sociales.

[10] Bureau-Point, E. (2016). *Les patients experts dans la lutte contre le sida au Cambodge, Anthropologie d'une norme globalisée*. Aix-enProvence: Presses universitaires de Provence.

impact may be long term, leading many scientists to claim they have the right to develop fundamental research with no immediate utility for RLCs.

This may include research in theoretical mathematics or in the humanities or social sciences, linguistics, or archeology, to name a few.

– Do participants, or the population they represent, draw a direct or immediate benefit from participating in the research? Or will they draw a medium- or long-term benefit? If a drug trial proves beneficial, will the population have access to the drug once the trial is over?
– How does/will the research benefit the team of local researchers (compensation, recognition, career advancement)?
– How does/will the research benefit local research institutions (technology transfer, strengthening local researchers' skills, development of research infrastructure)?

Equitable distribution of research benefits assumes certain outcomes, such as: (i) access by participants and populations to knowledge from innovations introduced through research; (ii) co-publication/co-authorship of findings by all involved researchers; (iii) respect of ownership of biocollections and databases from the country where research is conducted, in easy-to-control conditions; and (iv) applications for patents or licenses for the benefit of all partners.

## Conclusion

This brief overview does not of course fully encompass the full range of issues to consider about the ethics of research in RLCs. Ethics guide practice, pointing us toward actions that are "good." It is clear that research practices are determined by strong structural aspects that sometimes—or often—disregard ethics; yet this should not prevent us from defining ethical research practices. Ethical principles are essentially voluntary standards without the weight of any legal regulations, but in recognizing them we imbue them with the meaning of law and thus help monitor and regulate practices.

Integrating scientific research conducted in RLCs into the global science system has raised new ethical issues, resulting in deeper reflection about research ethics. Reflecting on ethics allows us to develop a thoughtful and critical perspective on our practices and is an integral part of scientific research. Just as our understanding is constantly evolving, so should our thinking on the meaning of our research practices and our individual and collective responsibilities.

* * *

# Bioethics in a Buddhist Context

## Louis GABAUDE[*]

Health care, medical research, and bioethics demand a deep understanding of and even warm empathy towards patients and families. This is why I have been asked to share the worldview of Southeast Asian people, often summed up as being "Buddhist." In fact, a unique, fixed essence of a "Buddhist context" is no easier to find than a unique or fixed essence of "Buddhism." Moreover, my description of the "Buddhist context" may be misleading. It may not be as Buddhist as we think, or it may be Buddhist, but not in the way we think of it in the West. Yet, if "Buddhist contexts" are different from one continent to another, or from one country to the next, or even, from one social class to another, there are certainly some factors we can identify as generating a vision of life that differs from that which is Christian or Muslim. This may not be true for ethnic groups that have never been exposed to Buddhism, but we must not forget that many of their "non-Buddhist" beliefs still remain active in the beliefs of most who pretend or are considered to be "Buddhists." So the actual and mixed Buddhist vision of life—i.e., of illness, aging, and death—that animates Southeast Asian minds should in any case be taken into account by health theoreticians and practitioners eager to confront their ethical concerns posed by the field in which they work and by the people with whom they work.

In order to identify these generative or matrix factors, we will proceed in two steps: First, we will look into the specific Buddhist approach to medicine and then to other systems found in the Southeast Asian context.

### The original "Buddhist context"

In the examination of the contemporary Buddhist context, we must not forget to look back at its historical foundations. Its past, its source, its roots, regardless of their distance and deviance, have not only formed the basis and inspiration for the present state of minds but, as in all major religions, provide reference to founding models, particularly in times of changes and crises. Far back, 2500 years ago in Northern India, we find many traces of "medical" images in the description of the Buddha's original intentions and discourses. At that time, we might have heard him saying,[1] rather boldly: "I am

---

[*] Historian of Religions, Professor Emeritus, École Française d'Extrême-Orient.

[1] When I write something like "the Buddha was saying... ," I mean: "Buddhists have recorded and believe that the Buddha was saying...."

[...] an unsurpassed doctor and surgeon."[2] And we could ask: Which kind of a doctor? Which kind of a surgeon? How can we explain such a claim?

Son of a king, Prince Siddhartha, the future Buddha, was not educated as a doctor. He was instead purposely raised in complete comfort, kept away from any misery and suffering, so that—at least according to his royal father's plan—he would remain attracted and bound to the pleasures of a world without suffering.

However, one day, the prince sneaks out of the palace and discovers a sick man, an old man, a corpse, and a renouncer: four encounters often called "divine messengers" in Buddhist literature. Let us note right away that the first three encounters—illness, aging, and death—are the proper fields of medicine. At 27, this prince, raised like a modern spoiled petit bourgeois, is surprised by the rather "intellectual" discovery that life actually involves illness, aging, and death, i.e., suffering. This is reported to be such a trauma for him that he goes through what modern psychologists would probably call a major depressive episode. Back at his palace, late at night, he contemplates his sleeping musicians, singers, dancers, and concubines in lascivious poses, and he is disgusted! He then looks at his naturally beautiful and loving wife, at his newly born son, and, after—or perhaps because of—a 10-year marriage, concludes that all this comedy really sucks!

The discovery of suffering outside the palace makes the prince realize that pleasures within the palace are vain. So vain that he decides to quit, to renounce his status, his power, his comfort, his duties, his wife, his son, his great future... everything. There we have the first DNA strand of Buddhism: inner suffering cannot be solved with external and worldly responses.

Throughout human history, "killing" one's father and rejecting one's family have been common features for building a self and becoming an adult. However, in India, this antisocial process is not simply the temporary symptom of a temporary crisis but has been paradoxically socialized by the recognition of groups of professional "renouncers" who reject all social responsibilities, duties, and rights—usually related to profession, marriage, and class or caste—in the search for their individual, inner, mental liberation. Peaceful rebels against the social order, they continue to wander today throughout India, as they did 500 years before our common era.[3] The French sociologist Louis Dumont has even suggested that these renouncers, the Buddha being the most famous ideal-type, by choosing a life outside that imposed by their social status and caste, have been the precursors,

---

[2] Source: *Itivuttaka*: The Group of Fours, Iti 100; Translated from the Pali by Thanissaro Bhikkhu, http://www.accesstoinsight.org/lib/study/beyondcoping/medicine.html.

[3] Levy, P. (2010). *Sadhus: Going beyond the dreadlocks*, New Delhi: Prakash Book Depot.

indeed the inventors of modern Western individualism.[4] If this is true, we cannot help but note it is a long way from, on one side, a free homeless individual, like the Buddha, who, for the right to beg for his daily food and be freed from any other social duty, abandoned all his social rights, and on another side, the modern, Western free individual who, sometimes, tends to expect everything from society in the name of his individual rights.

Far from being only a picturesque scene in a pious tale, the Buddha's tiptoeing out of the bed chamber and flying out of the palace with the help of gods, was actually not only a primal act, setting the conditions for his possible enlightenment, but also, a structuring of a scene that conditioned modern minds obsessed by individual rights.[5] In other words, contemporary Buddhist monks tell us long stories of the ways in which humans have reacted to social constraints and duties in history. They are the reflexive, but opposite, images of our own individualism.

Unlike most of the renouncers of his time, the Buddha left two important living legacies: a corpus of articulate teachings[6] and a rule for communities of renouncers.[7] We can look at them again from a medical perspective.

After a few years of wandering with various spiritual masters, Siddhartha the renouncer awoke to his supreme truth and came up with a diagnosis regarding life. He expressed it in a form similar to, albeit different from, the Indian Ayurvedic medical theory: "The best physician—one fit to treat a king—is he whose knowledge is fourfold: the cause [*hetu*], symptom [*liṅga*], cure [*praśamana*], and non-recurrence [*apunarbhava*] of diseases."[8]

---

[4] Dumont, L. (1959). Le renoncement dans les religions de l'Inde. *Archives de sciences sociales des religions*, 7, 45–69. http://www.persee.fr/doc/assr_0003-9659_1959_num_7_1_1695. Dumont, L. (1983). *Essais sur l'individualisme : une perspective anthropologique sur l'idéologie moderne*. Paris: Éditions du Seuil. English version: Dumont, L. (1986). *Essays on individualism. Modern ideology in anthropological perspective*. Chicago: University of Chicago Press.

[5] For discussions on Dumont, see: Madan, T. N. (Ed.). (1988). *Way of life: King, householder, renouncer. Essays in honour of Louis Dumont*. Delhi: Motilal Banarsidass, 2nd ed.

[6] Readers interested in exploring concise presentations of these teachings may refer to a myriad of books among which two stand out: Rahula, W. S. (1974). *What the Buddha taught* (revised edition) with a Foreword by Paul Demiéville and a collection of illustrative texts translated from the original Pali. New York: Grove Press. http://www.ahandfulofleaves.org/documents/What%20the%20Buddha%20Taught_Rahula.pdf; Gombrich, R. (2009). *What the Buddha thought*. London: Oxford Centre for Buddhist Studies Monographs.

[7] See: Bhikkhu, T. (2007). *The Buddhist monastic code I* (2nd revised ed.). Valley Center, CA: Metta Forest Monastery; Bhikkhu, T. (2005). *The Buddhist monastic code II* (2nd revised ed.). Valley Center, CA: Metta Forest Monastery.

[8] See the discussion in Zysk, K. G. (1998). *Asceticism and healing in ancient India: Medicine in the Buddhist monastery*. Delhi: Motilal Banarsidass, 38.

Here is the Buddha's first official teaching after his enlightenment:

> *Now this, monks, is the noble truth of stress: Birth is stressful, aging is stressful, death is stressful; sorrow, lamentation, pain, distress, and despair are stressful; association with the unloved is stressful, separation from the loved is stressful, not getting what is wanted is stressful. In short, the five clinging-aggregates are stressful.*[9]
>
> *And this, monks, is the noble truth of the origination of stress: the craving that makes for further becoming—accompanied by passion and delight, relishing now here and now there—i.e., craving for sensual pleasure, craving for becoming, craving for non-becoming.*
>
> *And this, monks, is the noble truth of the cessation of stress: the remainderless fading and cessation, renunciation, relinquishment, release, and letting go of that very craving.*
>
> *And this, monks, is the noble truth of the way of practice leading to the cessation of stress: precisely this Noble Eightfold Path—right view, right resolve, right speech, right action, right livelihood, right effort, right mindfulness, right concentration.*

While the parallel between a medical diagnosis and the Four Noble Truths is certainly striking, a medical practitioner cannot but notice important differences. The first difference is that, usually, a medical diagnosis deals mainly with physical ailments while, here, the diagnosis deals mainly with mental suffering originating in desire. This is why the translator quoted above has chosen to replace "suffering"—the standard way of translating *dukkha*—by "stress." This "mental" acceptance of "suffering" caused by desires is obvious in the following quote where the Buddha told his disciples how to explain his own message:

> *When one is not free from passion, desire, love, thirst, fever, and craving for form, then from any change and alteration in that form, there arises sorrow, lamentation, pain, grief, and despair. When one is not free from passion... for feeling... for perception... for fabrications... When one is not free from passion, desire, love, thirst, fever, and craving for consciousness, then from any change and alteration in that consciousness, there arise sorrow, lamentation, pain, grief, and despair. Seeing this danger, our teacher teaches the subduing of passion and desire for form... for feeling... for perception... for fabrications. Seeing this danger our teacher teaches the subduing of passion and desire for consciousness*.[10]

---

[9] "*Dhammacakkappavattana Sutta*: Setting the Wheel of Dhamma in Motion," translated from the Pali by Thanissaro Bhikkhu: http://www.accesstoinsight.org/tipitaka/sn/sn56/sn56.011.than.html

[10] "Devadaha Sutta: At Devadaha," *Samyutta Nikāya* 22.2, translated from the Pali by Thanissaro Bhikkhu: https://www.accesstoinsight.org/tipitaka/sn/sn22/sn22.002.than.html

The second difference is that, in common practice, a medical diagnosis is worded by a "doctor" for someone else, e.g., the "patient." Here, the patient must internalize the diagnosis for him- or herself through usually long processes of meditation coupled with ascetic life.

The third difference is that, for a physical ailment, the cure and the non-recurrence of the disease apply to external, physical, "objective" symptoms and causes. Here, the cure must begin with the discovery that suffering is not only subjective but also self-generated, that is, self-inflicted by the patient. As a contemporary master of Thai Buddhism[11] used to say: "[Mental] Suffering does not exist in nature: we do create it"; we make it up by being attached to things that do not deserve attachment.

This does not mean, however, that the Buddha ignored the reality of physical suffering because he himself was exposed to pain either from illness or injury. Texts report that, from a certain date, he was visited twice a day by his personal doctor, Jīvaka Komārabaccha who, up to the present day, remains the model of Southeast Asian Buddhist doctors and healers.

To make a wandering life possible, the Buddha ruled that, in spite of being ascetics, his monks could use four requisites: robes, food, lodging, and *medicines*. So, medicines were and are one of the four necessities permitted for homeless mendicant Buddhist monks *(bhikkhu)*. Health care for their ill brothers in monkhood should occur naturally, within certain limitations:[12] "*Bhikkhus, you have no mother, you have no father, who might tend to you. If you don't tend to one another, who then will tend to you? Whoever would tend to me, should tend to the sick*."[13]

Outside the monastic community however, exercise of medicine and chirurgy as a livelihood was forbidden for Buddhist monks by the Buddha because they are classified among the "lowly arts":

> *Administering emetics, purges, purges from above, purges from below, head-purges; ear-oil, eye-drops, treatments through the nose, ointments, and counter-ointments; practicing eye-surgery (or: extractive surgery), general surgery, pediatrics; administering root-medicines and binding medicinal herbs—he [the bhikkhu] abstains from wrong livelihood, from lowly arts such as these. This, too, is part of his virtue*.[14]

In real life, monks in Thailand, Laos, and Cambodia have often been considered as doctors too—hopefully within the limits of their disciplinary

---

[11] Buddhadasa Bhikkhu (1906–1993).

[12] See: Bhikkhu, T. (2007). *The Buddhist monastic code I* (2nd revised ed.). Valley Center, CA: Metta Forest Monastery, 375.

[13] Quoted by Bhikkhu, T. (2007). *The Buddhist monastic code II* (2nd revised ed.). Valley Center, CA: Metta Forest Monastery, 55

[14] Bhikkhu, T. (2001). *The Buddhist monastic code II* (2nd revised ed.). Valley Center, CA: Metta Forest Monastery, 54

rules—using mostly phytotherapy, massage, and non-invasive treatments.[15] One reason for this is that monasteries have been repositories of traditional knowledge—including medicine—in the form of manuscripts and gardens.[16] These manuscripts are available to be explored by contemporary researchers looking for possibilities for scientific medical research.[17] Besides this experimental medicine practiced by common monks, there was and still is a spiritual form of healing attributed to monks considered to be "saints." They are believed to have spiritual and/or magical gifts to protect people from malevolent hidden powers and to heal devotees from various illnesses and plagues. This may occur through mental concentration, the chanting of sacred texts, or through the distribution of amulets and various talismans.[18] A particular case was, in a now almost forgotten past, that, unlike commoners who could not touch and attend to royalty and nobility, monks could be called within the palace in case of necessity.[19]

## Balancing a crude vision with practical compassion

The Buddha's diagnosis exposed above rests upon the vision of a whole world made of things and beings void of any "essence" that could ensure their sustainability, their continuity, and their permanence. Since each thing and every being is impermanent, no one thing and no single being deserve identification or attachment, otherwise suffering will arise.

The Buddhism we have in Southeast Asia—Theravāda Buddhism[20]—has

---

[15] Tomecko, D. (2009). *Buddhist healing in Laos: Plants of the fragrant forest*. Bangkok: Orchid Press.

[16] Grabowsky, V., & Berger, H. G. (2015). *The Lao sangha and modernity. Research at the Buddhist Archives of Luang Prabang. 205–2015* (pp. 198–199). New York & Luang Prabang: Anantha Publishing.

[17] Elkington, B., Southavong, B., Sydara, K., Bouamanivong, S., Souliya, O., Xayveu, M., ... & Soejarto, D. D. (2010). The Search for Anti-Malarial Plants in Lao Palm-Leaf Manuscripts. In K. L. Adams & T. J. Hudak Eds.), *Multidisciplinary perspectives on Laos studies* (pp. 277–287). Tempe, AZ: Southeast Asia Council, Center for Asian Research, Arizona State University.

[18] See for example: Hayashi, Y. (2003). *Practical Buddhism among the Thai-Lao: Religion in the making of a region* (pp. 288–289). Kyoto: Kyoto University Press & Melbourne: Trans Pacific Press. Kitiarsa, P. (2012). Magic monks and spirit mediums. In P. Kitiarsa (Ed.) *Mediums, Monks, & Amulets: Thai popular Buddhism today* (pp. 35–56). Chiang Mai: Silkworm Books in association with University of Washington Press, Seattle.

[19] Yoddumnern, B. (1974). *The role of Thai traditional doctors* (pp. 29, 31, 33). Institute for Population and Social Research, Mahidol University, Bangkok.

[20] "Theravāda Buddhism" is a common but problematic way of naming Buddhist traditions that are still alive mainly in Sri Lanka, Myanmar, Thailand, Cambodia, Laos, and among minor groups of Yunnan, Vietnam, Malaysia, India and Nepal, to say nothing of emerging communities in the West. This type of Buddhism is the only remnant of several Buddhist traditions, which were called "hīnayāna"

been mainly interested in the "voidness," or the "emptiness," that is the absence of any "essence" in living beings, while Mahayanist currents have developed a more radical view of emptiness—the absence of essence, in all conceivable "things," be they material or conceptual.

The impermanent character of things and beings has been analyzed by the Buddha and Buddhist theoreticians in multiple ways. For the purpose of this chapter, the most common concept is the division between physical and mental components because it is easily understood by most. However, an ethical concern must be noted in our inquiry. In Buddhism, unlike in Christian traditions, there is no fundamental difference between beings that enjoy some kind of mental ability through a mind process, be they humans, animals, gods, demons, spirits, etc. Furthermore, this mind process cannot be regarded as an object, an entity, that is, a "soul" that would be permanent. The apparent continuity of what we call "mind" hides an actual discontinuity—a process—of mental moments, in the same way that an electric current hides tens of cycles per second. A living and thinking being is but a mere flash that takes itself for a light. Death is just the separation of momentary discontinuous mental elements from momentary discontinuous physical elements, all waiting for some new provisional composition in a new momentary discontinuous process of existence.

The consequences of the radical impermanence of beings are tough to hear when it comes to beloved beings. Buddhist texts offer several cases of people desperately crying over the death of a child or a beloved where the Buddha begins by saying something like: "That's the way it is."[21] One of the most heart-rending stories is Kisa Gotami's plight. When her young child dies, she refuses to believe he is dead. She searches in vain for medicines to revive him and is finally directed to the Buddha. He says that he could provide medicine for the child if he only had a mustard seed coming from a house in which no one had died. The woman walks from house to house asking for a mustard seed, but in every house, someone has died. She ends up understanding that death is universal and leaves the child's body on a charnel ground, before going back to the Buddha and becoming a nun.[22]

---

or "small vehicle" by theoreticians of "mahāyāna Buddhism" born in India and now alive in China, Tibet, Vietnam, Korea, Japan, and the West. For a discussion of the term "Theravāda," see: Skilling, P. (2009). Therava□da in history. *Pacific World, Journal of the Institute of Buddhist Studies*, 3rd Series, Nr.11, Fall 2009, 61–93; and Skilling, P., Carbine, J. A., Cicuzza, C., & Pakdeekham, S. (Eds.). (2012). *How Therava□da Is Therava□da? Exploring Buddhist Identities*. Chiang Mai: Silkworm Books.

[21] "Piyajatika Sutta: From One Who Is Dear," translated by Thanissaro Bhikkhu. 2006, https://www.accesstoinsight.org/tipitaka/mn/mn.087.than.html

[22] See: "Kisagotami Their," translated by Thanissaro Bhikkhu. 2006, https://www.accesstoinsight.org/tipitaka/kn/thig/thig.10.01.than.html; http://path.homestead.com/kisagotami1.html; http://path.homestead.com/kisagotami.html;

If, in a Buddhist vision of the world, living beings are seen just like impermanent heaps of impermanent elements, just like glow-worms flashing in the cosmic night, is it really worth thinking beyond mere practicality, mere utility, mere interest in our social behavior, especially in health care and medicine?

In the founding texts and the daily life of Buddhists, the general and radical inevitability of death is engineered on a case-by-case basis by what is often called the "law of karma," in other words: nothing happens to a living being by chance. Everything may be explained *a posteriori* by previous actions, beginning with birth: as a God or as a worm, as a man, as a woman, or in the middlesex, as a handsome prince or as a monster, as a saint or as a gangster. One is what one has done. However, Buddhist karma is not just the "action" per se, it is the action as defined by its intention, and intentions are basically twofold. They are either *kusala*, which means profitable, wholesome, salutary, skillful, and blameless, or they are *akusala*, which means non-profitable, non-wholesome, non-salutary, unskillful, and blameworthy. For this reason, an action must not be considered with a cursory or superficial glance but with a view on its deep rationale, i.e., its intention.

The intention, the policy, that the Buddha recommends is of course the "*kusala*" one. *"Kusala"* and *"akusala"* are among the most commonly used words in Buddhist teachings for people. They are the measure of the value of life, as monks recall at funerals. They make of Buddhism an ethical system that does not derive authority from a God of from a hidden power, but from the simple, straightforward observation of the world where some actions "work" and others do not.[23]

Consequently, any discourse on "ethics in a Buddhist context" must primarily be based upon two notions formulated in these two questions: what is beneficial and what is not? The answers will not give ready-made solutions to complex problems, but they will help to think beyond the degree zero of morals and inspire fundamental choices.

Moreover, the cold, insensitive, materialistic reaction to the death of a beloved person, as illustrated above, is compensated, in Buddhist scriptures, by the pervasive insistence upon compassion *(mettā)* towards all beings. Throughout 25 centuries of history, Buddhist teaching has not been transmitted to people by Socratic, often tedious and cryptic *suttas*, repeating Buddha's discourses. They have been passed on through tales telling of the previous lives of the Buddha. These lives describe the play of karmic actions, i.e., the play of profitable and unprofitable acts, the play of intentional behavior on the destiny of one being presented as a model of humanity. The thread that provides a link between these lives is karma, but it is the karma of compassionate acts: compassion to help, compassion to give, and,

---

[23] I am indebted to Richard Gombrich for this attention to the link between karma and ethics in Buddhism in his *What the Buddha Thought* book *(op. cit.)*.

especially for the life of the Buddha, compassion to teach. All acts committed by the future Buddha, i.e., the *Bodhisatta* or *Bodhisattva*, are inspired by some kind of compassion towards others. This compassion ranges from that of a petty gift to the gift of one's life. In effect, the Buddha's unique life, that of a renouncer, in principle unconcerned with the welfare of others, was preceded by hundreds of lives where the future Buddha was not yet a renouncer and exercised the virtue of compassion.

Consequently, we may be confronted with Buddhist people and contexts that offer dual and apparently opposite stances: one may be inspired by the cold vision of a impermanent and laughable living being leading to renouncement and strict ascetic life, as the other may be nourished by compassion for companions in karma leading to commitment in the world.[24] The paradox, if not the contradiction, between the basic tenet of impermanence of things and beings on one side and the basic tenet of universal compassion on the other exceeds the limits of this chapter, but must not be overlooked. It may explain the endurance of Buddhism throughout 2500 years. While systems of thought—religious or secular—committed unilaterally either to asceticism or to social justice may wither and die rather quickly, Buddhism has managed to survive and inspire minds from a multitude of time horizons. It holds together the radical vision of the Buddha tentatively followed by the monks and the practical exemplary life of the *Bodhisatta* tentatively followed by lay Buddhists.

## The larger "Buddhist context"

Until now we have considered a few features that may be exploited and developed to define Southeast Asian Buddhism. They are not sufficient to define the "Buddhist context" in and around the Mekong Valley. While it is true that the "unbearable lightness" of empty Buddhist beings or the law of karma governing individual fates often generate stoical responses to life's dramatic hazards, these Buddhist keys are not the only ones used in the region to draw pictures of fates or decipher meanings of lives.

### *The "khwans"*[25]

According to what is perhaps the first rationalization of individual ups and downs in the region, our well-being depends mainly on the presence within our body of all our vital principles called "*khwans*." Should one or several of

---

[24] See examples in: Condominas, G. & Gaudillot, C. (2000). *La plaine de Vientiane: Étude socio-économique - Rapport de mission, octobre 1959*. Paris: Seven Orients; Librairie orientaliste Paul Geuthner.

[25] See: For Thailand: Rajadhon, P. A. 1962. The Khwan and its ceremonies. *Journal of the Siam Society*, 50/2, 119–164, http://www.siamese-heritage.org/jsspdf/1961/JSS_050_2d_PhyaAnumanRajadhon_KhwanAndItsCeremonies.pdf; For Laos: Zago, M. (1972). *Rites et cérémonies en milieu lao*, Roma: Universita Gregoriana, 133–144 & *passim*; Holt, J. C. (2009). *Spirits of the Place: Buddhism and Lao religious culture*. Chiang Mai: Silkworm Books, 271–74.

them be away, our health would deteriorate and a ritual to call them back has to be implemented.

### *The “spirits”*[26]

Beyond the visible world that we awake to every morning, there is an invisible world of “spirits” that surrounds us at every moment but that we cannot see. Some spirits, related to topography, keep an eye on the geological and geographical order of the land. Others based on genealogy look after the historical order of the world. Only humans with a special gift can perceive and reveal what happens behind the invisible curtain. Some of them are mediums who, by definition, are messengers traveling between our visible world and the other;[27] others are not necessarily but usually Buddhist monks with a special “eye,” able to see what you think just now, or who you were in a past life, or what you did the day before. The visions of these couriers allow them to tell you what has happened to your deceased mother or to the fetus you aborted. Like economists after a crisis, they explain to you in detail why your business went bankrupt, or why your marriage failed.

### *Astrology*

Southeast Asian people who have inherited parts of the Indian cultures have necessarily assimilated astrology. From the very moment of a baby’s birth, planets and constellations participate in and even define his or her destiny. Logically, they help to explain the upsurge of an illness. From the natal chart, the astrologer will conclude that, just now and for x days, there is a defect or depletion in this or that element. He will accordingly give a prescription that, in a Buddhist milieu, will generally involve an offering to the temple.

### *The four “elements”*

Unlike the *khwans* and the spirits that are non-material, the four “elements” or *that* (from *dhātu* in Sanscrit/Pāli) form the material body itself. If *khwans* and spirits come from an indigenous, very ancient, and pre-Buddhist substratum of beliefs, the Southeast Asian pathology calling for four *dhātu* or elements—earth,[28] wind,[29] water,[30] and fire[31]—to explain health and illness originates from India.

---

[26] Tambiah, S. J. (1970). *Buddhism and the spirit cults in north-east Thailand* (pp. 312–326 & *passim*). Cambridge: Cambridge University Press.

[27] Heinze, R-I. (1998). *Trance and healing in Southeast Asia today*. Bangkok: White Lotus co., Ltd.

[28] Hair, quills, nails, teeth, skin, muscle, guts, bones, tissues, spleen, heart, liver and pancreas, membranes, kidneys, lungs, intestines, new food, excrement, and brain.

[29] Wind that blows from feet to head; Wind that blows from head to feet; Wind that blows within the abdomen cavities; Wind that blows within the stomach and the intestines; Wind that blows within blood vessels.

[30] Bile, sputum, lymph, blood, sweat, fat, saliva, nasal discharge, marrow, and urine.

[31] Group of elements that keep the body’s temperature in balance, help digestion (enzymes), and wear out the body.

Prince Damrong Rajanubhab (1862–1943) told how the human body was formerly conceived as a tree or a house. Human organs work the same way the leaves or the roots of the tree do. A body is a house of one soul. All bones are the posts and the house structure. Skin makes up the walls that cover the whole structure. Hair is a grass or thatch roof. Eyes are the windows. The equipment of the body is made up of blood vessels, mouth, and so on. The structure of the house is supported by all elements. If one house element is out of order, it should be repaired. The human body as well is made up of many organs. When people get sick, it means that one element or more should be taken care of.[32]

Naturally, only properly educated doctors could know the intricacies of such a system for which manuals were transmitted from generation to generation.[33] However, at least in certain parts of the region, astrology was and still is a way of knowing which element needs invigoration.

If the rationalizations or explanatory systems briefly exposed above do not belong to Buddhism *stricto sensu*, they must not be considered as antagonistic to Buddhism, at least from the point of view of Buddhists. Their view of the world is both open and inclusive. On the stages of karma retributions, there is room and space for all possible types of beings, from hell's pensionaries to the highest paradises' subtle gods. In between, there is ground for animals, humans, spirits, semi-gods, and whatever being you can fancy. While the anthropologists may play with typologies and theories of illnesses and therapies,[34] Buddhist monks have an encompassing explanation for everything: karma retribution.

## Conclusion

These cursory notes on Southeast Asian rationalizations of pathologies and therapies may look strange if not foolish to Western eyes. They would look even stranger if exposed with ethnographical details. However, any health worker, whatever their responsibility, who happens to be involved in ethical questioning should always humbly remember that they are not the only one who believes in their rationality. To begin with, if they are able to look back on their life with a pinch of humor, how could they have been so rational? If they think of the rational weight of their own religious or atheist

---

[32] Damrong Rajanuphab, Prince. 2466 [1923]. *Kai kharueha rue ruean khue kai*. Bangkok: Fine Arts Department. Translation borrowed, with minor changes, from: Yoddumnern, B. (1974). *The Role of Thai traditional doctors* (p. 13). Institute for Population and Social Research, Mahidol University, Bangkok.

[33] See a list in Yoddumnern, B. (1974). *The Role of Thai traditional doctors* (pp. 7–10). Institute for Population and Social Research, Mahidol University, Bangkok.

[34] For health practitioners working in Laos, the following book should be a compulsory reading: Pottier, R. (2007). *Yû dî mî hèng [Feeling good, having power] Essai sur les pratiques thérapeutiques lao*. Postace by Didier Sicard. Paris: École française d'Extrême-Orient.

beliefs, of the rational weight of their own love choices, of the rational weight of their own political dogmas, of the rational weight of their own economic certainties, all proclaimed with plain complacency throughout the past 10, 30, 50 years, what remains of their axioms, of their postulates, of their superior demonstrations? If they find that they have never failed, may he or she then imagine that, perhaps, humans do not necessarily want to believe what is true, but that it is instead always what they believe they say is true. Because it suits them in one way or another. Then, may the health worker consider that, in the end, the Mekong Valley people, with their planets and their stars, with their souls and their spirits, with their good and bad karma, try similarly to find some meaning and reason in this chaotic world. This modesty might allow the researcher to hear and better understand the seemingly irrational reasons he or she listens to, and finally adopt and adapt ethical principles brought in from another world.

The Western way of promoting ethics in research—even if it is grounded on more essentialist worldviews than the Buddhist one and even if, up till now, it has been much more articulated and formulated—may in practice use the Buddhist conception of karma as a work grid. In any project, trial, or research, the basic questions are: what is profitable *(kusala)* and what is not? This does not offer any practical solution for any specific health study, problem, or dilemma. It leaves many questions to answer: profitable for whom? in which manner? for how long? with which risks? ... So many questions, so many answers that reveal that, unlike morals that are satisfied with minimal results, ethics always raise the level of requirements and never stop questioning. This could be a guideline for all health workers whoever they are, wherever they come from, whatever religion or ideology they believe in because it would help them to keep the welfare of living beings at the center of their experiences.

* * *

# *Part I*

# Ethics in Public Health Studies and Clinical Research

# Introduction:

**Mayfong MAYXAY,[*] Bansa OUPATHANA,[**]
Bernard TAVERNE[***]**

Throughout human history, the search for medical remedies has advanced through trial and error. No doubt even early healers questioned or rationalized whether or not to give a treatment whose efficacy could never be fully guaranteed in order to test its effect.

In the Western world, ethical reflection often refers to the medical practice of Hippocrates, the famous Greek physician born in the fifth century B.C. The Hippocratic Oath defines the principles of proper conduct and ensures physicians are honest and respectful of any suffering individual who seeks their help. This code, the first to be recognized in the West, applies to the healing arts and the physician's practice and how his or her knowledge is used. However, it does not concern the experimentation that physicians use to acquire new knowledge.

Today, although routine care and experimentation are closely linked, they are seen as emerging from different approaches. Care is the implementation of knowledge recognized by members of the profession, even if it does not always produce the desired result, while research confronts the unknown while exploring how a healthy or sick body functions. Routine care and research must respect ethical principles, which may not completely overlap, despite a common foundation—respect for the human individual.

Conducting research, at least theoretically, has always conformed with underlying social values. In Ancient Greece, the physicians Herophilus and Erasistratus (300 B.C) performed human dissection on convicts to study human anatomy.[1] Clinical knowledge progressed in hospitals where the poor

---

[*] Physician, Faculty of Postgraduate Studies, University of Health Sciences, Ministry of Health, Lao PDR.

[**] Physician, Rector's Office, University of Health Sciences, Ministry of Health, Lao PDR.

[***] Anthropologist, Physician, IRD UMI 233, Inserm U 1175, University of Montpellier, France.

[1] von STADEN, H. (1989). *Herophilus: The art of medicine in early Alexandria,* Cambridge, Cambridge University Press.

were treated for free.[2] In eighteenth-century Europe, smallpox inoculation was tested on convicts condemned to death in exchange for a lighter sentence,[3] and experimentation on prisoners continued well into the twentieth century.[4] Throughout human history, experiments on potentially dangerous or painful treatments were often performed at the expense of those considered marginal, dependent, or inferior (e.g., prisoners, the disabled, the poor).[5]

National codes of conduct for physicians did not prevent large-scale experimentation in Manchuria in the 1930s or in the Nazi concentration camps of World War II.[6,7] The Doctors' Trial held in Nuremberg in 1945–1946[8,9] led to the development of the Nuremberg Code in 1947. This code spells out 10 principles to ensure that any medical research on a human being is ethical.

Research ethics were further codified under the leadership of the World Medical Association (WMA), resulting in the first Declaration of Helsinki (1964), entitled *Ethical Principles for Medical Research Involving Human Subjects.* Yet during this same period, several studies were denounced in the United States, including injections of cancerous cells in the elderly and inoculation of viruses in mentally disabled people in institutions. The biggest scandal involved an experiment that lasted from 1932 to 1970 in which researchers observed the effects of syphilis on 400 untreated African Americans in Tuskegee despite the availability and proven efficacy of penicillin.[10] These revelations led to the creation in 1974 of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which in 1979 authored the Belmont Report, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Today, the WMA Declaration of Helsinki—which has been repeatedly updated, most recently in 2013—and the Belmont Report are the main international frameworks for ethics in medical research to prevent the abuse of study participants.

---

[2] Foucault, M. (1963). *Naissance de la clinique : une archéologie du regard médical.* Paris: Presses universitaires de France.

[3] Moulin, A.M., & Chuvin, P. (1991). *L'islam au péril des femmes*. Paris: La Découverte.

[4] Bonah, C. (2007). *Histoire de l'expérimentation humaine en France. Discours et pratiques 1900-1940*. Paris: Les Belles Lettres

[5] Chamayou, G. (2008). *Les corps vils. Expérimenter sur les êtres humains aux XVIII^e^ et XIX^e^ siècles*. Paris: Les Empêcheurs de penser en rond/La Découverte.

[6] Isambert, F.A. (1983). Aux sources de la bioéthique. *Le Débat 25*: 83–99.

[7] Isambert, F.A. (1987). L'expérimentation sur l'homme comme pratique et comme représentation. *Actes de La Recherche en Sciences Sociales*, *68*, 1: 5–30.

[8] Wieviorka, A. (2006). *Le procès de Nuremberg.* Paris: Éditions Liana Levi.

[9] Halioua, B. (2007). *Le procès des médecins de Nuremberg. L'irruption de l'éthique médicale moderne*. Paris: Vuibert.

[10] Jones, J.H. (1993). *Bad blood: The Tuskegee syphilis experiment*, New York, Free Press.

Ethics documents address new medical techniques as they appear (e.g., medically assisted reproduction, transplant), and they examine methodologies (e.g., placebo use). Ethical positions are fine-tuned as new ethical gaps are found in interventions that modify the human body and its essential functions. Ethics also considers how values change over time and how societies across the globe view them from potentially contrasting perspectives. For example, an animal's status and suffering during a scientific experiment may be viewed by Buddhist and Hindu cultures in a different light than by Christian ones.

In 2017, numerous documents provide a framework for the various ethical aspects of research: the Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, the UNESCO Universal Declaration on Bioethics and Human Rights, the Oviedo Convention and its Additional Protocol, the Guideline for Good Clinical Practice of the International Council for Harmonisation (ICH), the WMA Declaration of Taipei, and so on. In addition to these documents that are international in scope, most individual countries have established structures to evaluate research ethics and have drawn up regulatory texts that encode the principles of international documents into local laws.

## • Ethical principles of medical research

The three fundamental principles of medical research ethics are respect for the individual, beneficence of the research for study participants, and justice.

– Respect for the individual refers to the concept of individual autonomy. Individuals have the right to decide for themselves whether or not to participate in a study. Therefore, they must be informed of the research objectives and procedures in order to determine freely to participate and to have the right to terminate their participation at any time.

– The risk-benefit ratio of the research means that the individual's interest must take precedence over that of society. The expected benefit for participants must be greater than the risks. These risks should be assessed and minimized and may result in stopping the study. By maintaining participants' anonymity and confidentiality, researchers protect individuals socially from revelations being made about them without their consent.

– Justice implies the obligation to treat everyone equally. In the ethics of research on human subjects, distributive justice means the benefits of participation in research should be distributed equally (CIOMS 2003).

Ethical reflection also focuses on:

– Methods for providing study information that are adapted to research participants (individual and/or collective),

– Methods for obtaining consent, which may be by someone independent of the research process; written or oral; based on age, degree of literacy, mental and physical state; etc.,

– The study's direct and indirect benefits (quality of care compared to a reference standard, reimbursement of expenses, compensation for the time spent on the study, etc.), use of biological samples or any medical and social information collected (biobanks, databases, anonymization methods, etc.),

– The modalities of medical management once the study ends for people presenting a chronic disease related to the study object, and

– Compensation for people who have suffered injury during the study, information on their results, provision of medicines arising from the study for the study participants, etc.

Numerous texts address these various aspects.

### • Applying the ethics principles of health research

Is there a single model of ethics in health research? The various international declarations and recommendations do not carry the force of the law or have any criminal penalties. They represent "soft law"—something health research actors have agreed to comply with, for fear of moral condemnation from their peers. Today, all international organizations that fund research and most institutions, editors of scientific reviews, and new social actors such as patient associations require that ethical principles are respected.

Since 2000, nearly every country in the world has created an Ethics Committee for Health Research that applies international recommendations to evaluate research projects. The projects must prove they respect ethics in the objective, methods, and resources envisaged for the research. Those that fail to respect ethical principles are denied.

### • The example of ethics in health research in Laos

In Laos before 2001, health research proposals received technical approval from the Ministry of Health Council of Medical Sciences, which was not an ethics committee. An Ethics Committee for Health Research was established in 2001 in the former Faculty of Medical Sciences at the National University of Laos (currently the University of Health Sciences, or UHS). This committee was set up following requests for ethical approval by a clinical research group at the Vientiane central hospital. Later in July 2002, the Ministry of Health of Lao PDR established another ethical committee at the national level, which is called the National Ethics Committee for Health Research, or NECHR.

Although a growing number of research projects are submitted to these two ethics committees, there remains a significant need for training in research ethics for the committee members and researchers since some members still have not received any. In fact, bioethics is still not taught in medical training programs in Laos.

- **Case studies**

The relevance of research ethics principles is best understood in the context of their application in actual practice. The six chapters that follow describe how ethical principles guided the approaches to and practices of research in a variety of situations. Two chapters focus on Laos: one describes the ethical dilemmas health professionals face in their treatment practices, and the other raises ethical issues in cervical cancer screening research. Two other chapters look at examples in Thailand: one is a general reflection based on research in preventing mother-to-child transmission of hepatitis B while the other is based on a survey among adolescents. A fifth chapter addresses the topic of consent to participate in medical research in Cambodia, and the last is an ethical examination of the use of biological samples.

## ETHICS AND REGULATORY REFERENCE DOCUMENTS

* The Nuremberg Code, 1947
https://history.nih.gov/research/downloads/nuremberg.pdf

* The Belmont Report, 1979
http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4178b_09_02_Belmont%20Report.pdf

* Declaration of Helsinki, World Medical Association (WMA), 1964
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

* International Ethical Guidelines for Health-related Research Involving Humans, (CIOMS), 2016,
https://cioms.ch/shop/product/international-ethical-guidelines-for-health-related-research-involving-humans/

* Universal Declaration on Bioethics and Human Rights, UNESCO, 2005
http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/

* The Oviedo Convention, 1997
https://www.coe.int/en/web/bioethics/oviedo-convention

* Guidelines for Good Clinical Practice, International Council for Harmonization (IHC), 1996
http://www.ich.org/home.html

* WMA Declaration of Taipei, 2002
https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

# Examples of Medical Ethical Issues in Laos: Dilemmas in Health Care Decisions

**Mayfong MAYXAY,**[*] **Bansa OUPATHANA**[**]

The main goal for medical practitioners is to offer the best medical care after accurately diagnosing their patient's condition. However, an appropriate treatment does not solely depend on the diagnosis and available therapeutics. In resource-constrained countries, the cost of treatment and care frequently poses a barrier for patients and their physicians. Difficulties in paying for care mainly arise in cases of chronic diseases that incur long-term costs or rare diseases for which no inexpensive drugs are available in the countries' supply chains.

In Laos, the impact of economic constraints on patients' ability to seek care raises major ethical issues for all health professionals. These issues lie at the heart of the relationship between patients and their doctors and concern everyday medical practices. The following two case studies shed light on different aspects of the dilemmas facing physicians when their patients are unable or unwilling to spend money on their medical treatment.

## Refusing care

### *– Case #1:*

A 72-year-old woman with diabetes was regularly taking her diabetes medicines and monitoring her blood sugar daily. She had been seen by a doctor at a public hospital for almost six years. One day she felt faint and nauseous, so her son took her to this hospital, where staff recommended a blood test to identify the cause of her symptoms. Based on the lab results, the doctor diagnosed kidney failure that required renal dialysis. The doctor explained to the patient why she needed to undergo dialysis and take additional medicines and then reviewed the cost of each dialysis session.[1]

---

[*] Physician, Faculty of Postgraduate Studies, University of Health Sciences, Ministry of Health, Lao PDR.

[**] Physician, Rector's Office, University of Health Sciences, Ministry of Health, Lao PDR.

[1] The price of a kidney dialysis session in a public hospital ranges between 550,000 Laokip (US$ 66) and 1,000,000 Laokip (approximately US$ 120) or higher. The price increases if the patient needs injections of complementary drugs or blood transfusions based on their blood work. The average monthly

The patient agreed to discuss it with her children and the rest of the family. They eventually agreed to share the costs of treatment and dialysis.

In the first year, kidney dialysis was performed once monthly at the hospital. But by the next year, she needed dialysis twice monthly, and then dialysis treatments were increased to once per week, then to three times per week. As the number of dialysis treatments increased dramatically, so did the family's medical expenses for the patient.

From the beginning, the doctor had informed the patient's family that initiating dialysis was an irreversible step, since dialysis was not meant to cure kidney disease but rather to perform the function of the kidneys. The number of dialysis treatments could increase as needed, up to three times per week. Kidney transplant, replacing the failed kidney with a healthy one, is not performed in Laos.

A few months later, during an appointment with her doctor during a dialysis session, the patient stated that she had decided to stop dialysis because her children no longer had enough money to pay for it and that she wanted to die in her home. Her children begged her to continue her treatment but were unable to convince her. The woman died a few days later.

### – Ethical issues:

Several aspects of this case highlight key ethical issues that arise in everyday medical practices in Laos.

#### *1. Providing patients with information*

Article 33 of the Health Care Law (no. 032/PLPDR, dated 30 January 2015)[2] of Lao PDR states: "Information for patients: Health-care professionals shall provide patients, their families or community with the following information: Non-confidential medical information at their request, or to satisfy their interest or wishes."

However, the doctor must first ask all patients if they can inform their families about their health condition and then discuss it with them. Article 37 of the same law states: "Ethics of Health-care Professionals: The ethics of health-care professionals shall have the following contents: [...] Listening to the opinions, purposes and decisions of patients on the basis of the laws and regulations and the rules of the medical profession."

---

per capita income in Laos is US$ 105, or US$ 1260 per capita per year. http://www.journaldunet.com/business/salaire/laos/pays-lao

[2] President of Lao PDR. (2015). The promulgation of the Law on Health Care, in Lao language, no. 032/PLPDR, dated 30 Jan. 2015. Retrieved from http://www.na.gov.la/docs/lao/laws/econ/14_Health_Care_Law30_01_2015.pdf

In the story about the diabetic patient, the doctor explained the reasons why the patient needed kidney dialysis. He also informed her that she would need to take additional medicines and what each dialysis session would cost. After the patient discussed this with her family members, they agreed with the doctor's recommendations. At that time, the family indicated that sharing the patient's treatment expenses was acceptable to them. After two years of treatment, the patient believed that her family no longer had the capacity to cover her medical care and dialysis expenses.

### *2. Physician attitude*

Despite her children's encouragement to continue treatments, the patient decided independently to discontinue kidney dialysis because her children could no longer pay for the medical expenses. It was obvious to this woman that her decision would lead to a quick death. The doctor had no other choice than to respect the patient's decision, even if that decision might appear to contradict the Hippocratic Oath, which states that a doctor will do whatever is required to relieve suffering.

Adult patients' decision-making power regarding the nature of the care they receive is a fundamental right, as stated in the World Medical Association Declaration of Lisbon[3] of 2015, recognizing that "a mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent."

The moral dilemma in this case stems from the patient having decided not to continue dialysis, not because of her lower quality of life or for any other religious or philosophical reasons, but for material reasons: a lack of financial means. Her choice was also altruistic because it allowed her to avoid burdening her loved ones.

Comparable situations are not uncommon in the lives of the poor and even the middle class in countries that do not have a comprehensive health insurance system or adequate social protection. In many countries, including the United States, creating an equitable State-run health insurance system is the primary means to resolving medical ethics dilemmas, such as those confronting doctors in this case study.

Some international insurance companies have also explored expanding insurance programs to the middle class. In low-resource countries, "micro-insurance" programs have also been proposed. The general trend in many

---

[3] WMA Declaration of Lisbon on the Rights of the Patient, 2015. https://www.wma.net/policies-post/wma-declaration-of-lisbon-on-the-rights-of-the-patient/

countries has been to move away from the welfare state model, an ideal espoused by many regimes in the period after independence; however, the Laotian State has continued to watch over the health of its citizens. The Lao People's Revolutionary Party (LPRP), the government, and mass organizations play various roles, depending on their level of responsibility, in the direction, governing, planning, execution, supervision, and evaluation of all activities related to their missions, including health policy.

In Laos, the Law on Social Security was established in 2013. The Government of Laos issued the Decree on National Health Insurance (no. 470/GO) of 17 October 2012, in which Article 2 states: "National Health Insurance (NHI) is an organization with a broad social mandate, which is composed of the Community Based Health Insurance, Health Insurance for State Authority for Social Security, Health Insurance for Social Security Organization and Health Equity Fund for the poor, and other related health financing schemes to pay for health services provided to its members under the guidance of the National Health Insurance Management Committee."

In clinical practice, physicians sometimes find patients who are diagnosed with treatable diseases but who do not want to stay in the hospital because they are running out of money. Sometimes, even if assistance is provided, they prefer to return home since Lao cultural beliefs maintain that family members should preferably die at home rather than in a hospital. There is another cultural issue at stake: when someone dies in a hospital, their families cannot take the corpse back home for mourning ceremonies, but must take the body directly to a temple. In Lao culture, when someone dies at home, the body is usually kept there for a few days before being taken to a temple for cremation ceremonies.

This raises an ethical issue for both clinicians and health managers: how can they help the patient and support his or her family's decision-making process? This is a challenging situation for the clinicians and their assistants, such as nurses, given the demands of their normal workload. In addition to caring for patients and explaining the nature of the disease and the patient's prospects for survival, they must also encourage the patients' family members to keep the patient in the hospital rather than taking him or her home to die, when the prospects for survival are higher in the hospital.

## Access to care through research

### *– Case #2*

Treatment of a rare infectious disease such as melioidosis exposes other ethical issues. Melioidosis, is an infectious disease that can infect humans and animals, caused by a Gram-negative bacillus, *Burkholderia pseudomallei* (*B. pseudomallei*) that lives in moist soil and water. Although it is treatable with antibiotics and despite important advances in treatment, the fatality rate in acute severe melioidosis is about 30% to 47% and may range from

40% to 75% in cases with sepsis.[4,5] The first case of melioidosis in Laos was reported in 1999. The recognition of this severe disease has opened a Pandora's box of economic and ethical challenges,[6] because the cost of antibiotic treatment to save a patient with severe melioidosis at that time was about US$ 424, equivalent to 1.2 times the per capita gross domestic product of Laos (~US$ 362 per person per year at that time).

Although the cost of treatment is currently less expensive than before, many patients still cannot afford the treatment since the majority of Lao patients (~86%) are uninsured and must cover their own health care costs.[7] Therefore, when melioidosis is diagnosed, some patients or their family members refuse treatment due to economic difficulties in their families, despite knowing that the disease is fatal but treatable. Frequently, health care professionals must repeatedly emphasize the very good prognosis of the disease if they receive antibiotics, but the family members prefer to take their patients home to die, to avoid multiple expenditures besides therapy, such as additional treatment costs or food and accommodations for family members accompanying the patient, which they cannot afford.

Comparable scenarios arise in clinical practice, which pose similar challenging ethical problems in Laos. This medical ethical issue raises a difficult question: What should health professionals do when facing this scenario and how can they behave ethically and gain trust while ensuring that they practice medicine safely and effectively? This medical issue does not usually surface in countries where health care is free of charge or where their citizens are covered by health insurance schemes. Poor quality health care and inequalities in its delivery plague poor countries,[8] but wealthier countries also face these problems following health care reform, resulting in changes in the physician-patient relationship.[9]

---

4. Spickler, A. R., Roth, J. A., Gaylon J., & Lofsted J. (2010). *Emerging and exotic disease of animals textbook* (4th ed.). Iowa: Center for Food Security and Public Health Iowa State University.
5. Currie, B. J., Ward, L., & Cheng, A. C. (2010). The epidemiology and clinical spectrum of melioidosis: 540 cases from the 20 year Darwin prospective study. *PLoS Negl Trop Dis*, 4 (11), p. e900
6. Phetsouvanh, R., Phongmany, S., Newton P., Mayxay, M., Ramsay, A., Wuthiekanun, V., & White N. J. (2001). Melioidosis and Pandora's box in the Lao People's Democratic Republic. *Clin Infect Dis*, Feb 15;32 (4), 653–4.
7. Akkhavong, K., Paphassarang, C., Phoxay, C., Vonglokham, M. Phommavong C, & Pholsena S. (2014). The Lao People's Democratic Republic health system review. *Health Systems in Transition,* Vol. 4 No. 1.
8. Chabikuli N., Schneider H., Blaauw D., Zwi A. B., & Brugha R. (2002). Quality and equity of private sector care for sexually transmitted diseases in South Africa. *Health Policy Plan*, 17 Suppl:40–6.
9. Dagi, T. F. (2017). Seven Ethical Issues Affecting Neurosurgeons in the Context of Health Care Reform. *Neurosurgery*, 80(4S):S83–S91. doi:10.1093/neuros/nyx017.

Wherever and whenever this type of medical ethics issue arises, it is crucial that health care professionals find an appropriate approach to deal with it properly and ethically.

Firstly, they have to listen to the opinions, intentions, and decisions of patients and their family members; attempt to persuade them to cooperate in the efforts to deliver treatment; and encourage them to consider their own interests.[10] This is a primary requirement for a safe and effective clinical practice. Secondly, they must inquire whether research projects that aim to improve therapies can include patients and provide them with appropriate treatments. Medical research on emerging diseases in Laos offers patients the opportunity to enroll in cohorts receiving innovative therapies and testing new promising protocols. Access to medicines through research protocols is often the only way to get new-generation treatments in resource-limited countries. Consequently, these research programs must explicitly refer to ethical principles for international medical research, and their research protocols must be submitted to the Ethics Committee for approval.

## Conclusion

As in many resource-limited countries, patients refusing care for economic reasons is a phenomenon observed in Laos. The context of poverty exposes patients, families, and health professionals to ethical dilemmas that are often quite dramatic.

* * *

---

[10] President of National Assembly, Lao PDR. The Promulgation of the Law on Health Care (updated Lao version), No. 017/NA, dated 24 Dec 2014. http://www.na.gov.la/docs/lao/laws/econ/14_Health_Care_Law30_01_2015.pdf

# Informed Consent in Medical Studies: An Essential Ethical Step

**Laurence Borand,[*] Bunnet Dim[**]**

For several years, the Epidemiology and Public Health Unit of the Institut Pasteur in Cambodia has conducted international clinical research studies. This medical research involves both adults and children and takes place in hospital settings, health centers, and even among village communities. It includes clinical trials, prospective observational studies, and retrospective studies of a variety of medical issues, with a focus on infectious diseases (such as HIV infections), respiratory diseases (including tuberculosis), encephalitis, microbial resistance to antibiotics, and vaccines.

For all these studies, what is known as “informed consent” is obtained from participants, or their parents for minors, before beginning any study-related procedure. Informed consent is the procedure through which a participant confirms in writing his or her agreement to participate in a study, after all of its components have been fully explained, in order to make an informed decision.

Before the study begins, the National Ethics Committee of Cambodia reviews the information sheet explaining the study and the consent form given to participants, along with other related documents.

The *Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*, May 29, 2017,[1] describes how the information sheet and informed consent form should be written and how informed consent should be obtained (section 4.8). This can be a delicate process, particularly in resource-limited countries or where medical research is a recent phenomenon.

The language used in the information sheet and informed consent form must employ the least technical and most concrete terms possible so that the subject or his or her legal representative can understand them.

---

[*] Pharmacist and Epidemiologist, Epidemiology and Public Health Unit, Institut Pasteur in Cambodia.

[**] Medical Doctor, Epidemiology and Public Health Unit, Institut Pasteur in Cambodia.

[1] International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), *Notice - Interim Implementation of International Council for Harmonisation (ICH) Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)*, May 29, 2017.

### • "Informed" or "knowledgeable" consent

#### – *The consent form*

The consent form must be written in the language commonly used in the country where the research is being conducted. Presenting scientific topics to a lay audience is always difficult and varies depending on the research areas. Added to this are translation challenges. In Cambodia, numerous medical terms, which physicians learn in French or English, do not exist in the country's language. To address these translation difficulties, over the past several years we have developed a method of providing participants with the clearest and most understandable explanation possible in Cambodian (i.e., the Khmer language). First, we work on a complete version in French/English, keeping the number of pages to a minimum, to present the study's key elements. Next, this version is translated within our team by staff trained in this exercise. This first translated version is then reworked in collaboration with patient-centered associations to incorporate their perspective and refine the phrasing to maximize comprehension by future participants. The final essential step is the back-translation: a new translation of the Cambodian-language document by someone who has never seen the original French or English version to ensure that the meaning is preserved in the local language version. This allows us to avoid any previously undetected misunderstandings or mistranslations.

#### – *The information sheet*

The information sheet is not used by itself to inform the participants; the person responsible for explaining the study will also use simple tools with many illustrations and few words as visual aids to present a verbal explanation. For example, we are developing displays like those used in treatment education sessions (support for treatment adherence) or counseling, such as for HIV or prenatal consultations, which Cambodians appreciate. We will also use pamphlets with the same information that the patients can take home so that they may discuss participation with their families if they wish to. Efforts are ongoing with illustrators and international and local researchers to create a bank of illustrations that can be used to explain the various types of studies, taking into account cultural differences that may influence how illustrations are perceived and identifying possible misunderstandings.

### • Obtaining consent

We pay close attention to how information is delivered and consent is obtained, especially regarding confidentiality—once known as medical "secrecy." The patient's privacy must absolutely be protected to avoid divulging any information that could lead to stigma or discrimination at work, in their communities, or in their private lives. This is especially important for studies involving people living with HIV. Precautions are taken so that the proposal to participate has no adverse effects on the individuals. For this reason, we diligently anonymize patient data from the very beginning of the study. The information is presented and informed consent is obtained during a calm and private session in a quiet space. It is conducted by staff trained by us, who explain the study in detail: the purpose of the research, its various stages, advantages and disadvantages, risks of participating, alternative non-study treatments, the option to withdraw from the study at any time, and the medical follow-up at the end of the study if necessary.

### • Training in clinical research: an ethical imperative

Few teams are trained in clinical research in Cambodia: there is no specific curriculum on clinical research at the university and no training outside of the occasional seminar. Consequently, health care staff are often unfamiliar with the research process. Before each study, we conduct training sessions dedicated to Good Clinical Practice, including practical exercises using role plays on how to conduct the explanation session and obtain informed consent. During these training sessions, we particularly emphasize the concept of the patient’s free and “informed” choice: this means that absolutely no pressure from anyone should be exerted on the individual about his or her participation, and that the patient must be given time to reflect before making a decision. Research staff are regularly reminded that people are free to make their own decisions and that it is normal and expected that some individuals may refuse to participate and that this refusal must in no way change caregivers’ attitudes toward them.

### • Illiteracy, customs, and signing

Confirmation that the individual has agreed to participate in the study is evidenced by the completion of a consent form that will be dated and signed. In Cambodia, a fingerprint is often substituted for a signature in everyday dealings, such as voting, acquiring property, or validating an official document. According to good clinical practices, when someone puts an “X” or his or her fingerprint on an informed consent form, this indicates that the individual is illiterate. In this case, the signature of a literate accompanying witness chosen by the individual must appear with the fingerprint on the document, in order to attest that the information provided orally to the potential participant matches the content of the information sheet.

In Cambodia, however, use of a fingerprint rather than a signature does not necessarily mean that the participant is illiterate. Thus, we have adapted to the local use of fingerprints. In order to avoid requiring signatures from people who would not use the same signature on different documents (because they are unaccustomed to signing), but to still be able to distinguish which individuals are literate, we ask participants who know how to read and write to write their names next to their fingerprints. Consent from an illiterate person can be differentiated by the absence of his or her name next to the fingerprint and by the presence of the witness's dated signature.

Sometimes people choose not to participate in a study. The most common reasons for refusal are: unavailability to attend the scheduled visits planned in the research protocol; refusal by the family; refusal to receive follow-up in a center close to home or the workplace, for fear of being seen at a specific consultation by colleagues or one's social circle; or even because the patient is completely satisfied with his or her care through the national program and does not want to change to another place.

Each individual, or his or her legal representative, has the right and power to decide whether or not to participate in a study. Respecting the patient's choice is an especially important ethical component in limited-resource countries because even though the individual has a choice, participation in the study may be the only opportunity to access appropriate treatment. If a patient cannot or does not want to participate in the study, he or she must be able to receive treatment through the national care program. In countries where access to diagnosis and treatment is challenging, participation in clinical research is often perceived as an opportunity to receive better care, a stroke of luck. Study participants enjoy the benefits of being diagnosed and treated using high quality standards for attentive care in collaboration with international teams of health professionals and scientists. Because financial compensation typically only covers the costs of transportation and study-related care, there is no financial appeal to participate given the limited monetary compensation.

Despite all efforts to provide the essential information for a decision and a real alternative for treatment through the study, individuals are not always able to correctly understand what is being offered and its implications. This may be especially true for patients who are significantly affected by their health condition or in a complicated situation, such as the end of a pregnancy or severe health status, cases in which all of the information is not necessarily assimilated at the time of informed consent. Participation in the study is often only one element among many for those in difficult situations.

It may be appropriate to repeat the information to the participant later during the study, when he or she is in a physical and/or psychological state that is more conducive to understanding. The consent process also gives the health care team the opportunity to reflect on the research objectives and their scientific and social legitimacy.

* * *

# Ethical Issues Surrounding a Study on Cervical Cancer Screening of Women Living with HIV in Laos

**Phimpha Paboriboune,*** **Bernard Taverne****

Cervical cancer, associated with human papillomavirus (HPV), is the second most common cancer among women in low- and middle-income countries. Worldwide incidence in 2012 was 528,000 new cases and 266,000 deaths;[1] approximately 175,000 new cases are diagnosed every year in the countries of Southeast Asia.[2]

Laos has a population of 1.79 million women aged 15 years and older. The annual estimated incidence of cervical cancer is 314 new cases per year, with 168 deaths,[3] making it the third leading cause of female cancer among Laotian women. No other data on the incidence and types of papillomavirus in circulation are available in this country. Like most low-income countries, Laos has no national policy on cervical cancer prevention through mass HPV vaccination. An estimated 3000 women are living with HIV in Laos, of whom 1100 are aware of their status, with half of them receiving free antiretroviral therapy through a national HIV control program. However, there is no routine screening of precancerous lesions and cervical cancer, Pap smears, or HPV DNA testing for HIV-positive women.

HIV infection and the resulting immunodepression are associated with an increased risk of persistent HPV infection and invasive cervical cancer, an AIDS-defining illness. Various studies show links between HIV infection, HPV

---

* Physician, Scientific Director of the Center Infectiology Lao-Christophe Merieux, Ventiane, Lao PDR.

** Anthropologist, Physician, IRD UMI 233, Inserm U 1175, University of Montpellier, France.

[1] UNAIDS. (2016). *HPV, HIV and cervical cancer: Leveraging synergies to save women's lives*. Geneva: UNAIDS.

[2] World Health Organization. (n.d.). *Cervical Cancer Estimated Incidence, Mortality and Prevalence Worldwide in 2012*. Retrieved from http://globocan.iarc.fr/old/FactSheets/cancers/cervix-new.asp

[3] Bruni, L., Barrionuevo-Rosas, L., Albero, G., Serrano, B., Mena, M., Gómez, D., ... de Sanjosé, S. (2017). ICO Information Centre on HPV and Cancer (HPV Information Centre). *Human Papillomavirus and Related Diseases in Laos. Summary Report 27* July 2017. Retrieved from http://www.hpvcentre.net/statistics/reports/LAO.pdf

infection, and cervical cancer. In a cohort of HIV-positive and HIV-negative women in the United States, HPV infection was found 10 times more often in cases of HIV infection with a CD4 count of less than 200/mm$^3$ (95% CI, OR = 7.32–14.04). It was seven times more frequent when the CD4 count was greater than 200/mm$^3$ and HIV DNA was greater than 20,000 copies/mL (95% CI, OR = 4.17–8.08) and three times more frequent when the CD4 count was greater than 200 mm$^3$ and the HIV DNA was less than 20,000 copies/mL (95% CI, OR = 2.36–4.12).[4] A Thai study that provided a routine Pap smear and HPV screening for HIV-positive women showed a high-risk oncogenic HPV prevalence of 38.6%, an abnormal cervical cytology of 20.4%, and cervical cancer prevalence of 1.9%.[5]

Women living with HIV are therefore particularly affected by HPV screening. Routine screening by Pap smear has reduced the incidence rate of cervical cancer by 60% to 90% in high-income countries.[6] In recent years, tests to detect DNA in oncogenic HPV have shown higher sensitivity, but lower specificity, than Pap smears for screening intraepithelial neoplasia.[7]

A new, easy-to-use test that detects oncogenic HPV DNA, called careHPV™, which can be performed without electricity or running water and provides results in two to five hours, was developed by QIAGEN, a company that sells molecular biology kits specifically for low-income countries. It has performed well, but further evaluation is needed at the local level to assess its conditions for use and its cost-effectiveness.

## The LaoCol-VP research project

The primary objective of the LaoCol-VP study[8] was to compare the efficacy of cervical cancer screening strategies using careHPV™ with a Pap smear and to determine its cost-effectiveness and the average cost per

---

[4] Palefsky, J. M., Minkoff, H., Kalish, L. A., Levine, A., Sacks, H. S., Garcia, P., ... Burk, R. (1999). Cervicovaginal human papillomavirus infection in human immunodeficiency virus-1 (HIV)-positive and high-risk HIV-negative women. *Journal of the National Cancer Institute*, 91 (3), 226–36.

[5] Sirivongrangson, P., Bollen, L. J., Chaovavanich, A., Suksripanich, O., Virapat, P., Tunthanathip, P., ... Levine, W. C. (2007). Screening HIV-infected women for cervical cancer in Thailand: Findings from a demonstration project. *Sexually Transmitted Diseases*, 34 (2), 104–7.

[6] Gustafsson, L., Pontén, J., Zack, M., & Adami, H. O. (1997). International incidence rates of invasive cervical cancer after introduction of cytological screening. *Cancer Causes Control*, 8(5), 755–63.

[7] Mayrand, M.-H., Duarte-Franco, E., Rodrigues, I., Walter, S. D., Hanley, J., Ferenczy, A., ... Franco, E. L. (2007). Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. *N Engl J Med*, *357*, 1579–88.

[8] “LaoCol-VP: Efficacy and cost-effectiveness of careHPV™ human papillomavirus screening versus Pap smear for the detection of precancerous and cancerous cervical lesions among HIV-infected women in Lao PDR”.

diagnosis. Secondary objectives were to study the performance of the two screening tests (sensitivity, specificity, and positive and negative predictive values), their concordance, prevalence results of the various types of oncogenic HPV, and cervical cancer prevalence among HIV-positive women in Laos.

LaoCol-VP also aimed to inform the country's health officials of the magnitude of the problem for women living with HIV and the effectiveness of available screening options. In addition, the study sought to strengthen the capacities of Laotian health providers, who received additional training through the study on the screening, diagnosis, and treatment of cervical cancer.

LaoCol-VP was a transversal multicenter study[9] conducted among 600 Laotian women living with HIV, aged 25 to 65 years, who provided written consent, and who were receiving follow-up care in the country's four main HIV treatment centers. The study was not open to pregnant women or any woman who had given birth in the last three months, or to women who had precancerous or cancerous cervical lesions, or women who were unable or unwilling to give their consent.

In practice, after presenting the study to a participant and obtaining her consent, we collected certain medical and demographic information and offered her a gynecological consultation appointment. The consultation was conducted by a gynecologist, who proposed a gynecological exam to the participant. During the exam, several samples were taken: (i) a cervical swab, (ii) a Pap smear,[10] and (iii) and a cervical exam using a colposcope[11] plus a biopsy if the gynecologist detected an abnormality on the cervix. The various samples were analyzed in two laboratories in Laos and one in Thailand.

The women who were diagnosed with precancerous or cancerous lesions received surgical treatment in accordance with the current practices in Laos. This treatment was provided free of charge through the project.

This study was conducted between May 2013 and June 2015.

## Ethical issues surrounding this study

A study of this type must consider the usual ethical aspects of any health research: informing participants, obtaining their consent, ensuring confidentiality, assessing benefits and risks for study participants, reimbursing travel costs, etc. For example, informing participants requires

---

[9] A transversal study collects all data needed for the study at a specific point in time, and a multicenter study is conducted simultaneously in several different places where the same data is collected.

[10] This involves using a small wooden spatula to scrape superficial cells from the cervix.

[11] A colposcopy is a direct visual examination of the cervix using a binocular microscope.

translating the information documents and consent forms into the country's various lingua francas to ensure they are easily understood.

Moreover, this type of research program highlights four key ethical aspects:

- ***The study's relevance relative to current global scientific knowledge and existing local medical infrastructure:***

Cervical cancer screening in low-income countries is a major public health issue. Until recently, one factor limiting screening was the complexity of screening techniques that required a level of medical infrastructure that was often unavailable in these countries. In 2012, a new screening technique was validated (HPV DNA test). Although the LaoCol-VP study was developed in 2013, the efficacy of this technique still needed to be validated in various epidemiological contexts. Therefore, this study was entirely appropriate given the scientific knowledge at the time. One of the study objectives was also to assess this technique's diagnostic efficacy and costs in order to guide the Government of Laos in defining its public health policy. Another goal was to strengthen health professionals' expertise by providing training on cervical cancer screening and therapeutic care for women diagnosed with lesions. Hence, this study improved cervical cancer screening and treatment in Laos.

- ***Enrolling and informing the women participating in the study:***

This study involved HIV-positive women, who were already diagnosed with HIV and who were being treated in suitable facilities. One major ethical issue is obtaining their consent to participate in the study. On the one hand, the women must have the right to refuse to participate in this study without being excluded from their treatment center. On the other hand, the information that they are given must explain that cervical cancer screening is recommended for all HIV-positive women, without implying that they already have cervical cancer. This distinction may prove difficult for the women to understand. Information that is imprecise or poorly adapted to the women's ability to comprehend it may cause them to think that in addition to being infected with HIV, they also have cancer. This lack of comprehension may have serious psychological consequences. Information for participants must also consider the women's concerns about modesty during a gynecological exam; they must know in advance whether a male or female gynecologist will conduct the consultation. Lastly, participants need a full explanation detailing exactly what happens during a gynecological examination, without minimizing the inconvenience or pain. For example, health professionals often present cervical biopsy as painless, even though many women describe actual pain.

- ***Confidentiality of medical information:***

The primary criterion for enrolling women in this study is that they are HIV positive and receiving care in specialized centers. As part of the LaoCol-

VP study, they underwent a gynecological consultation. Based on the research protocol, the gynecologist and any assisting staff would obviously know that the women were HIV positive. These health professionals must ensure that they fully respected doctor-patient confidentiality about the HIV disease so that participation in this research did not constitute a risk of revealing the diagnosis to a third party without the women's consent.

- ***Adapted medical care based on the diagnoses:***

This study enables early diagnosis and treatment of cervical lesions. The study also covers all medical costs: consultations and care—including treatment of the diagnosed cancers—are free of charge for study participants. This study therefore provided a genuine benefit for participants. The diagnostic and treatment methods were the same in the four treatment centers, thus ensuring the women had equal access to care, despite living in different areas of the country.

## ETHICS AND REGULATORY REFERENCE DOCUMENTS

The ethical issues presented above are highlighted (but not exclusively) in the following documents:

### 1. The World Medical Association Declaration of Helsinki:

- **General principles:**

Article 9: It is the duty of physicians who are involved in medical research to protect the (…) privacy, and confidentiality of personal information of research subjects.

- **Informed consent:**

Article 26: (…) each potential subject must be adequately informed of the aims, methods, (…) the discomfort it may entail.
Article 31: The physician must fully inform the patient which aspects of their care are related to the research.

- **Privacy and confidentiality:**

Article 24: Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

### 2. International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS, 2002

- Guideline 5: Obtaining informed consent: Essential information for prospective research subjects: Before requesting an individual's consent to participate in research, the investigator must provide the following information [about] (…) any foreseeable risks, pain or discomfort, or inconvenience to the individual (or others) associated with participation in the research (…)."

- Guideline 10: Research in populations and communities with limited resources: the research is responsive to the health needs and the priorities of the population or community in which it is to be carried out.

- Guideline 18: Safeguarding confidentiality: The investigator must establish secure safeguards of the confidentiality of subjects' research data. Subjects should be told the limits, legal or other, to the investigators' ability to safeguard confidentiality and the possible consequences of breaches of confidentiality.

### 3. Universal Declaration on Bioethics and Human Rights, UNESCO, 2005

Article 9: Privacy and confidentiality: The privacy of the persons concerned and the confidentiality of their personal information should be respected.

Article 10: Equality, justice and equity: The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11: Non-discrimination and non-stigmatization: No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 21: Transnational practices: Transnational health research should be responsive to the needs of host countries.

* * *

# Ethical Issues to Consider Before Starting Research: Example of a Study on Preventing Mother-to-Child Transmission of the Hepatitis B Virus

Gonzague JOURDAIN,* Woottichai KHAMDUANG,**
Vatthanaphone LATTHAPHASAVANG***

## Distinction between treatment and research

Clinical research investigates interventions that may affect human health. This may be observational, limited to a description, or interventional, evaluating the consequences of an intervention on the wellbeing of a population or group; but no matter the form, it always involves interactions with the participants. The possible immediate or future consequences of these interactions must be taken into consideration, especially because the patient is not the one seeking the research. Usually it is a physician who designs the research study and proposes participation in it to a person who contacts him or her for treatment, not to be a research subject. In a way, this changes the tacit contract between doctor and patient. In order to not mislead the patient, the doctor must clearly explain the objectives of the research, thus assuming two roles: first as a physician trying to provide the best possible care to improve a specific patient's health condition (using current medical knowledge), and second as a researcher trying to answer an unresolved scientific question with the ultimate goal of adding to the body of knowledge about human health as a whole.

In the early twenty-first century, biomedicine is increasingly based on the results of clinical studies, i.e., experiments on patients that have demonstrated the efficacy and effectiveness[1] of diagnostic tests, prophylactic or therapeutic interventions, or explorations. This scientific foundation gives credibility to public health systems and justifies their funding. The most convincing recommendations from health authorities must be based on data generated when evaluating interventions. In the

---

* Epidemiologist, Institut de Recherche pour le Développement (IRD), France.
** Faculty of Associated Medical Sciences, Chiang Mai University, Thailand.
*** Physician, Mahosot Hospital, Vientiane, Lao PDR.

[1] Efficacy: exhibits some health benefit, as predefined and evaluated in a clinical study; effectiveness: provides benefits to patients in real-life conditions.

absence of such data, the analysis of data collected from groups over a period of time (called cohorts) may be used.

Yet in many situations such data are either unavailable or of uncertain quality. Thus, some recommendations are only based on expert opinions formed through personal experience and/or a thorough review of the scientific literature and pathogenesis rationale. Due to subjectivity and uncertainty, the best course of action may remain unclear. Should we—can we—question a practice recommended by experts when it seems useful despite a lack of decisive evidence?

Is it ethical to conduct a clinical study comparing a recommended intervention versus no intervention, to determine its efficacy? For example, randomized “controlled” clinical trials can be conducted to compare the effects of a drug against a comparator. In such trials, patients are randomly assigned to one of two groups, one group receiving the drug and the other receiving something that looks similar but does not contain the active ingredient (a placebo).

This question is not specific to a place or a period of time, but arises in a specific context that may influence how we think about it. We will illustrate this issue of research ethics by describing our approach in a specific example: the use of antivirals to prevent mother-to-child transmission (MTCT) of hepatitis B virus in Southeast Asia.

## Preventing mother-to-child transmission of the hepatitis B virus

Chronic hepatitis B virus (HBV) affects 257 million people in the world.[2] Hepatitis C affects 71 million people, and viral hepatides B and C together were the seventh leading cause of death worldwide in 2013.[3] These diseases led to 1.34 million deaths in 2015 (more than HIV-related deaths), a number that has increased by 22% since 2000.[4] Asia is disproportionately affected by this pandemic, where MTCT is the primary source of new HBV infections.[5] WHO recommends universal HBV immunization, i.e., vaccinating all children regardless of maternal infection, beginning with a first dose of the vaccine administered shortly after birth. This strategy has considerably reduced the

---

2. World Health Organization. (2017). *Global hepatitis report 2017*. World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/255016/1/9789241565455-eng.pdf?ua=1.
3. Stanaway, J. D., Abraham D., Flaxman, A. D., Naghavi, M., Fitzmaurice, C., Vos, T., Abubakar, I. (2016). The global burden of viral hepatitis from 1990 to 2013: findings from the global burden of disease study 2013. *Lancet*, 388, 1081–1088. http://dx.doi.org/10.1016/S0140-6736(16)30579-7
4. World Health Organization. (2017). *Global hepatitis report 2017*. World Health Organization. Available at: http://apps.who.int/iris/bitstream/10665/255016/1/9789241565455-eng.pdf?ua=1
5. WHO. (2015) *Guidelines for the Prevention, Care and Treatment of Persons with Chronic Hepatitis B Infection*. WHO: Geneva, Switzerland, p 136.

prevalence of HBV everywhere it has been implemented. When infants are born to infected mothers, the additional administration of a vaccine composed of specific antibodies (anti-HB immunoglobulins) taken from immunized, uninfected individuals is considered to be effective, even though it is based on old studies that were not conducted in accordance with today's quality standards. The efficacy of this practice is not known with great certainty, especially if the mother's viral load is not high. Because of this uncertainty, and the fact that this additional intervention increases program costs and logistics (cold chain), this strategy is not universally recommended and is not always covered by a country's health insurance systems.

Furthermore, despite this dual intervention (vaccine plus immunoglobulins), HBV may still be transmitted when the mother has a very high viral load. Therefore, it has been proposed that anti-HBV antiviral treatment be prescribed to these mothers during the end of pregnancy and first weeks following birth.

In 2015, no studies meeting international clinical research quality criteria had clearly demonstrated the efficacy or safety (absence of adverse effects) of this approach for the mother and child. An antiviral prescribed during the end of pregnancy does reduce the maternal viral load. Therefore, the approach seems logical and similar to the approach used to prevent MTCT of HIV. More and more physicians have been prescribing antivirals to pregnant women infected with HBV, even though this practice is not formally approved by the health authorities that regulate and monitor the use of medicines because of the lack of well-established evidence. Exposure to antivirals, even for a few months, may actually cause adverse effects of varying severity to both mother and child. These risks should be compared against the uncertain benefits of the intervention. Neither the U.S. Food and Drug Administration (FDA) nor the European Medicines Agency (EMA) have approved this indication for an antiviral because of the lack of data. And yet the three main associations for the study of liver diseases (APASL, EASL, and AASLD[6]) recommend the use of this prophylactic treatment, though the strength of recommendation varies. The American Association for the Study of Liver Diseases, for example, bases its recommendation on a retrospective meta-analysis, yet recognizes its limitations and does not give specific guidelines on treatment administration. In its most recent (2015) recommendations for hepatitis B treatment, WHO decided not to formulate guidelines on the use of antivirals for this indication, preferring to wait for conclusive evidence of their efficacy and safety.[7]

---

[6] Asian Pacific Association for the Study of the Liver Diseases, European Association for the Study of the Liver, and American Association for the Study of the Liver.

[7] WHO. (2015). *Guidelines for the Prevention, Care and Treatment of Persons with Chronic Hepatitis B Infection*. WHO: Geneva, Switzerland, p 136.

Given the wide range of expert opinions on this issue, the question doctors ask themselves—or should—is how to know whether or not it is legitimate to expose women and children to an antiviral treatment when the efficacy and tolerance of the treatment by individuals is unknown. This is a question best answered by a clinical study, which could tell us if such prophylactic treatment actually helps prevent the transmission of HBV without causing any major adverse effects. If such a study were submitted to an ethics committee, what type of questions would need to be addressed?

## Ethical review of an experimental clinical study project

First and foremost, for research to be ethical it must (i) be based in science, (ii) address an actual issue, and (iii) be likely to reach a conclusion, whether expected or unexpected. Researchers must convince patients—potential participants—that the research is useful and that there are good reasons for conducting it. They must also explain the benefits patients might expect both for themselves and for others with the same condition in the future. In our example, the investigator is personally convinced that a clinical study can provide unique information that will definitely support recommendations for the use of this prophylaxis or provide a rationale for not using it. Pending the results of the study, it is unknown whether patients will benefit from receiving the treatment.

Investigators also need to explain any risks the research might pose for the patients, their families, or others close to them. In our example, the knowledge gained from systematically recording the pregnancy outcomes among women who took the drug during pregnancy was reassuring, but we could not rule out the possibility that this type of treatment during pregnancy might affect the fetus or the child.

One of the methods used by people who review the ethical aspects of research like clinical research is to "put yourself in the place" of the participant, and ask if you yourself would agree to participate in it. In our example, without any treatment a mother may transmit the virus to her child. However, due to the lack of evidence from clinical trials, we cannot be sure that treating the mother will in fact decrease this risk.

Another key aspect of ethical research is summarizing and explaining the scientific questions being investigated so that patients can make what is called an informed choice. An informed decision can only be made after a patient has understood the issue, which requires explanation at an appropriate level (see the chapter on informed consent). One way of devising a simple explanation is to talk about the study with, and explain its important details to, someone who is not a health professional. When an institution has a community advisory board in place, such exchanges occur naturally. When research involves people from several cultures, this becomes an essential step towards clearing up any of the ambiguities or misunderstandings that abound in intercultural relations, especially because ideas can have culturally based meanings that may cause confusion, even when the words are translated into the appropriate language.

## Researchers must examine their own conscience

While investigators are rationale beings, they are also human beings. As such, they must question their own motivations for conducting the research. Is there a personal interest involved (financial or otherwise, such as academic or professional advancement) that would steer the research to be performed in a certain way, to obtain a particular result? An investigator's organization could also influence how a scientific question is asked and studied. These aspects may be discussed with the ethics committee for the research organization where the investigator works.

Another issue is that the research may be largely funded by a foreign organization. Are there any reasons for the participants to believe that they are taking risks that would not be taken in the country providing the funding? Patients and investigators both may question the motivations of those behind the research program. Who will benefit financially from the scientific results? The country where the funds come from, or the country where the research is being conducted? In the case given here, it makes sense to conduct research in a country in the Mekong region because over 100 million people are infected with HBV in Asia, so the primary expected benefit will mainly be for populations in the countries on that continent. Any treatment, once its hoped-for efficacy and tolerance have been proven, must be available and accessible to the population from which patients were selected.

## Special case of pregnant women

Some texts on ethics as well as regulations in many countries consider pregnant women, fetuses, and children to be "vulnerable" populations that are fragile and unable to defend themselves, thus requiring additional protections when involved in research (e.g., the committee chairperson cannot approve the research on his or her own, there is no exemption for written consent). An additional question in our case was whether or not it was acceptable to expose the mother to any treatment-related risks when the treatment was for the exclusive benefit of the child.

## Conclusion

This summary does not presume to cover all ethical questions that should be asked when designing a study involving an intervention in human health. There are manuals that provide thorough coverage of these questions. We hope that the real-life example given here can help readers in their own journey of introspective enquiry when designing a clinical trial.

# Ethical Aspects When Using Biological Samples for Research

**Audrey Dubot-Pérès,[*] Claire Lajaunie,[**]
with Manivanh Vongsouvath[***]**

Biological samples are indispensable in biology research, whether as part of basic research to better understand physiological or pathological function; in epidemiological studies; or in the development of diagnostic tests, treatments, or vaccines. A sample is a small quantity of a substance that is collected to study its characteristics, along with information about the sample. A sample without information has no scientific value. There are various types of samples: healthy or diseased tissue from humans or domestic or wild animals, elements from the environment (water, soil, air), or derivatives from these samples (proteins, nucleic acids, associated pathogens). This section will address the ethical issues related to the collection, use, storage, circulation, and sharing of samples between institutions, individuals, and countries.

## Data collection and use

### *Sample collection: what*

The type, volume, and number of samples collected should be limited to only what is necessary to achieve the objectives of the research. Samples should also be collected using the least invasive method possible: a blood sample is preferred over a tissue biopsy, for example, and blood samples should involve minimal volume and be age-appropriate. This should be clearly specified and justified in the research protocol submitted to the ethics committee before the study begins. The rules for sample collection should not change during the study without the prior approval of an ethics committee. It is not an opportunity to “collect as many samples as possible.”

---

[*] Virologist, Emerging Virus Unit, University of Aix-Marseille – IRD 190 – Inserm 1207 – EHESP – IHU Méditerranée Infection, Faculty of Medicine of Marseille, France.

[**] Researcher, Inserm. UMR CNRS 7318, University of Aix-Marseille, International Comparative and European Law, Ceric, Faculty of Law of Aix, Aix-en-Provence; Researcher with the Strathclyde Centre for Environmental Law & Governance, Strathclyde University, Glasgow, Scotland.

[***] Director of the Microbiology Laboratory at Mahosot Hospital, Vientiane, Laos.

For example, in a study of arboviruses in febrile patients that only requires a blood sample for diagnosis, there may be a temptation to also take throat and rectal samples, which could be used for future research. Such thinking raises ethical issues: it would be dishonest to hide the actual reason for the collection, which could result in “dehumanizing” the patient into a mere source of biological samples.

New technologies have been developed that allow research on wild animals to use droppings in place of tissue samples for some types of research (such as antibody or pathogen detection).

Would it be ethical to take a sample of cerebrospinal fluid (CSF) via lumbar puncture in patients with no neurological symptoms to study asymptomatic carriers, similarly to what is often done with blood samples, given that the lumbar puncture procedure is painful and not completely harmless?

### *Sample collection: how*

The collection procedure should be detailed in the research protocol and should include the sampling method, associated information, collection duration and period, and the list of those who will perform the procedure. The method should be selected to minimize any discomfort for the participant, such as by using small amounts that are age-appropriate. Thus in a study of seroprevalence in the general population, it is preferable to take a blood sample by pricking the fingertip rather than using the more invasive procedure of venous puncture. When collecting samples from human subjects you must obtain their consent. This involves authorization to take the sample itself but also includes consent to participate in the research, and possibly storage of the sample for a specific use at a later date. Participants may leave the study at any time, even after sample collection, in which case their samples are destroyed. A sample may also be taken as part of medical treatment, such as the removal of a tumor that is later used in a research project.

For samples taken from animals and associated environments, the World Organisation for Animal Health (OIE) has established guidelines (OIE Terrestrial Manual, 2016) that detail sample collection (safety measures to avoid contaminating the environment, volume and type of sample appropriate for the tests to be performed, animal-appropriate sampling technique, and necropsy by a veterinarian), sample size (to be calculated based on epidemiological data and study objectives), and the information to collect along with the sample (location, description of the organism sampled, and epidemiological information).

The researcher is responsible for complying with local regulations. Authorization may be needed from the competent local authorities. The manner in which samples are collected should also be considered from an ethical perspective. The procedure should respect the target environment and population, individual and group sensitivities, and the safety of those collecting the samples.

In a research project to characterize a type of local flora, authorizations must be obtained (from private land owners, directors of national parks, etc.) for the collection of a particular type of plant in a defined location. The researcher must take care to neither degrade nor deplete the flora during collection, and verify that the plant in question is not subject to national or international protective measures. Once on site, if the team discovers another plant of interest that is not included in the study protocol, a new protocol should be drawn up and new authorizations obtained.

How do we manage a local population's perceptions of scientists, dressed in lab coats, masks, and gloves, arriving in the countryside to take potentially pathogenic samples from wild animals?

## Limitations in the use of research samples

Samples may only be used within the strict framework specified in the research protocol and included in the consent form signed by participants. Before samples can be used for any other purpose, individual consent must be obtained once again from each participant after the ethics committee has approved the new research protocol. This is also true for samples taken as part of a medical treatment, before they can be used for a scientific purpose other than the one for which they were originally collected.

When a sample is taken as part of a medical treatment, one might think that any experiments conducted on the sample that do not affect the patient have no ethical implications. However, the research that led to the development of the first immortal cell line shows us that this is not the case.

In 1951, Henrietta Lacks died from the complications of highly aggressive cervical cancer. Without her consent, her treating physician gave a sample of her tumor to an oncologist, Dr. Gey, who developed the first line of immortal cells, HeLa. Scientists later took blood samples from Henrietta's children under the guise of oncology follow-up, which they used to conduct research on HeLa cells. The scientists produced thousands of kilograms of cells for research laboratories. They are the most widely used human cells in the world. Sales of these cells have created millions of dollars of profit, but the Lacks family did not receive any share of the financial windfall and continued to live in poverty. When her children were finally informed, more than twenty years later, they publically denounced the researchers' behavior towards them and lamented the fact that their mother did not even have a decent gravesite for her service to science.[1]

---

[1] Skloot, R. (2010), *The immortal life of Henrietta Lacks*, New York: Crown Publishers.

When a sample is received for pathology analysis on behalf of a patient, can it subsequently be used in a research program?

## Storage and sharing

### *Why store samples?*

Biological samples are precious both by their very nature and for their scientific value, and may harbor far more information than that gleaned from their initial use. It became clear early in medical studies that human-derived samples and pathogenic agents needed to be conserved in order to understand diseases and improve treatments.[2] Specimens from wild animals are usually stored by recognized institutions such as natural history museums. Samples containing microorganisms are generally stored at medical institutions.

While it is not considered ethical to use biological samples for anything other than the original purpose, it can also be argued that it is equally unethical to dispose of samples at the end of experimentation. Take the example of a study of the seroprevalence of dengue viruses circulating in a general population, during which serum samples are taken from individuals of all ages. Once the study is completed, the samples are thrown away. If another research team is subsequently interested in studying the public health significance of hepatitis C virus infection and wants to conduct a seroprevalence study in the same population, they would need to subject this population to another needle stick to collect more blood samples, when the previous ones could have been used had they been conserved.

Biological sample collections are evidence of a biological situation at a given place and time. New technologies may be able to extract new information from them at a later date. Advances in molecular biology, for example, have resulted in some species being reassigned to a different taxonomic classification.

A researcher's decision to store or dispose of samples at the end of a study should be included in the research protocol and information for participants.

### *What is a biobank?*

The term "biobank" has several definitions, depending on its contents and purpose. A group of experts from the European Commission defined the

---

[2] Lajaunie, C., & Morand, S. (2015). Barcoding, biobanking, e-banking: From ecological to ethical and legal aspects. Insights from the PathoDivSEA Project. In S. Morand, J-P. Dujardin, R. Lefait-Rollin, & C. Apiwathnasorn. (Eds.), *Socio-ecological dimensions of infectious diseases in Southeast Asia*. Singapore: Springer, 217–27.

term as “the biological samples themselves, plus the related databases, allowing a certain level of accessibility, availability, and exchange for scientific studies.”[3]

A biobank is a way for the scientific community to share samples and related information, and thus has an obligation to provide high-quality storage of materials and related information. The quality of the collection may differ from one biobank to another, depending on their resources. Anne Cambon-Thomsen[4] makes the following distinctions: (i) simple sample storage (several samples in a laboratory); (ii) an organized collection for the specific purposes of research, diagnosis, or donation; and (iii) a sample bank operating independently with storage as its primary activity.

Many researchers are unaware that the samples stored in their laboratory constitute a biobank. There is no international standard as of this writing for biobank operations, although there are ethical standards in human health to guide researchers (statements from UNESCO, Council for International Organizations of Medical Science (CIOMS) Guidelines). For samples to be useable, a certain amount of information must be stored with them: type (blood, liver biopsy, etc.), species, collection site, and date. Other additional data are often quite useful as well, such as the nucleic acid sequence, results of analyses, environmental information, photos of the collection site, photos of the specimen the sample was taken from, GPS coordinates, and so forth. Medical and personal information is usually stored for human samples, which are rendered anonymous to ensure confidentiality. However, researchers must be able to contact every donor personally for any future request for consent, and the source of every sample must be known in case the donor decides to withdraw from the study. Therefore identification data must be stored in such a way as to maintain strict confidentiality vis-à-vis those who use the samples.

An example of the process: I have returned from collecting mosquito samples. How should I organize the storage of these samples in my laboratory?

### *Who owns the samples?*

Biological samples collected as part of scientific research belong to the research body itself and not to its researchers. When samples are transferred from one institute to another, these bodies sign an agreement defining the rights of both the source and the receiving institute regarding the use of the samples and any derivatives therefrom. The transfer of

---

3. Lajaunie C., et al., *Op. cit.*
4. Cambon-Thomsen, A. (2001). Les problèmes pratiques et éthiques que pose le stockage des échantillons biologiques. In: Dossier : Médecine prédictive : mythe et réalité, *Actualité et dossiers en santé publique, 34,* 55–61.

samples from one country to another is more complex; the regulations of each must be followed, including any rules about leaving the territory. The Nagoya Protocol addresses access to genetic resources and the fair and equitable sharing of benefits arising from them, including when such resources leave a country.

The issue of ownership is even more complex for human samples, because it relates to the question of who owns the human body and its parts. Consent must be obtained from an individual before any of his or her body parts can be used, but this person cannot derive any financial gain from such use.[5]

Every year flu vaccines are developed in countries in the global North using strains circulating in the southern hemisphere. Going forward, sharing of these benefits between the pharmaceutical companies and the countries where the viral strains originate should be considered within the context of the Nagoya Protocol.

## Conclusion

It is important to work with local actors when collecting any types of samples, bearing in mind the basic principle that use of the samples should primarily benefit the source population. Fieldwork does not end with sample collection. Consideration should always be given as early as possible to the local impact, in accordance with the Nagoya Protocol. Some of the non-monetary benefits suggested in the Protocol include contribution to scientific research programs and local development; international collaboration between researchers; and contributions to education and training. Such benefits should be envisioned and clearly formulated from the start of the research project.

---

[5] Council of Europe. (1997). Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. Convention on Human Rights and Biomedicine.

## ETHICS AND REGULATORY REFERENCE DOCUMENTS

CIOMS, WHO. International Ethical Guidelines for Health-related Research Involving Humans [Internet]. 2016. Available at: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

OIE. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (known as the Terrestrial Manual) [Internet]. 2016. Available at: http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

Convention on Biological Diversity, United Nations. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization [Internet]. 2012. Available at: https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

* * *

# Ethical Perspectives on a Survey of Adolescents Born with HIV in Thailand

**Sophie Le Cœur,[*] Éva Lelièvre,[**]**
**Cheeraya Kanabkaew[***]**

In recent decades, antiretroviral therapies have significantly improved the life expectancy of children born with HIV.

Nevertheless, these children reach the critical age of adolescence following what was often a difficult childhood: a family history often disrupted by the disease and the subsequent death of one or both parents, the experience of a disease punctuated by episodes of serious illness, the shock when they learn of their infection, and experiences of discrimination from other children or adults in their social circle. In this especially challenging family and social context, relatives, caregivers, patient association members, and government officials must give serious thought to these children's situations and futures in order to guide a public health response.

The TEEWA (TEEns living With Antiretrovirals) study was designed to respond to this need.[1,2] Its primary goal was to assess the family and social situation and needs of Thai children infected with HIV at birth who are on treatment as they enter into adulthood. This involved understanding these adolescents' situations as well as their aspirations, behaviors, and living arrangements throughout their lives and medical care trajectories.

---

[*] Epidemiologist, Physician, Institut National d'Etudes Démographiques (INED), F-75020 Paris, France; Institut de Recherche pour le Développement (IRD) UMI 174-PHPT, Marseille, France; Faculty of Associated Medical Sciences, Chiang Mai University, Chiang Mai, Thailand.

[**] Demographer, Institut National d'Etudes Démographiques (INED), F-75020 Paris, France.

[***] Research Nurse, Institut de Recherche pour le Développement (IRD) UMI 174-PHPT, Marseille, France; Faculty of Associated Medical Sciences, Chiang Mai University, Chiang Mai, Thailand.

[1] Le Cœur, S., Lelièvre, É., Kanabkaew, C., & Sirirungsi, W. (2017). A survey of adolescents born with HIV: the TEEWA Project in Thailand. Population-E, 72 (2), 2017, 333–356. pope.1702.0333.

[2] Xu ; L., Munir, K., Kanabkaew, C., & Le Cœur, S. (2017). Factors influencing antiretroviral treatment suboptimal adherence among perinatally HIV-infected adolescents in Thailand. *PLoS ONE* 12(2): e0172392. https://doi.org/10.1371/journal.pone.0172392

We designed a survey that captured the diversity of their life trajectories, family situations, and living arrangements. The process also needed to avoid rekindling painful past experiences and maintain confidentiality and anonymity. Lastly, it was important not to risk revealing the HIV infection to adolescents who did not necessarily know their status.

Since access to adolescents born with HIV was only possible through the hospitals where they receive follow-up care and treatment, we set up a survey using lists provided by the hospitals, supplemented with information collected from various respondents to gain a broad view of adolescents' lives:

1. Regardless of whether or not they were aware of their status, the adolescents completed a questionnaire that did not mention HIV infection or the disease. This self-administered questionnaire asked the adolescents about people who live in their households, their personal space, participation in household chores, schooling and/or employment, hobbies, social networks and interactions with peer groups, risky behaviors, and relationships with adults. It also addressed perceptions of their health, physical appearance, puberty, dating, sexuality, and how they view their futures. Each adolescent completed the questionnaire individually and could ask the survey coordinator questions if needed.

2. We also approached their parents or the person responsible for the child (their guardian) to collect information about events in the adolescents' family life. The questionnaire for the parent or adult guardian was administered face to face. It explored the child's family history (separation and/or death of parents, successive guardians), residential mobility, schooling, disease history (date and circumstances of the diagnosis, date of initiation of antiretroviral therapy, date of disclosure), circumstances for treatment administration (responsibility of adults, assessment of treatment adherence), the adolescent's behavior and well-being, along with any reported experiences of discrimination within the family, village, or school. The interview took place in a private room that met the conditions for confidentiality.

3. Lastly, the hospital files at the facility where the adolescents received follow-up care were consulted to record details about their treatment regimen and the stage of the disease.

Of the 941 adolescents treated in the relevant health facilities, 709 (75%) agreed to participate in the survey. Detailed information about the project was provided face to face, with the interviewer encouraging the respondent to ask questions. After hearing about the study, all parents/adult guardians and the adolescents agreed to participate.

How do researchers ensure that ethical conditions are met in this type of study, guaranteeing that study-related risks are minimized and that respondents are protected and can give consent (or assent) without risking untimely revelations?

## Ethical issues for this type of research

The ethical issues of this type of research primarily concern the interviewees' vulnerability, due to their HIV infection as well as their age. Because of the HIV component, respecting study participants' privacy is crucial, especially since the disease still suffers widespread stigmatization and because divulging HIV status to HIV-positive youths who are unaware of their disease or to their social circles can have serious social and psychological consequences.

### *Consent and assent*

In the specific case of our study, the adolescents were predominantly minors (the legal age of majority is 18 years in Thailand). Furthermore, since many had lost their parents to AIDS, a grand-parent, other family member, or even someone outside the family was frequently legally responsible for the child.

Participation in the survey required prior consent from the adult guardian, who was informed of the study objectives and the questionnaires' content. The parent or guardian agreed to let the adolescent participate in the data collection and to be interviewed. For the adolescents, despite having not reached the age of legal majority, they were mature enough to answer questions about themselves in the self-administered questionnaire. Before signing the assent form, they received an information sheet specifying that they would be interviewed about their life styles and health and that their parent/adult guardian would also be interviewed about them.

The consent and assent forms were reviewed by the Community Advisory Board (CAB) and by the Youth Community Advisory Board (Youth-CAB) to ensure that a young audience could easily understand them.[3]

The **Community Advisory Board** is composed of patient association members, family members, NGO representatives, medical staff, and community leaders to discuss projects and priorities with research teams. They receive training in HIV counseling, clinical research, and the ethical issues of research. When consulted, they provide feedback on the data collection documents (forms and others) submitted to them. They also act as a channel for sharing the study results with relevant populations and health officials.

---

[3] Consent and assent forms were first written in English then translated into Thai, then retranslated into English to check the translation's accuracy.

The **Youth Community Advisory Board** was established to respond to the specific issues posed by HIV infection in children and adolescents. Supervised by the adult CAB members, the board is composed of adolescents who are HIV positive or who have a parent who is positive along with other adolescents affected by HIV. Similar to the adult CAB members, the youth members are trained in HIV and research ethics; they check collection documents and patient information sheets for studies relevant to them.

### *Confidentiality*

Managing confidentiality was also challenging. Questioning a third party, namely an adolescent's parent or guardian, about an adolescent's social or sexual life, requires precautions. It seemed especially important to inform the adolescents and gain their approval before the responsible adult could respond to questions about them and to ensure the adolescents' own answers to the questions would remain confidential. Likewise, the responsible adults were assured their responses about the child were confidential.

### *Risk of untimely revelation of HIV infection during the survey*

Another ethical issue in our study was protecting the surveyed adolescents from an untimely or accidental revelation of their serological status during the survey, since some adolescents born with HIV might still have been unaware of their HIV status even if they were older than 12 years. Consequently, any documentation about the project had to be accurate but selective, corresponding to the topics addressed with each category of respondents. The survey information sheet and the questionnaire for adolescents made no mention of HIV but referred to a broad understanding of health and well-being.

The protocol, questionnaires, and information sheets were submitted, reviewed, and approved by the Ethics Committee of the Faculty of Associated Medical Sciences, Chiang Mai University, and the protocol was reviewed by the Comité consultatif de déontologie et d'éthique (CCDE) of the Institut de Recherche pour le Développement (IRD).

### *Risk of rekindling psychological suffering*

Biographical information about the health of the adolescents' parents was collected from the guardians (the parents might have died) or the parents themselves to avoid having the adolescents revisit potentially traumatizing past events, such as a parent's illness or death. Specific precautions were taken to prevent this: the two TEEWA interviewers, who had experience in a similar survey of adults, were supervised by a research assistant who was also a trained nurse. They could report problematic situations that warranted psychological or medical care. In about 10 cases, the survey coordinator warned the referral physician about difficult familial or social situations that adversely affected the adolescent's care.

### *Benefits/risks for adolescents participating in the research*

This survey met a pressing social demand from families, caregivers, and patient associations. While having no direct benefit for the adolescents, this study sent a clear message about their needs and aspirations to the country's health officials to help them set appropriate policy. Pediatricians along with the CAB and the Youth-CAB served as communication liaisons with Ministry of Health representatives.[4,5]

The survey addressed some sensitive topics for adolescents, such as puberty, dating, and sexuality. We knew that all adolescents in Thailand receive sexuality education—either in school, in youth camps, or from their doctors—and we did not believe it was necessary to offer them a specific space to discuss these issues, especially since the survey objective was not to specifically investigate their sexual practices, nor to assess their knowledge about sexuality. Instead, we primarily wanted to know if they had actually received sexuality education and whether they had initiated their sexual lives. Analysis of the survey results shows that 89% of the boys and 96% of the girls aged 15 to 19 years had had sexuality education courses and that only 16% of boys and 8% of girls had engaged in sexual relations.[6]

### Conclusion

Surveying a population of adolescents born with HIV about their life trajectories, treatment, and living conditions requires a specific approach that is supportive while avoiding aggravating their situation. The fact that

---

4. Nammuang, S., Punyasriwichai, S., Charauonwong, S., Saimee, A., Chalermpantmetagul, S., Kanabkaew, C., Sukrakanchana, P., Le Cœur, S., Jourdain, G. (2013). Community advisory board for HIV and infectious disease research: experience from PHPT, Thailand. In 11th International Congress on AIDS in Asia and the Pacific. Bangkok, Thailand. 18–22 November.
5. Ya-a-nan, P., Saengkham, S., Taboon, C., Sanyabhumi, Y., Satthathaweekun, S., Chamnong, K., Chalermpantmetagul, S., Le Cœur, S. (2013). Youth Community Advisory Board (Youth-CAB) for HIV research: experiences from PHPT research unit. In 11th International Congress on AIDS in Asia and the Pacific. Bangkok, Thailand. 18–22 November.
6. Rolland-Guillard, L., de La Rochebrochard, E., Sirirungsi, W., Kanabkaew, C., Breton, D., & Le Cœur, S. (2017). Reproductive health, social life and future plans of adolescents born with HIV: a case-control study in Thailand. 9th IAS Conference on HIV Science, Paris, France, 23–26 July 2017.

they may or may not be aware of their HIV status and that they are minors who are often cared for by relatives rather than their parents also means choosing a survey methodology that guarantees that data collection poses no harm while ensuring that information is accurate.

### Ethics and Regulatory Reference Documents

**The World Medical Association *Declaration of Helsinki***, 2013 states that: “All vulnerable groups and individuals should receive specifically considered protection” (**Article 19**) and that: “Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research” (**Article 20**).

### *International Ethical Guidelines for Health-related Research Involving Humans*, Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Healt Organization (WHO), Geneva, 2016

**Guideline 17** specifies the circumstances in which children and adolescents may be included in a study.

“Children and adolescents must be included in health-related research unless a good scientific reason justifies their exclusion. As children and adolescents have distinctive physiologies and health needs, they merit special consideration by researchers and research ethics committees. However, their distinctive physiologies and emotional development may also place children and adolescents at increased risk of being harmed in the conduct of research. Moreover, without appropriate support, they may not be able to protect their own interests due to their evolving capacity to give informed consent. Specific protections to safeguard children’s rights and welfare in the research are therefore necessary.

Before undertaking research involving children and adolescents, the researcher and the research ethics committee must ensure that:

- a parent or a legally authorized representative of the child or adolescent has given permission; and
- the agreement (assent) of the child or adolescent has been obtained in keeping with the child’s or adolescent’s capacity, after having been provided with adequate information about the research tailored to the child’s or adolescent’s level of maturity.”

"For research interventions or procedures that have the potential to benefit children or adolescents, the risks must be minimized and outweighed by the prospect of potential individual benefit.

For research interventions or procedures that have no potential individual benefits for participants, two conditions apply:
– the interventions and procedures should be studied in adults first, when these interventions and procedures target conditions that affect adults as well as children and adolescents, unless the necessary data cannot be obtained without participation of children or adolescents; and
– the risks must be minimized and no more than minimal.
When the social value of the studies with such research interventions and procedures is compelling, and these studies cannot be conducted in adults, a research ethics committee may permit a minor increase above minimal risk."

***Regarding assent, the guidelines state:***

"Children and adolescents who are legally minors cannot give legally valid informed consent, but they may be able to give assent. To give assent means that the child or adolescent is meaningfully engaged in the research discussion in accordance with his or her capacities. Assent must be considered as a process (see Guideline 9 – Individuals capable of giving informed consent) and is not merely the absence of dissent. Furthermore, the researcher must involve the child or adolescent in the actual decision-making process and use age-appropriate information. It is of major importance to inform the child or adolescent and obtain assent as described above, preferably in writing for children who are literate. The process of obtaining assent must take into account not only the age of children, but also their individual circumstances, life experiences, emotional and psychological maturity, intellectual capabilities and the child's or adolescent's family situation.
As adolescents near the age of majority, their agreement to participate in research may be ethically (though not legally) equivalent to consent. In this situation, parental consent is ethically best considered as 'co-consent' but legally, the adolescent's agreement remains assent. If child or adolescent participants reach the legal age of majority according to applicable law and become capable of independent informed consent during the research, their written informed consent to continued participation must be sought and their decision respected."

**_Ethics Charter for Research in Developing Countries_, ANRS, 2017**

The ANRS Ethics Charter also specifies the case of children and adolescents: "In research involving children and adolescents, who are not empowered to give consent, the legally authorized representative (as per national rules) needs to give permission for research participation. Every effort should be made to obtain the consent of the two parents or guardians, following the regulations of the country where the research is being carried out.

Researchers must also ensure that a child and/or an adolescent able to understand the implications of her/his participation in the project, give his assent, to the extent of her/his capacities, as per conditions described above (§3.2, 7th paragraph). Not all children and adolescents have the same maturity, thus a case-by-case process is recommended."

# *Part II*

# Ethics in Environmental Studies

# Introduction

## Marie-Geneviève PINSART*

Human beings hunt, gather, farm, and raise animals for food; they use plants to make medicines and to build their homes. Nature provides humans with a means of survival but also plays a spiritual and religious role in their lives: human beings are able to respect the forces of nature because they seem to manifest the power of a creator or spirits; they can revere the sacred nature of an animal (the cow), a tree (the banyan), or a mountain.

Throughout their entire history, humans have maintained a dual attitude toward nature. On one hand they try to control and shape it (rice terraces), while on the other they have protected and revered it.

Therefore, humans have always had an ethical relationship with nature: their behavior has been value-driven, defining what they may or may not do to nature. So why was it necessary to create "environmental ethics" at the end of the nineteenth century in industrialized countries?

Because it was apparent that nature was seriously endangered—by industrial pollution (causing climate change today); by the population explosion (resulting in massive deforestation to farm new land, which pushed animals from their habitats and food); by the desire to get rich by using natural resources with no regard to the harmful effects on humans and nature; by poaching so intense that some animal species now face extinction; and so on.

The "environmental crisis"[1] embodies the realization that human activity puts nature at risk. The very existence of numerous plant and animal species is threatened (loss of biodiversity) because flora and fauna can no longer counterbalance the harm and destruction caused by industrial and demographic development.

In response to the "environmental crisis," four main schools of thought have emerged in industrialized countries to identify the ethical dimensions of human activities that imperil the environment.

---

* Philosopher, Professor of Philosophy and Ethics at the Free University of Brussels (ULB), Belgium.

[1] See: Lynn White Jr, "The historical roots of our ecological crisis," *Science*, 1967. The author defends the idea that reducing nature to a mere resource to be used by humans who ascribe to the Christian ideal that they are "made in God's image" lies at the root of the environmental crisis.

The Asian elephant serves as a useful example to help us understand these four ways of thinking about the relationship between humans and the environment.

## 1. Anthropocentrism: “The elephant only has ethical value because it is used by human beings”

Critics often point to anthropocentrism as the cause of the “environmental crisis.” This philosophy puts humans at the center of ethics, as the ones who decide what is right and wrong depending on their own interests. Speciesism is another way to refer to this human behavior that only applies ethical considerations when it is useful to the human species.

Therefore, if the elephant helps humans by transporting them on its back or by dragging tree trunks through the forest, it has a positive ethical value because it is useful to humans. Voluntarily hurting an elephant would be considered wrong from an ethical perspective because the elephant is useful to its owner and, therefore, must be protected.

Here, the concept of utility is broad. Even if the elephant is used less and less in the forest as a means of transport, people may still want to protect it because it continues to be an important religious and cultural symbol or because it is an especially intelligent and sociable living creature that scientists want to study.

In anthropocentrism, the justification for protecting a non-human living creature is always relative to human beings. But what about animals or plants that humans do not regard as valuable? Surely they must be treated ethically as well.

## 2. Biocentrism: “As a living being that can experience pain and pleasure, each elephant has the right to be respected and protected, even if it is not useful to humans”

Since 1960, the environmental effects of anthropocentricism have been increasingly criticized.[2] Thinkers and philosophers[3] claim that every living

---

[2] See: *The Limits to Growth*, by D. Meadows, prepared by the Club de Rome http://www.donellameadows.org/wp-content/userfiles/Limits-to-Growth-digital-scan-version.pdf and the book on pesticides by Carson R.L., *Silent Spring*, Boston, Houghton Mifflin, 1962.

[3] See: Sylvan, R. (Routley), “Is there a need for a new, an environmental, ethics?” in *Philosophy and science: morality and culture: technology and man*, Proceedings of the XVth World Congress of Philosophy, Varna, Sophia Press, 1973, p.205–210; Rolstom III, H., “Value in Nature and the Nature of Value,” in R. Attfield & A. Belsey (Eds.), *Philosophy and the Natural Environment*, Cambridge, Cambridge University Press, 1994, p.13–30; Taylor P.W., “The Ethics of Respect of Nature,” *Environmental Ethics*, vol.3.3, 1981, p.197–218; Callicott, J. B., “Intrinsic Value in Nature: a Metaethical Analysis,” *Electronic*

being must be respected and protected for its own inherent value, independent of its utility for humans, a philosophy known as biocentrism.

Two types of arguments are asserted to justify this position.

The first is based on the observation that living beings are constantly using their surroundings in diverse ways to ensure their survival and reproduction. So even while the elephant is transporting someone on its back, it will extend its trunk to grab leaves in a continuous effort to find food. Thus, the elephant is at the center of its environment and sees that environment as a potentially useful resource. For biocentrists, a living being that cares for itself has its own ethical value (an “intrinsic value” or a “value in its own right”), independent of this creature’s possible usefulness to humans. The American philosopher Paul Regan[4] goes so far as to argue that animals have rights and, consequently, human beings are obliged to protect them.

The second argument is based on the observation that animals can experience pleasure and pain.[5] If the goal of an ethical action is to maximize pleasure and minimize suffering for the greatest number of living beings, then this action must consider animals as members of a moral community. In 1972, this argument was radicalized by Australian philosopher Peter Singer in his book *Animal Liberation*.[6] Freeing animals from painful treatment suffered in research laboratories and industrial farming aligns with the imperative to free oppressed human beings (slaves, women, etc.).

Biocentrism does not claim that all living beings are moral agents (capable of ethical reflection and responsible for their actions, similar to humans), but that all beings have the right to be treated ethically.

One limitation of biocentrism is that it assigns ethical value to individuals, but not to entire species or ecosystems.

### 3. Ecocentrism: “The elephant, its species, and its natural environment depend on each other for their existence. They form an ecosystem that must be a central focus of any ethical consideration”

Ethical awareness of environmental protection first arose in the United States at the end of the nineteenth century.[7] In 1949, the American forester

---

*Journal of Analytic Philosophy*, 3, 1995 reprinted in Callicott J.B. *Beyond the Land Ethic. More Essays in Environmental Philosophy*, New York, SUNY Press, 1999, p.239–261.

[4] Regan, P. (1983). *The case for animal rights*, Berkeley, University of California Press.

[5] For the origin of this concept, see, Bentham, J. (1780). *An introduction to the principles of morals and legislation*. (ed. 1789).

[6] Singer, P. (1975). *Animal liberation. A new ethics for our treatment of animals*, New York: New York Review/Random House, New York.

[7] See: Henri David Thoreau, *Walden, or, Life in the Woods* (1854), describing the beauty of the wilderness and criticizing its industrial transformation.

Aldo Leopold coined the phrase “thinking like a mountain,” in his book *A Sand County Almanac*,[8] and invited his readers to adopt the point of view of a mountain, whose very existence depends on a network of relationships between trees, rivers, animals, soil, and so on. Human beings, like everything that exists, are part of a greater whole—one that must be included in its entirety in our concept of ethics. What we do to an elephant has repercussions on its species and its environment; every change to the environment reverberates through the life of an individual elephant, the survival of its species, and beyond.

In an article published in 1973,[9] the Norwegian philosopher Arne Næss drew a distinction between “deep ecology” and “shallow ecology.” Deep ecology gives environmental ethics a political dimension by criticizing individualism and the consumer society, which fail to consider the totality of existence.

## 4. Ecological pragmatism: “In every situation, the utility and the ethical value of the elephant, its species, and its ecosystem must be debated”

Faced with biocentrism’s and ecocentrism’s inability to solve the environmental crisis caused by anthropocentrism, the American philosopher Bryan G. Norton[10] proposes seeking ethical compromises through discussion. Compromise requires admitting that individuals can understand the same concept or value differently. Thus, an elephant may be considered useful in a material sense (as transport) but also in a religious sense (as a sacred animal in some countries).

During a discussion, each participant can argue for a different understanding of the elephant’s utility, yet arrive at the same conclusion that the elephant—or its species or its environment—must be protected. The goal of ecological pragmatism is to arrive at a final decision that best protects human beings, living beings, species, and ecosystems.

These four primary movements in environmental ethics form the basis of the principles that support ethical evaluation and decision-making in research. Two are presented below, the first concerning animals specifically and the second encompassing any research subject.

---

[8] Léopold, A. (1949). *A sand county almanac*, New York, Oxford.

[9] Næss, A. (1973).The shallow and the deep, long-range ecology movement. A summary. *Inquiry*, 16, 95–100.

[10] Norton, B. G. (1984). Environmental ethics and weak anthropocentrism. *Environmental Ethics*, vol.6.2, 131–148.

## The Principle of the "3Rs"

The "3Rs"[11] are three behaviors intended to spare research animals from pain and suffering.

**1. R**eplacement: The guiding concept is to replace the most sensitive animals with less sensitive living beings (invertebrates, insects, plants, micro-organisms, etc.) and to replace animals with non-living things (cybernetic and mathematical models, audio-visual methods to teach experimental practices).

**2. R**eduction: This principle aims to reduce the number of animals used in experimentation. It encourages awareness about previous experiments to avoid repeating them unnecessarily, to standardize experimental design to decrease inter- and intra-experimental variations, and to use computer technologies.

**3. R**efinement: Using anesthesia, applying quick killing methods, and observing needs based on the animal's behavior are ways to eliminate or minimize the animal's suffering and distress. Appropriate living conditions are also important: accommodations (for example, cage size), food, and care as well as contact with fellow members of the same species, etc.

## The Precautionary Principle

First appearing as a public policy principle in Germany in the 1960s, the Precautionary Principle entered into the spheres of public health and food security after several "scandals," including the infected blood scandal (transmission of HIV and hepatitis C by blood transfusion between 1980 and 1990) and the "mad cow" affair.[12] In 1987, the Precautionary Principle was explicitly recognized in an international legal document, the Second North Sea Ministerial Declaration. It also appears in the Rio Declaration,[13] issued at the Earth Summit in June 1992, in which Principle 15 states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

---

[11] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. Following a request in 1954 by the British Universities Federation for Animal Welfare to study the ethical aspects of animal research, two scientists—William Russell and Rex Burch—produced a report that became a book in 1959: *The Principles of Humane Experimental Technique*. This work established the Principle of "the 3Rs."

[12] Identified in 1986, bovine spongiform encephalopathy is linked to feeding meat-and-bone meal to cattle.

[13] http://www.unesco.org/education/pdf/RIO_E.PDF

Applying the Precautionary Principle is controversial because it requires agreement on the definition and scope of the terms that define it. What constitutes a risk of serious or irreversible damage? Who, what authority, decides what constitutes such a risk? What is meant by “effective measures”? Many such questions remain unresolved.

The four case studies that follow build on this theoretical and historical overview of environmental ethics to illustrate ethical issues of environmental research as seen from real-life situations in the field.

* * *

# Electronic Waste Dumped in the Global South: Ethical Issues in Practices and Research

**Florence Rodhain**[*]

Although some humans still consider planet Earth worthy of respect in their day-to-day actions—whether as a shared asset or a sacred treasure—Michel Serres asserts that the majority of humanity has waged an ongoing war against the planet. Moreover, the philosopher points out that for the first time in human history, humans could possibly win this war.

This chapter restricts itself to just one of the many battles Humankind is waging in this great war against the planet, and thus against itself, since combatting the planet is tantamount to unconsciously sawing off the branch on which you sit. Few are aware of this battle; actually, it is fought in silence.

Nature does not produce waste. The concept of “waste” was invented by humans. In nature, outputs become inputs, and everything is recycled naturally. Yet, clearly humankind is not (or is no longer) mature enough to imitate nature’s wisdom. Industrial processes have yet to make imitating nature part of their agendas, and the capitalist system, founded on a policy promoting a development economy geared toward a consumer society, relies on producing waste. This situation has become the norm.

## Hazardous waste

One such type of industrial waste, WEEE (waste electrical and electronic equipment) is constantly increasing. Commonly called “e-waste,” WEEE comprises electric and electronic products that are considered to be at the end of their “useful life” (which does not mean they no longer function, but that they might simply be seen as obsolete and are, therefore, unloaded by their owners). This waste is hazardous. For example, computers contain toxic substances that harm the environment and human health, such as antimony, barium oxide, beryllium, cadmium, chlorine, bromine, lead lithium, mercury, phosphorus, arsenic, brominated flame retardants, etc. It takes just one gram of mercury to pollute a square meter of land or 1000

---

[*] Senior Lecturer, Organizations Management and Information Systems, University of Montpellier, France.

cubic meters of water for 50 years. In China, a water sample from the Lianjiang River, near a village that recycles e-waste, found lead levels 2400 times higher than WHO-recommended standards.

The United States is the champion in generating electronic waste. It is estimated that the average American produces 30 kg of electronic waste per year. Electronic waste is constantly increasing in the world. Lack of recycling, shorter and shorter product life (e.g., cell phones), planned obsolescence, and population growth are among the many factors contributing to generating more and more waste.

The e-waste recovery rate oscillates between 10% and 20% in the global North. This means between 80% and 90% of this waste is either incinerated or buried with no pre-treatment, or exported to countries in the global South.

### A contamination free-for-all

This e-waste has had a violent effect on the environment, resulting in air pollution, soil pollution (acidification), and water pollution (groundwater and rivers). Some 40% of the lead that contaminates soil is directly linked to e-waste. Moreover, once they cross into the South, numerous containers from countries in the North transporting e-waste are dumped... straight into the sea: thrown overboard right into open waters, far from any witnesses. After the 2004 tsunami, dozens of containers carrying e-waste were found near Somalian shores, leaving no clues about when they were dumped or by whom, providing further evidence of this practice in open waters.

Humans, particularly illegal workers in the South, are also violently affected. The bodies of “recyclers” are exposed: these workers inhale toxic gases and fumes, and abrasive products come into contact with their unprotected skin. Exposed bodies suffer greatly. Reported symptoms include persistent migraines; insomnia; asthmatic bronchitis; lung cancer; skin problems; reproductive problems (miscarriages among women living near landfills); abnormal brain development in children; heart problems; and damage to the nervous system, liver, kidneys, and spleen.

### From desktops to kitchen tables

People working illegally in the South (often women and children) are especially affected, because they are “inhaling” computers from the North (workers often use their bare hands to burn the waste material in rudimentary conditions to recover precious components). Men, women, and children breathe in these toxic fumes. But inhabitants in the North are also affected. While children in the South are “inhaling” personal computers (80% of children from Guiyu—one of China’s largest recycling centers—suffer from respiratory diseases), children in the North are “eating” them. Imagine a cyber stomach. Rainwater leaches heavy metals from nonrecycled waste that has been simply dumped into landfills and enters the water table. Nearby garden produce is directly contaminated by rainwater pouring into the fields.

## Illegal exportation: regulation and control

Transport of e-waste from countries in the global North to those in the South is completely illegal—yet 80% of the e-waste from the United States is shipped to these very countries.

However, a global agreement was signed in 1992 (International Basel Convention) that seeks to limit the exportation of dangerous waste from "developed" countries to "developing" countries. In addition, a 2002 European directive (2002/96/CE) required the recovery of WEEE, making the producer responsible for waste handling and treatment. This was followed in 2012 by another directive (2012/19/EU) prohibiting the illegal export of waste: all exports must be declared.

A special group was created in 2009 in Interpol to control illegal movements: the "Global E-Waste Crime Group," whose mission was to combat crime related to e-waste.

## Why circumvent the laws?

Whether in the North or South, certain parties benefit from operating outside the laws.

In the North, the rationale is purely economic: the cost of responsible e-waste treatment is considered too expensive compared to the cost of transporting it to countries in the South. Transferring to the South is 10 times less expensive. For example, it costs US$ 18 to properly remove aluminum from a computer screen. Recycling is too expensive in an economy where the environmental costs related to consumption are not passed on to corporate taxation.

Responsible recycling is no match for organized crime: according to the rationale of the capitalist system, good recycling behavior does not pay and offers no competitive advantage.

We directed a doctoral student in France who investigated what motivated companies to manage their e-waste responsibly. She showed that the primary motivation had no ethical basis and reflected no sense of responsibility. Instead, the companies were merely interested in either following the letter of the law or practicing institutional mimicry (behaving like other companies in their sector). It turned out the only people that the PhD student interviewed who maintained an ethical stance were employees who had no decision-making power in the company.

In the South, choices are also economically motivated: a recycler in China earns three to four times more than a worker in a rice paddy. Smugglers also benefit from this windfall, earning substantial additional income.

Both in the North and the South, illegal recycling is a bonanza for actors in organized crime: the return on one ton of e-waste transported illegally is 450 euros. Even the United Nations Environment Programme (UNEP) found that the e-waste sector is the best sector for mafia organizations to invest in, given the lack of statistics and studies on the subject, the virtual total lack of control, and the absence of any monitoring reports.

In a sector that is both informal and illegal, transferring e-waste recycling generates an estimated income between 12.5 and 18.8 billion dollars annually, according to Interpol, or the equivalent of two years of Laos' GDP, or the combined GDP of the world's 49 poorest countries. In short, it is a lucrative business sector with little regulation, and the benefits far outweigh the risks for unethical organizations.

## How to circumvent laws: cynicism and "newspeak"

Although the United States signed the Basel Convention of 1992, it did not ratify it. Furthermore, many components identified as toxic in the convention are not labeled as such in the United States. But without a doubt, the trophy for cynicism goes to US politicians and lobbyists who claim that sending waste to the South allows IT equipment to be re-used, and thus closes the digital divide!

In the same way that a minister of peace can oversee war (a principle of newspeak) in George Orwell's dystopian society described in *1984*, the transfer of e-waste from the North to the South—illegal, yet illogically increasing despite regulations—is more and more often disguised as "humanitarian donations." While the Basel Convention and European directives prohibit the transfer of "waste," transferring so-called "second-hand products" is fully authorized. Interpol estimates that 75% of the containers of used goods shipped to Nigeria are in fact full of waste. False declarations are made when describing the container's contents. This practice only applies to OECD countries, since the United States has not ratified the Basel treaty and holds its head high as it exports its waste without even trying to cover it up.

Vietnam (like China) applies stricter regulations than those outlined in the Basel Convention. However, since the country needs resources and raw materials, it accepts second-hand products while confronting the enormous challenge to differentiate between disguised waste and actual second-hand goods.

## Ethical issues raised by the problem of e-waste management

Dumping e-waste from the North to the South is an ecological timebomb constructed in a climate of widespread indifference. However, it raises several ethical issues involving numerous actors, virtually affecting the entire world at all levels.

### • *Ethical issues for all actors*

Hans Jonas, in *The Imperative of Responsibility* (1979, *Das Prinzip Verantwortung* in German), proposes this guideline: "Act so that the effects of your actions are compatible with the permanence of genuine human life." According to Jonas, in response to this new power invested in humans through technology, a new form of collective and individual responsibility (that every individual must uphold) must emerge that prohibits taking any action that can threaten either the existence of future generations or the future quality of existence on earth.

However, responsible does not mean guilty, an expression made famous by the contaminated blood scandal in the 1980s.[1] Companies, governments, and users comprise the three levels of responsibility. This game of "responsible, but not guilty" brings into play the relationships between corporate social responsibility (CSR), government social responsibility (GSR), and individual social responsibility (ISR): it devolves into a card game of Old Maid, where players must discard the "guilty" card. Social responsibility is a game played in three dimensions: democracy (between governments and individuals), government regulation (between companies and governments), and justification (between companies and individuals).

*– Government social responsibility*

Where does responsibility begin and end for governments? Is it just complying with laws and conventions? With no supranational regulation, how can we limit the abuse of power by dominant countries that exploit others who are less well-off (either as a source of abundant resources or as a dumping ground)?

*– Corporate social responsibility*

Where does social responsibility begin and end for producers? (In the United States, there is no legislation to make producers aware of "end of useful life" product management that encourages them to take responsibility

---

[1] A former French minister, accused of failing to take measures to stop the use of batches of blood products contaminated by an unknown virus (the future HIV) pleaded "responsible" but not guilty, establishing a distinction between the responsibility for administrative measures and an understanding of the epidemiological impacts of the delayed destruction of suspected samples.

for it). Is the practice of planned obsolescence for products to drive up consumption ethical?

– *Individual social responsibility*

Where does social responsibility begin and end for wasteful consumers?

### • *Ethical issues for researchers*

Numerous ethical issues arise when researching this topic. Here we only address the one that seems the most "sensitive": What should be done when a researcher discovers practices that are obviously unethical?

If we want to investigate this question in-depth in terms of e-waste, researchers must conduct their research in multiple locations, using various types of surveys in the North and the South. Ethical issues can be differentiated according to the geographical origin and location of the researcher's field.

– *Researchers "in the South"*

If a researcher ever has access to dumping sites for electronic products, where individuals recycle this garbage, how should that researcher use the collected information? If he or she uncovers information that might pose major health hazards, who should it be reported to? What should one do with this information? Contact the country's Minister of Health? Should the researcher go back to the population that was interviewed? This raises the issue of confidentiality. And if the researcher manages to contact the population that is sorting waste, won't some of its members be put at risk if the researcher exposes confidential information that involves them?

– *Researchers "in the North"*

If a researcher is conducting interviews "in the North" and through interviews with a company discovers that it is sending waste overseas illegally, how should this discovery be handled? This raises issues of neutrality and maintaining distance between the study object and the researcher. If the researcher discovers real or potential dangers in the practices he or she has uncovered, should that researcher raise this issue? If yes, to whom? If the research clearly reveals real dangers, should researchers continue to distance themselves from their observations? These are the typical questions whistleblowers ask themselves before deciding to inform the public about the unethical practices of organizations that employ them. What are the boundaries of ethical activism?

* * *

## BIBLIOGRAPHY

Ait Daoud S. (2012). *Le management responsable des technologies de l'information (MRTI) : entre approches éthique et institutionnelle*. Doctoral Thesis, University of Montpellier.

INTERPOL (2009). *Electronic waste and organized crime. Assessing the links, phase II report for the INTERPOL Pollution Crime Working Group* (PCWG).

Jonas H. (1979)(2013. *Le principe responsabilité*. *Une éthique pour la civilisation technologique*. Paris : Flammarion, collection Champs.

Rodhain F., & Fallery, B. (2010). Après la prise de conscience écologique, les TIC en quête de responsabilité sociale. *Actes du 15ème Congrès de l'AIM,* June, La Rochelle, 28 p.

Rucevska, I., Nellemann, C., Isarin, N., Yang, W., Liu, N., Yu, K., ..., Nilsen R. (2015). *Waste crime – Waste risks: gaps in meeting the global waste challenge*. A UNEP Rapid Response Assessment. Nairobi and Arendal, United Nations Environment Programme and GRID-Arendal.

UNEP (2014). *Basel Convention on the control of hazardous wastes and their disposal – Protocol on liability and compensation for damage resulting from transboundary movements of hazardous wastes and their disposal*, Texts and Annexes, United Nations Environment Programme, UNEP/BRS/2014/3.

# Ethics of Biotechnology Research

**Frédéric THOMAS**[*]

## Ethics, scientific controversies, and risk management

Genetically modified organisms (GMOs) have been hotly debated by scientists since they first appeared, and many of their questions remain unresolved. Since the initial genetic manipulations were performed in the 1970s, questions have swirled around the possible risks these new organisms might pose to human and animal health. An appeal by Paul Berg in *Nature* in 1973 ignited the debate.[1] He and the others who signed the article led the first DNA manipulations in the United States, but later recommended a moratorium on genetic manipulations such as those that introduced antibiotic-resistant genes into bacteria like *Escherichia coli*. This appeal was at the origin of the 1975 Asilomar Conference, an example of ethical reflection by the scientists of the time, who questioned whether they had the right to continue research if they did not fully understand the associated risks. Perceptions of the risks and uncertainties of biotechnology have evolved quite a bit in the years since that conference. Issues have ranged from the impact of GMOs on human and animal health to broader environmental concerns (e.g., reduced biodiversity, transgene flow to related wild relatives, and the development of herbicide resistance in plants).

More recently, studies of the socioeconomic impact of GMOs on agriculture and innovation systems (the coexistence of GMO and non-GMO crops, “organic” labeling, concentration of seed industries, appropriation of genetic resources, etc.) have further expanded the field of GMO risk analysis. Each of these issues has been the subject of scientific controversy. Researchers will therefore increasingly need to consider the ethical implications of the uncertainties associated with biotechnology to guide them in their work.

---

[*] Historian of Science and Technology, Research Officer at IRD, UMR PALOC (Local Heritage), IRD-MNHN, Paris, France.

[1] Berg, P., Baltimore, D., Boyer, H. W., Cohen, S. N., Davis, R. W., Hogness, D. S., ... Zinder, N. D. (1974). Potential biohazards of recombinant DNA molecules. *Science, 185*, 303.

## Biotechnology through the lens of the ethics of conviction, responsibility, and values

Ethicists contrast three types of ethics: conviction, responsibility, and values. How can these principles help us address the issues raised by the emerging biotechnologies in the countries in the Mekong region?

The ethic of conviction takes an absolute stand on an action, regardless of the context. The answer can only be “yes” or “no,” as in the question “is it ethical to eat meat?” The ethic of responsibility shifts the focus from the action itself to its consequences: can someone continue to eat industrial poultry knowing how the animals are treated? The values approach questions the motivations that underlie behavior. Not eating meat may in fact simply be a matter of taste and not involve ethics at all.

The ethic of conviction, as it pertains to biotechnology, asks if it is ethical to modify a living organism. Differing beliefs may clash: “life is sacred and should not be modified”; “life is a biochemical process devoid of any sacred meaning”; “genetic modifications are a drop in the ocean of evolution”; “modifying microorganisms is acceptable but not complex organisms”; “modifying plants is acceptable but not animals”; “modifying animals is acceptable but not humans”; and so on. Other arguments may include “long live augmented humans!” or even the Orwellian “why not diminished humans who we can control?”

Questions about the consequences of our choices can also be debated: “What are the effects on health? On biodiversity? On ecosystems?”; “GMOs represent the privatization of living organisms for the benefit of multinationals”; “Biotechnologies aren’t only GM plants; they also represent important tools for healthcare, like gene replacement therapy”; and so on.

Let’s look at a case study to better understand these ethical principles.

### Is it ethical to genetically modify mosquitos?

***Case no. 1: GM mosquitos for the prevention of dengue***

The Vietnamese Ministry of Health released a genetically modified (GM) mosquito to combat dengue outbreaks. The *Aedes aegypti* (AA) mosquito is the conventional transmission vector to humans. The GM version contains Wolbachia bacteria, which inhibits the insect’s ability to transmit dengue, and also happens to shorten its lifespan. This mosquito has been tested in Vietnam by the National Institute of Hygiene and Epidemiology since October 2012. It was released in April 2014 on the island of Tri Nguyen, within the city of Nha Trang, and in the province of Khanh Hoa (southern Vietnam). Studies conducted in May 2015 indicated that 95% of the AA mosquitos carried Wolbachia. No cases of dengue have been reported on the island since mid-2014. The Institute is preparing to release the mosquito throughout the entire city of Nha Trang.

This issue has been extensively discussed among medical doctors. In 2015, 40,000 people were diagnosed with dengue in Vietnam, 25 of whom died. Mortality for this disease is increasing by 72% per year. Modifying the *Aedes aegypti* mosquito may seem ethical to any reasonable person; in fact, it would appear unethical not to!

Yet there are other ways of looking at the situation, including from an ethic of nature perspective. The term “biocentrism” refers to the practice of ascribing every living organism with intrinsic value (such as in Jainism in India). “Ecocentrism” takes a more pragmatic approach, assigning intrinsic value to biotic communities or ecosystems as a whole. The ethic of nature may also be anthropocentric, or utilitarian, if it holds that humans have a self-serving interest in taking care of nature. In this view, man is the proud “master and owner of nature,” who should be cautious when using biotechnology to alter the natural balance.

Thus the genetic modification of a mosquito poses a series of ethical problems, from the intrinsic value of maintaining a species (biocentrism), to the consequences of a species disappearing from the food chain (other species that feed on *Aedes aegypti* mosquitos could themselves disappear (ecocentrism)), to the more utilitarian: humanity may grant itself the right to disrupt ecosystems to our advantage as long as we do not compromise the resilience of these systems. In ecology, the Rivet Hypothesis[2] postulates that the loss of one species is not necessarily dangerous for an ecosystem (just as the failure of one rivet on an airplane wing is not necessarily devastating for the flight), but the N+1 subsequent extinction may result in a general disruption to the equilibrium in unpredictable ways.

Note that there is no way to counter the position against the genetic modification of mosquitos if it comes from an ethic of conviction (belief in the animal “cause”), because it is sealed against any other considerations, or to counter the more responsible pro-biotechnology position that judges consequences more than actions. Both positions are based on personal convictions and a sense of responsibility, but they do not focus their attention on the same consequences and the same legal entities (do humans alone have rights or does nature have rights as well?):

1. The ethical position defending genetic modification is anthropocentric because it only considers the positive consequences for humanity or societies; and

2. The challenge to genetic modification is based on a different ethic, one that extends to non-humans at least some of the moral principles that societies generally bestow on human beings and acknowledges that every element of nature has intrinsic value.

---

[2] Ehrlich, P., & Ehrlich, A. (1981). Extinction: the causes and consequences of the disappearance of species. New York: Random House.

We should also consider the values that drive the actors. What motivated the research on genetically modifying *Aedes aegypti* mosquitos? Why, for example, did the Bill and Melinda Gates Foundation finance this research in Vietnam? Are similar tests being conducted in the United States? Why are experiments being conducted in Vietnam and other developing countries? Are the precautionary principles too demanding (and restrictive) in rich countries? Is civil society there more watchful? Is technical democracy more vibrant? The list of questions goes on, each deserving of in-depth research to better understand the values that inspire the various actors involved as partners in the Mekong region programs. Doubtless most are motivated by true altruism, but it is a good bet that others have less lofty intentions.

What can we learn from this first case study? First of all, the genetic modification of a mosquito, even for the best of reasons (saving human lives), poses ethical questions. Second, a well-constructed ethical argument should be cross-pollinated by a variety of beliefs and concepts of responsibility and should examine both the explicit and implicit values of the actors. Third, an ethical opinion must be rooted in reality and when possible based on scientific evidence.[3] This last point leads to a central question in research ethics: how do we act ethically in a context of scientific controversy and uncertainty?

Let’s look at a second case study.

### Do GMOs provide a definite benefit by decreasing pesticide consumption across the world?

#### *Case no. 2: GMOs and pesticides*

**Decrease…**

“GM crops (...) have been rapidly adopted. By 2012, GM crops were grown on more than 170 million [hectares], and for the first time, more than half of this land was located in developing countries. The economic benefits GM crops can now be fully described (...) For example, (...) the calibrated yield effect of GM cotton for Argentina is 33% [and] pesticide reduction [is] 46%... For the United States, the increased yield effect is 11% [and] pesticide reduction [is] 30%. GM crops, especially GM insect-resistant cotton, have contributed to a large reduction in insecticide use globally, whereas there are contradictory estimates of the effect of GM herbicide-treated crops on herbicide use.”[4]

---

[3] In France, for example, the use of GM mosquitos was evaluated by the Haut Conseil des Biotechnologies. HCB (2017). Avis du conseil scientifique du HCB concernant l’utilisation de moustiques génétiquement modifiés dans le cadre de la lutte anti-vectorielle. Retrieved from: http://www.hautconseildesbiotechnologies.fr/sites/www.hautconseildesbiotechnologies.fr/files/file_fields/2017/06/06/aviscshcbmoustiques170607.pdf

[4] Bennett, A. B., Chi-Ham, C., Barrows, G., Sexton, S., & Zilberman, D. (2013). Agricultural biotechnology: Economics, environment, ethics, and the future.

**... or increase?**

“Herbicide-resistant crop technology has led to a 239 million kilogram increase in herbicide use in the United States between 1996 and 2011, while *Bt* crops [which produce insecticides] have reduced insecticide applications by 56 million kilograms. Overall, pesticide use increased by an estimated 183 million kg, or about 7%. Contrary to often-repeated claims that today’s genetically-engineered crops have, and are reducing pesticide use, the spread of glyphosate-resistant weeds (...) has brought about substantial increases in the number and volume of herbicides applied. If new (...) forms of corn and soybeans tolerant of 2,4-D are approved, the volume of 2,4-D sprayed could drive herbicide usage upward by another approximate 50%.”[5]

The issue of whether GMOs have led to a decrease or increase in pesticide consumption across the world is a debate that the scientific data do not appear to resolve.

In an article published in *The Annual Review of Environment and Resources* in 2013, the authors state that GM cotton has led to a 46% reduction in pesticide consumption in Argentina and a 30% reduction in the United States. They conclude that GMOs have contributed to a massive global reduction in the use of insecticides, and therefore represent significant progress both for the environment and for farmers’ health. Reading this article, which was published in a scientific journal with a peer-review committee, one concludes that GMOs provide indisputable benefits for the health of farmers and the environment.

A second article, by Benbrook and published in 2012 in *Environmental Sciences Europe*, comes to precisely the opposite conclusion. The use of herbicide-resistant GM plants led to a 239-million kg increase in the use of herbicides in the United States between 1996 and 2011, while *Bt* crops (which produce their own insecticides) reduced the application of insecticides by 56 million kg. The overall use of pesticides (herbicides + pesticides) increased by 183 million kg, or nearly 7%. The Benbrook article also sounds the alarm for the dual problem of insects and weeds that become resistant to herbicides through the use of GMOs. Studies in the U.S. on the emergence of glyphosate-resistant (GR) weeds show that there are currently 22 GR species, which sources say may affect between 6 and 40 million hectares. This last figure comes from a study by the Dow Chemical Company to convince American authorities to allow 2,4 D to be sold in order

---

*The Annual Review of Environment and Resources*, 38:19.1 19.31, DOI 10.1146/annurev-environ-050912-124612

[5] Benbrook. C. M. (2012). Impacts of genetically engineered crops on pesticide use in the U.S.—the first sixteen years. *Environmental Sciences Europe*, *24*, 24.

to launch its new 2,4 D-resistant strain of corn. In other words, Dow Chemical, a multinational agrochemical company and major global producer of GMOs, makes scientific use of GMO failures to obtain more relaxed rules on the sale of long-banned pesticides in order to market new GMOs. For multinational firms like this, scientific data have become political and economic weapons.

How do you arrive at an ethical stance in such controversial contexts? You must examine the quality of the data, consider the honesty of the authors, gather additional information... in short, conduct research to reduce the uncertainty to a level where a consensus can be reached. This is the hurdle faced when crafting an expert consensus or conference consensus, which strive to come up with at least temporary solutions. There is often some residual scientific uncertainty, but the decision to authorize or ban a product or procedure cannot be delayed. Fortunately today we have several institutional mechanisms to help manage this uncertainty when making such decisions:

1. The Precautionary Principle, based on the idea that we do not have to wait for absolute, definitive scientific certainty before taking measures to limit the potential risks of research or technological innovation. This principle was behind the de facto moratorium on GMOs in European markets until 2005. The Precautionary Principle can be understood in different ways, from strong to weak. The concept of “known risk” assumes there must be a certain probability of the risk occurring before cautionary measures are applied.

2. Common rules for assessing the risks of disseminating GMOs have been established at the international level. The international reference text is the Cartagena Protocol, which defines biosafety standards, i.e., protocols for assessing the environmental and health risks of GMOs.

3. Many national biosecurity standards have been established on the basis of this international legal framework. Some countries use the principle of “substantial equivalence” i.e., they consider GMOs to be identical to other products so no particular marketing regulations are needed. However most countries have defined rules for tracking and labeling GMOs. Regardless of one’s position on the issue, administrative mechanisms create an essential basis for moral and legal responsibility for research and industry in case of any problems.

4. One other important institutional mechanism for managing risks should be mentioned: public debate, citizen forums, and consensus conferences. Ideally, political decisions are based on scientific truths, but in reality uncertainty is an integral part of science in action. The solution to this conundrum is to create mechanisms through which scientists, citizens, and political decision-makers can deliberate. Jürgen Habermas and Bruno Latour talk of “dialogical frameworks,” or theoretical mechanisms to facilitate dialogue between

various actors who may have access to unequal levels of information. The goal is to construct a consensus for controversial issues to better inform the public and allow citizens to take responsibility for supporting or opposing one technology or another, or finding yet another path.

## Conclusion

Like elsewhere in the world, there is no blanket solution to the wide variety of ethical issues raised by the spread of biotechnology in developing countries. The only reasonable recommendation is to analyze each situation on a case-by-case basis. Unlike wealthy countries, resource-limited countries face a deficit of information and independent experts, leaving them vulnerable to the full force of industrial lobbies as they seek to direct their scientific choices.

Scientific cooperation between public research institutions should play a key role here. It is an area of development aid that should be strengthened at all levels of scientific cooperation. Most emerging countries have the scientific expertise necessary to formulate their scientific guidelines but generally lack the political and administrative culture to implement mechanisms to manage the types of scientific controversy that we have described.

Europe and the United States have been engaged in furious diplomatic battles over rules to frame the use of GMOs, and developing countries have been inexorably drawn into this conflict. The U.S. considers a ban on GMOs on the Precautionary Principle to be an infraction of World Trade Organization (WTO) free trade rules[6] (non-tariff barriers) and has brought the issue before the dispute settlement body of the WTO. We therefore find ourselves caught between the strong opposition of two sides: “science-based decision-making” on the American side, which states that any risk must be demonstrated scientifically, and the “Precautionary Principle” on the other, which was invented precisely to face the issues of scientific uncertainty. At this time the U.S. is clearly winning this battle, imposing the Sanitary and PhytoSanitary (SPS) standards of the FAO’s Codex Alimentarius as the sole basis for discussion to determine whether or not GMOs are dangerous to our health.[7]

Technical democracy still has a long road to travel in resource-limited countries. It is both a great challenge and a great opportunity: ethical debates on technical issues are fertile ground for the practice of democracy and with intervention from civil society could lay the groundwork for political democracy.

---

6. World Trade Organization.
7. Bonneuil C., & Levidow L. (2012). How does the WTO know? The mobilization and staging of scientific expertise in the GMO trade dispute. *Social Studies of Sciences*, *42 (1)*, 75–100.

## FOR FURTHER INFORMATION

### – Moral philosophy, theory of justice, and ethics

Jonas, H. 2008 (1979). *Le principe de responsabilité : Une éthique pour la civilisation technologique*. Paris: Flammarion.

Rawls, J. (2009). *Théorie de la justice*. Paris: Points [Essais], 665 p.

### – Bioethics

Sicard, D. (2015). *L'éthique médicale et la bioéthique*. Paris: Presses Universitaires de France [Que sais-je ? No2422], 3rd edition, 128 p.

### – Ethics of nature

Blandin, P. (2009). *De la protection de la nature au pilotage de la biodiversité*. Versailles: Quae.

Callicott, B. J. (2010). *Éthique de la terre*. Marseille: Wildproject, Domaine Sauvage, 315 p.

Hess, G. (2013). *Éthique de la nature.* Paris: Presses Universitaires de France, 422 p.

Larrère, C. (2009). La justice environnementale. *Multitudes*, 36(1), 156–162.

Larrère, C., & Larrère R. (1997). *Du bon usage de la nature. Pour une philosophie de l'environnement*. Paris: Aubier, 355 p.

### – Science, controversy, and managing uncertainty

Beck, U. (2001). *La société du risque : sur la voie d'une autre modernité*. Paris: Aubier [Alto], 521 p.

Bonneuil, C., & Joly, P.-B. (2013). *Sciences, techniques et société.* Paris: La Découverte [Collection Repères], 125 p.

Callon, M., Lascoumes, P., & Barthe, Y. (2001). *Agir dans un monde incertain: essai sur la démocratie technique*, Paris: Seuil, 357 p.

Kourilsky, P., & Viney, G. (2000). *Le principe de précaution. Rapport au Premier ministre*. Paris: Odile Jacob - La Documentation française, 425 p.

Latour, B. (1999). *Politiques de la nature. Comment faire entrer les sciences en démocratie*. Paris: La Découverte, 383 p.

### – Ethical biotechnologies and intellectual property

Bellivier, F., & Noiville, C. (2009). *La bioéquité. Batailles autour du partage du vivant*. Paris*:* Autrement [Collection Frontières], 172 p.

Hermitte, M-A. (2016). *L'emprise des droits intellectuels sur le monde vivant*. Versailles: Quae.

Thomas, F. (2016). Appropriation des innovations végétales et gouvernance des communs agricoles au Brésil et au Vietnam. *Revue Tiers Monde*, 2016/2, [Hors série], 223–248. DOI 10.3917/rtm.hs02.0223.

Thomas, F., & Boisvert, V. (2015). *Le pouvoir de la biodiversité. Néolibéralisation de la nature dans les pays émergents*. Marseille and Versailles: IRD Éditions and Quae [Objectifs Suds], 296 p.

# Ethical Questions Associated with Research on Soil-Based Ecosystem Services

**Oumarou MALAM ISSA,[*] Damien HAUSWIRTH,[**]**
**Damien JOURDAIN,[***] Didier ORANGE,[+]**
**Guillaume DUTEURTRE,[++] Christian VALENTIN[+++]**

Soils are one of the many resources provided by nature, and we must utilize them carefully. The concept of "ecosystem services," which emerged at the end of the 1970s, became more widely known after the 2005 Millennium Ecosystems Assessment (MEA) conducted at the behest of the United Nations. The term refers to the benefits that humans derive from ecosystems and natural resources like soils; the concept has given rise to discussions within various scientific communities about environmental issues and drawn the attention of both the public and decision-makers to the importance of nature conservation.[1,2] However this idea reinforces and disseminates an anthropocentric view that reduces nature to a purveyor of services for the benefit of human well-being.[3] The attempts to put a monetary value on ecosystem services that developed in the 1990s have been hotly debated: one side views them as new tools for environmental conservation, while the other sees them as part of a greater trend towards the commodification of nature.[1] A third position, falling between the other two, recommends incorporating several kinds of values along with scientific knowledge and local know-how to assess ecosystem services.[4]

---

* Soil scientist, IRD, UMR iEES - Paris, France; IRD representative in Niger.
** Agronomist, Coopération française - AGRHYMET, SFR RACINES, Niger.
*** Agro-economist, CIRAD, UMR G-EAU, France.
+ Soil scientist, IRD, UMR iEES-Paris, France.
++ Agro-economist, CIRAD, UMR SELMET, France.
+++ Soil scientist, IRD, UMR iEES-Paris, France.

[1] Maris V. (2014). *Nature à vendre. Les limites des services écosystémiques*. Versailles: éditions Quæ.

[2] Rives, F., & Méral, P. (2015). *Terminologie et classifications autour du concept de service écosystémique*. ANR Serena program. Retrieved from http://www.serena-anr.org/.

[3] Schröter, M., van der Zanden, E. H., van Oudenhoven, A. P. E., Remme, R. P., Serna-Chavez, H. M., de Groot, R. S., Opdam P. (2014). Ecosystem services as a contested concept: a synthesis of critique and counter-arguments. *Conservation Letters*," *7*(6), 514–23.

[4] Méral P., & Pesche D. (2016). *Les services écosystémiques. Repenser les relations natures et société*. Versailles : éditions Quæ.

Soils supply us with food, raw materials, and energy. They play an important role in regulating the flow of water and solid materials, in processes like runoff and erosion, and in water and air quality. They also provide cultural services, in the form of recreational activities, natural heritage, and beautiful landscapes, and support many key ecosystem functions such as water, nutriments, and carbon cycles; and plant photosynthesis.

Soils are also vulnerable to threats, which society should work to prevent. Most such threats are primarily associated with human activities—farming, industry, and others—that may interfere with the ability of soils to provide ecosystem services. These threats include the loss of organic matter, impermeability, erosion, pollution and microbial contamination, compaction, loss of biodiversity, salinization, acidification, aridification—the list goes on and on. Soil is both a precious asset for society and a resource whose sustainability must be ensured through measures that limit the loss of organic matter, promote deep rooting and water storage, prevent the loss of biodiversity, minimize pollution, and others. Achieving these goals is often a balancing act between short-term societal use and long-term soil preservation.

The Twelfth Conference of the Parties (COP12) of the United Nations Convention to Combat Desertification (UNCCD) adopted the principle of a land-degradation neutral world. It expressed the common desire to limit soil degradation and promote the long-term conservation of soil capacity to provide services. The target is to stabilize productive, healthy soil surfaces by 2030. A two-billion-dollar fund will be devoted to designing indicators for implementing and monitoring measures to reduce soil degradation and enrich soils that are already depleted.

Research plays an important role in evaluating and assessing the value of measures taken to conserve soils and ecosystem services provided by nature as a whole. Here we will identify some ethical issues in research on soil-based ecosystem services from an analysis of the land use changes in the countries of the Mekong Delta.

## The case of Mekong Delta countries: lessons learned from research on land use changes

The Mekong Delta region is experiencing strong economic growth that, although beneficial for agriculture (market demand, job creation) also accelerates agrarian transitions. The rural space is rapidly becoming saturated due to demographic growth and the expansion of urban and industrial spaces and transportation networks (roads, railways, airports). Agricultural production is increasingly market-driven, with increased demand for agricultural, human, and animal products (which is also related to general trends in standards of living and consumption) and for raw materials (wood, latex, medicinal products, plant-based fuels, etc.). All of these factors lead to land use changes, whose effects on natural resources must be understood if we want to continue to control these resources.

Output from agricultural systems must increase to accommodate current demographic transitions and lifestyle changes. This is particularly true for agriculture on sloping land in mountainous regions, where increased output could result in serious consequences for the environment. Agriculture in the Mekong Delta is predominantly the domain of small family farmers with little capital. Highly intensive farming has developed in the most fertile areas (lower slopes, rice paddies) that maximizes yields by using significant labor and inputs. The possibility to increase production has mainly shifted to slope areas with specific social, economic, and environmental characteristics: these are areas where ethnic minorities live and implement a wide diversity of farming systems, with biodiversity reserves and significant capacity to provide fresh water for rice paddies, industries, and urban populations. These sloping lands are at high risk of soil erosion, which affects planted areas, waterways, and infrastructure located downslope and in rice paddies, and leads to conflict between the people who live in the plains and those who live on the mountainside.

Slope farming has traditionally used the practices of clearing, slash-and-burn, and long-term fallowing to maintain soil fertility over time. With arable land now filled to capacity, farmers have modified their soil practices and usage with detrimental effects, such as inefficient water use, soil loss by erosion or landslides, pollution (affecting the soil itself as well as water and food products), decrease of animal and plant biodiversity due to alterations of local habitats and the loss of forests, increase in flooding due to poor permeability and the increase in runoff area. The intensive use of chemical fertilizers and phytosanitary products, combined with poor management of both organic (animal) and inorganic (chemical residue, plastic packaging) waste products, have created new environmental risks for the short, medium, and long term. This situation urgently calls for developing more sustainable agriculture systems that are more sustainable than the ones currently being used to remedy the problem of soil degradation. Climate change only exacerbates the problem, as events like uneven and torrential rainfall complicate farming on sloping land and increase the risk of erosion and unbalanced water supply to crops.

An environmentally friendly way of intensifying agricultural production on slopes requires innovations in farming and animal rearing. For over 20 years now, researchers from the Institut de Recherche pour le Développement (IRD), the Centre de coopération internationale en recherche agronomique pour le développement (CIRAD), and their partners in Vietnam have been working in collaboration with and for farmers in the Mekong Delta to design ecologically conscious agronomy. But have these practices been adopted by the local population? It is not enough to simply develop new production systems: people must adopt them and adapt them to their own uses. Rural actors must become part of new forms of collective organization in order to manage natural resources. Methods that make it easy to adopt new practices must be found. The harmful consequences of farming on sloping land are associated with producers' lack of attention to ecosystem regulation measures like erosion control, water flow regulation, biodiversity conservation, and soil regeneration. Research studies have proposed innovative incentive mechanisms (e.g., payment for environmental services) to encourage new practices that strengthen ecosystem services related to ecological functions. The goal of these mechanisms, which are based on the logic of market forces (supply and demand), is to compensate for the increased costs of new practices to make them economically attractive to small family producers. The mechanisms may include land access practices to eliminate problematic usage, for example, or environmentally based tax and grant systems.[5]

## Ethical issues in research on soil-based ecosystem services

One of the threats to sustainable land use is the way people and society use soil for their immediate needs. Making good choices that reconcile profitable use with the sustainable management of this resource requires a sense of ethical responsibility. Often choices have to be made that pit individual use against collective use[6] or short-term yields against long-term conservation. We must fully understand the resource itself as well as the interests of stakeholders in order to make decisions that will preserve the soil. Researchers must be cautious when advising decision-makers, given the considerable uncertainties about the exact cause-and-effect relationship between the current status of the resource, the impact of conservation interventions, and the benefits and services it provides to humans and society.[7] The various actors (users, direct and indirect beneficiaries) may have widely differing viewpoints and interests. Researchers must adopt a global approach in their work that makes room for all such perceptions and expectations.

Innovation may seem like a matter for technocrats, which makes it all the more important to incorporate local practices and realities along with

---

[5] Orange, D., Pham Quang Ha, Tran Duc Toan, Clément, F., Jouquet, P., Nguyen Duy Phuong, Nguyen Van Bo (2012). Agriculture sur pentes au Vietnam : une nécessité pour la sécurité alimentaire et un risque pour la durabilité du système agricole. In E. Roose, H. Duchaufour, & G. De Noni (Eds.). *Lutte antiérosive, réhabilitation des sols tropicaux et protection contre les pluies exceptionnelles*. Marseille: IRD éditions.

[6] Barnaud, C., Antona, M., & Marzin, J. (2011). Vers une mise en débat des incer-titudes associées à la notion de service écosystémique. *VertigO*, *11*, 1, 1–21.

[7] Barnaud, C. *et al*. 2011. *Op. cit.*

past experiences, both good and bad. Alternative techniques cannot be developed and assessed without involving local actors. The top-down approach to innovation, in which new techniques are created under experimental conditions, does not lead to true “popularization” in rural areas and such innovations may turn out to be poorly adapted to real-world applications.

We must therefore seek compromise and arbitration when defining short- and long-term sustainability goals and performance, such as between short-term economic profit and medium- or long-term environmental and health impacts. Negotiations must keep in mind that capacities for adaptation vary and often differ between actors, since active non-farm workers, industrial agriculture companies, and small family farms operate with different amounts of flexibility and margins of error.

Another ethical issue specific to countries in the Mekong Delta is the cost-sharing arrangement for both the benefits and negative effects of increasing production in slope areas. Several populations are concerned by such increases: the various farmers who plant in this zone, residents and farmers in the plains areas, and consumers of products that come from the soil. Who should pay the cost of measures to prevent soil degradation? The benefits of these measures must be assessed in terms of improvements to health, water quality, and the environment. Who will pay to develop and implement technical innovations? Traditionally local actors, especially downstream users, i.e., the direct beneficiaries of practices that limit erosion and flooding, are asked to pay to solve problems that should be viewed as broader in scope. The demand for meat and raw materials continues to grow throughout Asia; this drives up the value of farming in fragile spaces like slopes, which in turn leads to the environmental predicaments discussed earlier such as flooding, erosion, soil degradation, and decreased biodiversity.

## Conclusion

Soil conservation in the countries of the Mekong Delta, as elsewhere, is an issue that faces a multitude of ethical issues: balancing the many actors involved and their often divergent interests; funding mechanisms and private sector intervention; the validity of the components of scientific proof; and how to compensate the people who provide soil-based services.

Researchers therefore cannot limit themselves to offering technical innovations for improving soil production, limiting degradation, and preventing accidents. They must collaborate and engage in mutual dialogue with representatives of the various interests and contribute to global reflection on soil issues, from the perspective of research ethics and with the goal of equity between actors depending on the natural resources.

* * *

## REFERENCE

Thompson P. B. (2011). The ethics of soil: Stewardship, motivation, and moral farming. In T. J. Sauer, J. M. Norman, & M.V.K. Sivakumar (Eds.), *Sustaining soil productivity in response to global climate change: Science, policy, and ethics*. Chichester: John Wiley & Sons,
DOI: 10.1002/9780470960257.

# Ethical Issues Arising from the Social and Environmental Impacts of Rapid Economic Expansion: The Experience of a Brazilian City

**Tereza MACIEL LYRA**[*]

## Ethics and research on economic development

According to the classic definition coined by Gro Brundtland, former Director-General of the World Health Organization, “sustainable development is development that meets the needs of the present without compromising the ability of future generations to meet their own needs.”[1] Amartya Sen, economist, philosopher, and Nobel laureate, distinguishes between sustainable development and economic growth.[2] Sustainable development is when the benefits of growth lead to changes that themselves benefit society, i.e., economic growth and improved living conditions for all members of the population, all the while preserving the environment and human quality of life as much as possible.[3] Sustainable development protects the natural environment over the long term; it meets basic human needs and promotes equity within and between generations. This should be the goal of all public policy.[4]

Ethics provides a framework for conceptualizing how to protect an individual, social group, or entire population against the potential risks that may arise from research, the application of research results, and the implementation of development policies. Ethics encourages us to reflect on the nature of sustainable development and to analyze any action intended to meet human needs that may affect the environment or society.

---

[*] Physician, Aggeu Magalhaes Research Center, FIOCRUZ, Professor at the Faculty of Medicine of the University of Pernambuco, Recife, Brazil.

[1] Brundtland, G. H. (1987). *Our common future, from one earth to one world*. Report of the World Commission on Environment and Development. Retrieved from http://www.un-documents.net/our-common-future.pdf

[2] Sen, A. (2001). *Development as freedom* (2nd ed.). Oxford: New York, Oxford University Press.

[3] United Nations Development Programme: *Sustainable development goals*, 2016, Retrieved from http://www.undp.org/content/undp/en/home/sustainable-development-goals.html

[4] Holden, E., Linnerud, K., & Banister, D. (2014). “Sustainable development: Our common future revisited. *Global Environmental Change*, *26(Supp. C)*, 130–139.

Here we present an example of ethics and sustainable development, in a community in northeast Brazil that experienced an abrupt change in its economic activities that resulted in economic growth but not necessarily sustainable development. This experience is hardly specific to Brazil. The challenge of boosting economic growth and providing access to goods and services for all members of society while still preserving the environment is one that low-resource countries, and indeed all countries, will recognize.

## The Brazilian experience

Goiana is a city located in the forest zone in the north of the Brazilian state of Pernambuco. Its economy has traditionally been based on sugarcane cultivation, small-scale fishing, light industry (e.g., cement manufacturing), shrimp farming, and folk handicrafts. Beginning in 2010, however, its economy underwent a radical change as part of a strategy that combined several communities together into a development sector and established two industries: pharmaceutical/chemical (primarily the Empresa Brasileira de Hemoderivados e Biotecnologia (Hemobrás) and automotive (Jeep/Fiat). The subsequent rapid economic growth exacerbated its previous problems and created new ones that the authorities were not always able to address.

Social indicators had been a matter of concern for this city, located 60 km from the state capital and home to 75,000 residents. The Human Development Index (HDI) for Goiana in 2000 was 0.692, compared to the national average of 0.718. The illiteracy rate in 2010 was 18.3, and 46.9% of its population lived at or below the poverty level, as calculated from the number of families receiving aid from the family allowance program (Bolsa Familia). The infant mortality rate, although in decline, remained greater than the national average at over 15 per 1000 live births. Indicators for violence in the city were high: violence was the third leading cause of death, primarily for young males (44.9 per 100,000 residents among youths under age 20). Teenage pregnancy rates were also high, with 25% of births to mothers under age 20 in a country where the national average was 19.3%.

Several environmental data points should be noted. Over 50% of the municipal territory was devoted to sugarcane monoculture. Shrimp farming, which is no longer practiced, left significant acreage unsuitable for farming due to soil degradation. Pollution had reduced fishing yields for all those who earned their living from the sea.

Goiana also has areas of potential, including the conservation areas of the Atlantic Forest and mangrove forests (marshy regions with particular vegetation). This latter is an abundant source of crustaceans.

From 2011 to 2013, a cross-discipline team of epidemiologists, social workers, psychologists, geographers, public health professionals, and student fellows conducted an analysis of the city's social and environmental reality. The concept was that sustainable development should prioritize participation by the population by promoting negotiation and encouraging politicians and civil society to take joint responsibility for activities intended to develop the area. The team used a research method that consisted of collecting documents and data from information systems. It also included attempts at participatory planning, group discussions of issues, and asking for proposals from the local population and public authorities, experts, and researchers on various themes.[5]

The research project was submitted to an ethics committee. However because of its participatory nature, the project required several initiatives even prior to its submission.

## Ethical considerations before, during, and after the project

Ethical issues arose from the very start of the project, in terms of its feasibility (authorizations) and how the beneficiaries could monitor the research on the planned actions in the short and long term.

1. The project was submitted to Hemobrás, which sponsored the research.[6] The researchers negotiated the freedom to choose the methodology and publish and share their results (an institutional document was published by Hemobrás[7] and articles were published by the researchers).

2. The project was presented to the city managers to obtain their authorization to access local data and bring together professionals and civil servants working with the public.

3. The project was presented to various state-level institutions—including those involved in development strategies and those working with survey and social and economic data—to create a partnership with them.

4. The project was presented to actors in social movements (meetings were organized to establish partnerships) to include participation by the population in the research.

The research did not begin until it had the approval of the Ethics Committee. All participants signed an informed consent form that included the use of images, since there would be archived photographs of meetings.

---

[5] Hemobrás (2013). Analise Participativa da Realidade Socioambiental da Goiana-PE / Empresa Brasileira de Hemoderivados e Biotecnologia. Retrieved from http://www.cpqam.fiocruz.br/index.php?option=com_remository&Itemid=17&func=startdownJson&id=584&lang=pt

[6] The decision to fund the research was, in the words of the Hemobrás Director, "the result of a commitment by Hemobrás to social and environmental responsibility, which is understood as a management philosophy that seeks to combine the interests of the community in which it operates with the interests of the company."

[7] Hemobrás. (2013). *Op. cit.*

The city's territory was divided into 14 zones in a way that made sense to the local population. Group workshops were held in each zone, followed by theme-based workshops (health, education, tourism and culture, environment, and social assistance). In this text we will focus on the environment theme: the consequences of development on infrastructure, employment, and income, and its effects on the youth.[8]

We discussed existing natural resources, urban expansion, and basic sanitation (water, sewers, solid waste disposal, and drainage). The participants told us that the original natural environment had been ravaged throughout the area's history by sugarcane monoculture, soil depletion, the destruction of coastal vegetation due to urban sprawl, intensive and highly polluting shrimp farming, and more recently by the establishment of industrial parks poorly adapted to the culture of the region. In addition, the local population faces the issue of being forced out of the central areas and living in *favelas* (slums). No protected areas are planned.

Access to water is a major problem.[9] Although there is plenty of water in the city, it is not distributed in a fair and equitable manner. It has always been available for sugarcane cultivation and the companies in the new industrial park but is consistently hard for local inhabitants to access, particularly those living on the outskirts of cities. Yet social justice is at the very basis of sustainable development, as we noted earlier. Major companies never lack for water while small-scale farmers growing crops without chemical fertilizer or insecticides always do. Waterways are sometimes diverted to benefit large-scale agricultural production (like sugarcane), to the detriment of small producers and the local population. The water issue is further aggravated by the fact that solid waste from households, factories, and farms (primarily sugarcane) is contaminating the area's waterways and groundwater.

Another ethical issue is the effect of economic development on employment. The establishment of new development sectors raised hopes that there would be more jobs for the residents of Goiana. However, because the community's economy was based extensively on sugarcane production, the rapid industrialization process instead led to the chaotic influx of laborers from outside the area, almost entirely bypassing local residents.

Because they lack adequate education and job training, the people of Goiana—especially its youth— were unable to find work with the new companies. The combined lack of policies to promote professional training programs or sports and recreation facilities led to a spike in drug use and

---

[8] Hemobrás (2013). *Op. cit.*

[9] Berthoud, A. (2008). La Terre, notre bien commun, *Développement durable et territoires. Économie, géographie, politique, droit, sociologie*. Retrieved from https://developpementdurable.revues.org/5693

trafficking, alcoholism, and prostitution among the youth, and in some cases even among children.

The city finds itself in a situation that is seen around the globe, trapped between the expected benefits of rapid economic growth and the problems arising from a lack of cooperative planning with the local population, the supposed primary beneficiary of sustainable development.

## After the research

During the course of the research project the preliminary results were presented to the local population and city managers. An event was held upon completion of the project that included local authorities and representatives from civil society and social movements. The results were discussed at a round table with participation from members of the research team, other researchers working in sustainable development, public administrators, and most importantly, community leaders.

The primary conclusion was that sustainable development should include collaboration with local society to define priorities and monitor progress. There can be no sustainable development if there is social exclusion. As one local resident put it, “development happens when it does not destroy people’s ability to develop themselves.”

## Ethical issues

1. Some ethical observations were quite clear and can be easily transferred to other areas of the world. The results of a research project should be examined in relation to the degree to which local populations were consulted about it and included in its monitoring. Negotiations before a project starts, dialogue with the research team as it progresses, and regular presentations of interim results are key elements to creating trust from the outset and maintaining a true partnership between the researchers and those who attend meetings and discussions. This type of research, conducted simultaneously with the implementation of growth measures adopted without the participation of local stakeholders, is clearly a potential source of conflict because it may reveal underlying contradictions and thus raise the issue of how strategic and political decisions are made.

2. The results of this research illustrate the ethical issues related to growth programs that do not ensure local acceptance and sustainable development. When public authorities encounter the opportunity that the arrival of large companies represents, they must be involved in every stage, from defining the location of new facilities to monitoring environmental damage.

“Common public goods” like water must not be monopolized by a few to the detriment of the many. The availability of sufficient amounts of good quality water is key for proper hygiene, sanitation, and daily life for the population. Human health is also dependent on a healthy environment, which requires access to water and waste management.

Groups that face additional challenges, like adolescents and young adults, should be the focus of specific policies.

### Application of these ethical lessons to countries in the Mekong Delta

The countries in the Mekong Delta, especially Laos, are facing rapid economic development programs, some of which even cross national borders. Despite the fact that every country faces a unique set of challenges, the consequences of such programs are similar from an ethical perspective, so the lessons learned in Brazil can be discussed and applied by other national and local committees.

* * *

# *Part III*

# Ethics and Research in the Social Sciences

# Introduction

## Anne Marie MOULIN[*]

The social sciences—anthropology, sociology, law, history—both contribute to and critically examine the field of research ethics. The focus on ethics is central and immediate to social science research: central to the "social" definition of these disciplines, and immediate in researchers' proximity to the individuals and groups that make up the society that serves as their "field laboratory." These disciplines are less dazzled by the seeming transcendence of ivory tower-based science and more inclined to a critical posture born of the philosophical approach that, to a greater or lesser extent, forms their common origin.

### A social science perspective on the sources of shortcomings in research ethics

The social sciences examine the sources of the increasing integrity deficiencies within the scientific community, from the collecting of academic degrees or the organization of research work, to collaboration on a publication and equality within teams.[1] During the colloquium, the Vietnamese researcher Quynh Thu Tran highlighted the frequency of such shortcomings in her country, which has experienced ideological upheaval and rapid entry into the era of markets and globalization that have compromised a long tradition of ethically focused research.

This is a global scourge, one that thrives on extreme competition and affects all levels, from job seeking to difficult economic crises. To address corruption, which exists everywhere to some degree but is particularly significant in countries with limited resources, studies have demonstrated the importance of teaching ethics, from elementary schools to universities, along with the responsibilities of a country's politicians with respect to its elites. Strategies to increase the number of publications are familiar to all countries. Redundant or irrelevant research is a legitimate concern

---

[*] Philosopher, Physician, Director Emeritus of Research at the CNRS (UMR SPHERE), Chair of the IRD Advisory Committee on Deontology and Ethics, France.

[1] Moulin, A. M. (2016). L'intégrité scientifique dans le contexte de la recherche en partenariat Nord-Sud. In C. Hervé, M-F. Mamzer, & M. Stanton-Jean (Eds.), *Autour de l'intégrité scientifique, la loyauté et la probité* (pp. 33–50). Paris, France: Dalloz.

everywhere, but is difficult to control, despite the constant increase in boards and assessment and screening bodies.

It is important to clearly define the bases for equitable partnerships within teams. This is especially true for international teams spread out over several continents and composed of researchers working in very different contexts. We should also keep in mind that the international indicators used today to assess research are not absolute standards, and their unilateral dominance, including the importance accorded to digital publication indexes, is a reflection of powerful networks that are not accessible to everyone. The criteria for excellence are constructions open to discussion. Other criteria could be considered, such as the importance of the social applications of research.

## The ethical function of the social sciences

Whether in health-related or environmental contexts, the social sciences use surveys to analyze baseline cultural values and incorporate representations of the populations and communities that make up that culture. In this way the social sciences can inform policies. They help construct a space for debate that bridges, albeit imperfectly, the distance between legislators and decision-makers on the one hand and populations' expectations and desires on the other. They thus contribute to a country's "development," using a broad definition that extends beyond the material and into the moral dimension of that term, and support the harmony of the social entity, their field of research. Such research seeks to explore the realities behind appearances to better adapt intervention programs of all types, including environmental, health, cultural, and natural resource management.

The social sciences improve both our understanding of the beauty and richness of Nature addressed in the 2012 Nagoya Protocol as well as the conservation and equitable sharing of natural resources. Take the long history of dams, for example: audacious interventions along rivers, justified by the on-site, potentially marketable, energy they produce, dams have historically caused irreversible changes to local habitats with clear winners and losers—consider the effects of the Aswan Dam on the Egyptian Nile. Laos is currently home to 23 dams, with another 40 projects under development. Decisions about these should be analyzed carefully, with their potential effects on arable land, the survival of Mekong River dolphins, and the fishing industry. In discussions about dam projects, between ASEAN riparian countries and within the countries themselves, the social sciences work with other sciences to inform debates and clarify options.

The field approach of the social sciences reveals the diversity of cultures around the world,[2] a common universal resource equal to that of nature.

---

[2] Goudineau, Y., & Lorrillard, M. (2008). *Recherches nouvelles sur le Laos*. Paris, France: Publications de l'École française d'Extrême Orient.

The many, varied ethnicities in the Mekong Delta countries illustrate this dialectic of the universal and the individual. Laos alone is home to over 50 officially recognized ethnic groups, which account for more than half of all its inhabitants. This diversity is difficult to define in terms of territory and administration, however. Definitions combine criteria that are rarely applied consistently, such as language, population movements, lands occupied, the possibility of intermarriage, specific handicrafts, and farming methods (e.g., clearing versus rice paddies). Grégoire Schlemmer has followed the establishment of an ethnographic museum in Laos, and describes the sometimes opposing concepts that the public authorities and the representatives of the various minorities had about their cultures and how to display them.[3] It is both these constructions, ever evolving, and the process of turning them into museum exhibits, that tend to define them as relics of the past.

## Examples of ethical issues raised by social science research

### • *The consequences of biomedical progress*

Jean-Daniel Rainhorn addresses the ethical questions raised by scientific and technical progress. Medical transplants, introduced in the 1950s (the first kidney transplant was performed in Boston in 1954), ushered in an era that prolonged the survival of countless patients with failing organs (hearts, livers, and lungs). Candidates for transplantation have always been selected using various criteria, and we now see flagrant social inequalities between countries in regard to eligible patients, a phenomenon quite apparent in the Mekong region. In addition, transplants performed using living donors, like the historic first transplant, are more common than those using an organ from a deceased donor, because it is less expensive and does not depend on a pool of “brain dead” donors whose families agree to organs being harvested from their loved one. This expansion of transplants from living donors has led to the appearance of “cannibal” markets[4] in many countries where poverty facilitates large-scale organ trafficking, as denounced by Jean-Daniel Rainhorn.

Similarly, although the spectacular application of medically assisted reproduction (in vitro fertilization, egg or sperm transfer, etc.) has eased the suffering of many sterile couples, it has also resulted in the exploitation of women who lack protection and resources and who serve as surrogates for others who are more fortunate around the world.

---

[3] Schlemmer, G. (2015). La mise en place d’un musée d’ethnographie au Laos, démarches et questionnements. In L. Vidal (Ed.) *Les savoirs des sciences sociales*. Marseille, France: Editions de l’IRD.

[4] Rainhorn, J-D., & El Boudamoussi, S. (Eds.). (2015). *New cannibal markets: globalization and commodification of the human body.* Paris, France: Éditions de la Maison des sciences de l’homme.

### • *Cultural diversity among health actors*

Mahavongsananh Khamphan and Nicolas Lainé explore local understandings of health through the mythic and threatened animal symbol of Laos, the elephant. They propose a dialogue that ends the latent opposition between veterinary modernists and mahouts, who have been keen observers for generations of their elephants' behaviors and capacities to treat themselves with forest plants. We should note here that belief in reincarnation increases attention to prestigious animals, unlike the long-held indifference towards animals in Western anthropocentric cultures that places humans above all. In Cambodia, illness may be associated with violence to an elephant by a patient's ancestor.[5] Western countries are only belatedly, and from a different philosophical background, now taking steps to prevent pain in animals used in laboratory experiments.

This chapter introduces reflection on the cultural diversity of health actors in the Mekong region. The World Health Organization, which in 1947 proclaimed health to be a universal right, proposed at the 1978 Alma-Ata Conference that "traditional healers" be integrated into health care systems. This acknowledges what anthropologists have told us, that health, or better yet "well-being," does not refer to a single physical integrity but rather to identifiable individual and cultural values.[6]

The social sciences have described "treatment itineraries" or the varied and eclectic combinations patients employ, using Western medicine if available, along with various forms of traditional or neotraditional treatments that are reinvented in a continually evolving context. Most people throughout the world—not just in the countries of the Mekong Delta—juggle the available resources, either as they are accessible or as they fulfill the various imperfect options in the existing health care system. It is common in India to consult multiple practitioners (Western, Ayurvedic, and *yunani* or Greco-Arab medicine); Vietnam and China offer a curriculum in traditional medicine.

During the recent tumultuous years in the Mekong region, sometimes the only medical treatments available were from various healers:[7] herbalists, mediums, exorcists, and religious specialists in writing healing mantras. This type of medicine continues to meet a specific demand for patients' internal spiritual and intellectual harmony, so such traditions and customs are not in opposition to universal scientific standards. Our current high-tech medical imaging capabilities—computed tomography (CT), ultrasound, and magnetic

---

[5] Ovesen, J., & Trankell, I-B. (2010). *Cambodians and their doctors: A medical anthropology of colonial and post-colonial Cambodia*. Copenhagen, Denmark: Nias Press.

[6] Napier, A. D., Ancarno, C., Butler, B., Calabrese, J., Chater, A., Chatterjee, H., ... Woolf, K. (2014). Culture and health. *The Lancet*, 384(9954),1607–1639.

[7] Pottier, R. (2004). *Santé et société au Laos*. Paris, France: Editions du CCL.

resonance (MRI)—may be able to reveal ever more about our internal structures and how they work, but medicine must maintain an exclusively technical view of health that resembles the quest for personal salvation. Buddhist philosophy does not involve a single rationality, but instead allows for a cause-and-effect relationship to exist between diseases and dreams and spirit activities.

### • *History of research ethics in southern China*

In their ethnic composition and poverty levels, the southern provinces of China (Yunnan and Guangxi) resemble their Mekong Delta neighbors, which have recently united to form an economic development entity called the Greater Mekong Subregion. Evelyne Micollier observes how quickly ethics committees were formed in accordance with international standards yet without serious consideration of the criteria that they be independent. Informed consent from individuals without their family's consent is also not practiced, and patients have difficulty grasping the difference between clinical trials and standard treatments. In this area of rapid development, social science researchers are observing the expected increase in vulnerability for migrants within the region.

### • *Ethics of communication to the general public*

Researchers are obligated to provide their subjects with all available information to limit disease transmission and strengthen preventive practices. Pascale Hancart Petitet and Vanphanom Sychareun explore health communication in the context of AIDS prevention and management. Their approach is a model of social science work at the crossroads of cultures. In Mekong Delta countries like Laos, a disease like AIDS that affects sexual relations between couples and in communities has a high risk of being stigmatized. How can we ensure that communications are fair and effective when directed towards an uncomfortable target population, in addition to issues related to language, status, political context, differences in politeness and courtesy conventions, and the acceptability of discussing sexuality?

## Research ethics in the social sciences

The social sciences, frequently critical of other branches of science, may have laudable goals, but they are not exempt from careful examination of their own conscience in terms of their proper practices. This is especially true of interdisciplinary, international projects that are conducted in different contexts that vary greatly.

One such issue is the method used to collect information: conducting one-on-one interviews, administering standardized questionnaires to obtain quantitative data, organizing focus groups for spontaneous discussions about a specific topic, assessing information programs, or consulting "citizen experts" such as those with a common disease experience.[8] Gathering opinions requires finesse and skill in considering the sum of intimate, sometimes painful, experiences. The intervention may be viewed as an intrusion into the private lives of survey participants. Promises of confidentiality must be kept, but this may be problematic.

Investigations may also encounter barriers that individuals have erected over time to protect their personal safety and privacy. For example, a survey of worker incomes conducted in Vietnam recently encountered significant resistance, and its results must be interpreted with caution, because of the probable distribution of the questionnaire responses. A study may also increase the vulnerability of its subjects by revealing their survival strategies, which they may prefer to conceal from the attention of authorities and public opinion.

## Magnitude and vicissitudes of the social sciences: sharing results with participants

Ethics requires not only that we carefully consider the results of our research, but also that we communicate the outcomes to those involved (e.g., clinical trial subjects, respondents to population surveys) once the research has ended. How do we impart these results to participants and make the data available to them? How do we adapt the information to the local culture? How do we express that the data may be revised later, or that there is some uncertainty in the conclusions?

Sharing results with participants is different from sharing them with other professionals. It is an ethical duty and an opportunity to experience an exchange with Others, which is at the very heart of the social sciences. It is also a chance for a deep encounter with the diversity of cultures, one that may involve obstacles but that is ultimately a gratifying experience in moving together towards greater knowledge and mutual understanding. This is work that requires stamina and patience, and in the end confirms the ethical component of social science research that we began with in this chapter.

Social sciences such as anthropology expand the identities and roles of actors in a country, who may adapt their practices and affiliations over time. Research in these domains is therefore a delicate and yet essential matter that both preserves the past (by inventorying idioms, arts, and literature) and represents the future (by defining and protecting heritage, ensuring the architectural integration of new construction, planning for the consequences of upheavals in the landscape and artisanal work, as well as those related to

---

[8] Bureau-Point, E. (2016). *Les patients experts dans la lutte contre le sida au Cambodge : Anthropologie d'une norme globalisée.* Aix-Marseille, France: Editions de l'université de Provence.

voluntary and forced migrations). As stated before, social science research consists by definition of studying and questioning. These actions may disrupt the superficial consensus and pose disturbing questions. They may upset governments, since they may criticize existing and future projects in the name of development or the interests of a national or international influential group. Not least of all, through their particular attention to the creation and operation of a public space, social science research creates a space for debate and dialogue, all with the intention of improving lives.

* * *

# Ethics for Research and Use of Medical Products of Human Origin

## Jean-Daniel Rainhorn*

Medical products of human origin (MPHO) are those obtained in whole or in part from a human body and used to treat either the donors themselves or another person. MPHOs—primarily blood and blood products, gametes, bone marrow, organs, corneas, various tissues, stem cells, and so forth—are products that can be transferred from one individual to another for specific medical indications under particular and rigorous technical conditions. Biomedical research is extremely active in this field, with the number of products and indications for such products increasing every day. Some are available throughout the world while others are restricted to specialized centers that only exist in certain countries.

The sampling, storage, and use of MPHOs give rise to a multitude of serious ethical questions. Researchers, professionals, and health systems are faced with such considerable challenges that the World Health Organization is seeking to promote an international consensus on principles to guide MPHO research, sampling, storage, and use.[1] Most apply to all issues in research on humans and the practice of medicine. Some, however, must be adapted to the specific conditions under which MPHOs are used: these products are first taken from a human (usually with consent), then generally stored in "banks" (unless transplanted immediately), and finally transferred to other human beings who are generally not aware of their origin. These conditions raise the issue of MPHO ownership in research and medical practice.[2]

### A concept that is both ancient and universal

The idea of replacing a diseased body part with a part or tissue from either the affected person or someone else is an ancient one. The

---

* Physician, Professor of International Health and Humanitarian Action, Institut de Hautes Études Internationales et du Développement (IHEID), Geneva, Switzerland.

[1] Warwick, R. M., Chapman, J., Pruett, T. L., Wang, H. (2013). Globally consistent coding systems for medical products of human origin*. Bulletin of the World Health Organization*, *91*, 314–314A.

[2] Goold, I., Skene, L., Herring, J., Greasley, K. (2014). The human body as property? Possession, control and commodification. *J Med Ethics,* January 2014, *40*(1), 1–2.

fundamental principles of autologous skin grafting, still used today, can be found in the Sushruta-Samhita, an Ayurvedic medical and surgical reference treatise written in India about 600 B.C.[3] The legend of the "Miracle of the Black Leg"—a lower limb transplant—immortalized in the famous painting by Fra Angelico in Florence dates to the third century A.D. More recently, the English writer Mary Shelley wrote her famed novel *Frankenstein, or The Modern Prometheus*[4] in the early nineteenth century, in which a scientist brings to life a being he created from cadaver parts. With the discovery of immunosuppressants, allogenic transplants have now become common practice.

The field of medicine has long been fascinated by blood. Early on it was believed that "bad blood" needed to be eliminated, so bleeding was often the only treatment offered for most diseases. It was not until the seventeenth century that the first transfusions were performed in humans;[5] today, of course, this practice is universal.

Thus the idea of using the body of one person to improve the health of others is hardly recent. Research in this area was often conducted on people on the margins of society (e.g., prisoners, mental health patients, those condemned to death). While ethical questions about respect for the individual were not completely absent in the past, they did not become fully developed until the twentieth century, first within the medical community and then in the broader community of public opinion.[6]

## Medical products of human origin at the crossroads between research, medicine, and commerce

Considerable advances have been made in the past 50 years in how to sample, store, modify, and use MPHOs. The three examples given below illustrate the opposing pressures of growing demand for these products and medical ethics.

### *Blood and blood derivatives*

Blood transfusion is the oldest and perhaps best known example of an MPHO that is taken from one person and transferred to another. Blood transfusion saves lives and improves health, but many patients requiring transfusion do not have timely access to safe blood (i.e., drawn, stored, and

---

3. Pasche, P. (2007). Principes de la reconstruction des pertes de substance nasale. *Rev Med Suisse*, *127*(2007-3, 2215–2220.

[4]. Shelley, M. (1997-. *Frankenstein or le the modern Prometheus: the 1818 text*. New York: Oxford University Press.

5. Institut National de la Transfusion Sanguine (n.d.). *Historique de la transfusion sanguine*. Retrieved from https://www.ints.fr/TransfusionHistorique.aspx.

6. Vollmann, J., Winau, R. (1996). Informed consent in human experimentation before the Nuremberg code. *BMJ*, *313(7070):* 1445–1449.

transfused in accordance with WHO-recommended guidelines). Providing safe and adequate blood should be an integral part of every country's national health care policy and services.[7]

According to WHO, there are over 110 million donations of blood every year in the world. Most of these come from unpaid volunteer donors. However, the need for blood products continues to rise, while the number of volunteer donors is stagnating or even decreasing. How can we increase the number of donors? Will we need to resort to paying them, introducing a market economy into a sector that has been a shining example of altruism and solidarity? Some countries pay those who give blood; are they still "donors"? Others, especially in the West, export blood products, thus furthering the development of international commerce in this ethically sensitive area.[8] Blood and blood derivatives are essential products with significant symbolic value. Will they become mere market goods, subject to the laws of supply and demand? Can we still defend the altruistic nature of donation?

### *Organ, tissue, and cell transplant*

Transplants of organs, tissues, and cells of human origin have increased around the world in the past several decades extending and improving the lives of thousands, thanks in large part to progress in immunology and transplantation techniques. Here again demand has rapidly outpaced supply, despite an increase in donor organs from both cadavers and living donors. This persistent shortage of MPHOs has led to an international black market for human organs and tissues, most of which come from living donors unrelated to the recipients.

In recent years we have seen the development of a veritable transplant tourism: thousands of people travel to countries where organs can be "purchased" from donors—or more accurately from vendors who recruit donors from areas where extremely poor, displaced, or refugee populations live.[9,10] Ethics condemns the exploitation of their bodies for the benefit of socially advantaged groups. This is a very real problem in South and Southeast Asia, where the doctors and health care professionals who provide these services breach the basic ethical tenets of the Declaration of Helsinki and the World Health Organization.

---

7. World Health Organization. Blood safety and availability. Retrieved from http ://www.who.int/mediacentre/factsheets/fs279/en/. 01/02/2017.
8. Tissot, J. D. (2014). La transfusion sanguine entre éthique, commerce et réalité. *Forum Med Suisse*, *14(4)*, 67–69
9. Mendoza, R. L. (2010). Colombia's organ trade: evidence from Bogota and Medellin. *Journal of Public Health, 18*, 375–84.
10. Goyal, M., Metha, R. L., Schneiderman, L. J. (2002). Economic and health consequences of selling a kidney in India. *JAMA, 288(13)*, 1589–93.

Trafficking in MPHOs assigns a monetary value to the human body, violating its integrity and dignity as affirmed by international ethical principles. Such trade is akin to slavery in the way it allows one individual to purchase another to serve his or her own needs.

WHO[11] and the international scientific community have developed an ethical framework—the Declaration of Istanbul—to limit this trade.[12] How can we solve this problem? Allow the trade to continue to compensate for the lack of MPHOs? Require governments to make these products available for free? Still, a black market could develop. Set a public price or "compensate" the donor? Some countries, like Iran, are moving in that direction.[13]

It is clear that the ethical use of MPHOs has become an area in which it is absolutely necessary to reach an international agreement with enforceable provisions.

### *Medically assisted reproduction*

Medically assisted reproduction is in some ways one of the most problematic areas of medical ethics today.

Tens of thousands of children are born every year around the globe as a result of in vitro fertilization (IVF) techniques, which allow infertile couples to have a pregnancy from their own gametes. We now have other methods for couples to become parents, in which the fetus is carried in the uterus of a woman who may not be recognized by law as the mother. In such cases the child may not share any genetic materials with either parent, or only with one of them. Sperm and egg donations, as well as so-called surrogate pregnancies, are widely practiced throughout the world, posing legal and ethical questions that are fiercely debated in certain countries.

New questions have arisen with the commercialization of medically assisted reproduction, which can lead to social inequalities of access. Differences between national legal and ethical frameworks that vary in their level of tolerance, as well as international price competition, have led certain countries—in South and Southeast Asia in particular—to promote semi-industrial levels of activity in this domain (sperm and egg banks, surrogate

---

[11] World Health Organization. (2010). *Guiding principles on human cell, tissue and organ transplantation.* Resolution WHA63.22. Geneva, Switzerland: 63th World Health Assembly.

[12] Participants in the International Summit on Transplant Tourism and Organ Trafficking convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey. (2008). The Declaration of Istanbul on organ trafficking and transplant tourism. *Kidney International 74* (7), 854–59. http://dx.doi.org/10.1038/ki.2008.388

[13] Mahdavi-Mazdeh, M. (2015). An alternative to trade: the Iran experience. In J. D. Rainhorn and S. El Boudamoussi (Eds). *New cannibal markets*. Paris, France: Éditions de la Maison des Sciences de l'Homme.

mother centers, etc.). International reproduction tourism actually exists, in which the wealthy of the world come to a resource-constrained country to "buy" a child who is "manufactured" from gametes and carried by a surrogate mother chosen from a catalog, who is herself invariably from a social underclass.[14]

Several of the myriad possible ethical and legal questions are particularly striking. What international law establishes who is the mother of a child born to a surrogate, conceived using IVF, with gametes purchased from a cell bank? Is it the woman who purchased the reproductive cells to raise a child, or the woman who sold her ovocytes and thus half of the future child's genetic material to a cell bank? Or is it instead the woman who carried the pregnancy for nine months? And who is the father? The man who purchased the gametes, or the one who sold his sperm, i.e., his genes?

## Conclusion

The emergence of a market economy in the sector of MPHO research and use raises a host of ethical issues that are far from reaching international consensus at this time. This is an area that demands our continued attention and reflection.

* * *

---

[14] Frankford, D. M., Bennington, L. K., Ryan, J. G. (2015). Womb outsourcing: commercial surrogacy in India. *MCN Am J Matern Child Nurs, Sep-Oct;40*(5), 284–90.

## ETHICS AND REGULATORY REFERENCE DOCUMENTS

- World Health Organization Executive Board EB136/32 136th session. (2014). *Blood and other medical products of human origin. Report by the Secretariat.* Geneva, Switzerland. Retrieved from
  - http://apps.who.int/gb/ebwha/pdf_files/EB136/B136_32-en.pdf
- Post, S.G. (Ed) (2004). *Encyclopedia of Bioethics*. Third edition. New York, N.Y.: Macmillan Reference. Retrieved from
  - http://www.worldcat.org/title/encyclopedia-of-bioethics/oclc/52622160
- World Health Organization. (2001). *Developing a national policy and guidelines on the clinical use of blood. Recommendations.* (WHO/BCT/BTS/01.3). Geneva, Switzerland. Retrieved from
  - http://apps.who.int/medicinedocs/documents/s15416e/s15416e.pdf
- UN General Assembly. (1948). *Universal Declaration of Human Rights* (217 [III] A). Paris, France. Retrieved from
  - http://www.un.org/en/universal-declaration-human-rights/
- World Health Assembly. (2010). *Human organ and tissue transplantation*. (WHA63.22). Geneva, Switzerland. Retrieved from
  - http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf?ua=1
- Participants in the International Summit on Transplant Tourism and Organ Trafficking convened by The Transplantation Society and International Society of Nephrology in Istanbul, Turkey. (2008). *The Declaration of Istanbul on organ trafficking and transplant tourism*. April 30–May 2, 2008. Retrieved from
  - https://www.edqm.eu/medias/fichiers/The_Declaration_of_Istanbul.pdf
- Australian Government National Health and Medical Research Council. (2007). *Ethical guidelines of the use of assisted reproductive technology in clinical practice and research*. Canberra, Australia. Retrieved from
  - https://www.nhmrc.gov.au/guidelines-publications/e78

***

# Ethical Dilemmas Raised by HIV-Related Research in Laos. From Scientific Research to Production of a Radio Program

**Pascale HANCART PETITET,[*] Vanphanom SYCHAREUN[**]**

Since the late 1990s, Laos has become more open to foreign research, especially in the medical and environmental sciences. However, only a few research departments in Laos are dedicated to social sciences, and anthropology is still not taught at the university level. When we had the idea in 2011 to propose a study documenting reproductive health issues in the context of HIV from an anthropological perspective, we decided to combine the anthropological skills of researchers from the Institut de Recherche pour le Développement (IRD) with the expertise of the team at the Department of Postgraduate Studies at the University of Health Sciences. This team already had considerable experience in leading research programs on this issue from a public health perspective using a qualitative approach. Our study was included in a health research program under the Ministry of Health, which established a department of Training and Research in 2013 to enhance the promotion and overall management of health research. As with all scientific studies, we followed all ethical clearance processes required by the National Ethics Committee for Health Research[1] and obtained the authorizations required to start the project.

This chapter describes and analyzes how and to what extent this research raised ethical issues and required methodological adjustments, and how those adjustments also led to scientific innovations. The chapter first retraces the research project's genealogy, then examines the specific conditions of scientific data production required when collecting personal accounts and facts related to HIV, which is still a sensitive issue in the context of Lao PDR, not unlike many other countries. We then share some preliminary results of this project and explain how these results raised ethical issues for researchers and how it led us to develop innovative ways to share results with the general public.

---

[*] Anthropologist, IRD, UMI 233 TransVIHMI, Inserm U 1175, University of Montpellier. Posted at IRD in Vientiane, Laos, since 2013.

[**] Public health physician, Dean of the Faculty of Post Graduate Studies, University of Health Sciences, Vientiane, Lao PDR.

[1] Since 2014, the ethical clearance requirement must be completed on the Lao PDR Health Research Portal (website: http://laohrp.com/index.php/hrp/index).

The University of Health Sciences in Vientiane and IRD developed a research project on the social and cultural aspects of using antiretroviral treatment (ART) to protect children, based on the WHO recommendations for the prevention of mother-to-child transmission (PMTCT) of HIV (Prems ANRS 12271). In 2010, a new PMTCT strategy was adopted at the international level, emphasizing ART initiation during pregnancy and breastfeeding. International agencies targeted the “elimination of mother-to-child transmission” by 2015 as a global goal.[2] Our research programs aimed to produce scientific knowledge related to this public health initiative in the Laotian context. We also wished to contribute to the anthropology of human reproduction in a rapidly changing Southeast Asian society. We collected data in various spaces (local organizations, health institutions, informants’ homes, and coffee shops), and our research raised questions on both the validity of anthropological methods and the local interpretation of internationally accepted ethics principles. We tested innovative ways to collect data and share research results with the general public in Laos. In May 2015, we started a radio program in Lao language to share research results to support efforts to limit mother-to-child HIV transmission.

Drawing from both theoretical and applied perspectives, our research follows the paths of anthropologists who have worked in the field of HIV/AIDS for over 20 years. They have documented social, cultural, and political issues related to HIV during the two main stages of the pandemic—first, during the pre-2000 era when only preventive measures were available, then during the post-2000 treatment era.[3] They have provided scientific arguments (by showing that patients could be adherent) in support of delivering free AIDS treatment in the poorest countries, when treatment was not immediately available in contrast to the more affluent ones.[4] They also showed how AIDS-related stigma could prevent access to health services for infected patients.[5] Since researchers involved in AIDS programs are ethically responsible for the practical consequences of their research[6,7] in

---

2. World Health Organization. (2010). PMTCT strategic vision 2010–2015. Geneva: World Health Organization. Retrieved from http://www.who.int/hiv/pub/mtct/strategic_vision/en/index.html
3. Hardon, A., & Moyer, E. (2014). Anthropology of AIDS: Modes of engagement. *Medical Anthropology 33*(4), 255–62. doi:10.1080/01459740.2014.889132
4. Desclaux, A. (2002). Impact of access to antiretroviral treatments on health programmes: Challenges, plan of action and scope of research. In J.-P. Moatti, I. Ndoye, H. Binswanger, P. Kahn, M. Grunitzky-Bekele, S. Hiras, & Y. Souteyrand (Eds.), *Improving access to care in developing countries: Lessons from practice, research, resources and partnerships*. Geneva: UNAIDS/WHO.
5. Songwathana, P., & Manderson, L. (2001). Stigma and rejection: living with AIDS in villages in southern Thailand. *Medical Anthropology,* 20, 1–23. doi: 10.1080/01459740.2001.9966185
6. Benoist, J., & Desclaux, A. (1996). *Anthropologie et sida. Bilan et perspectives.* Paris: Karthala.

the field,[8] how can anthropologists best interact with actors from other disciplines to improve local public health outcomes?

In Lao PDR, HIV prevalence is said to be low. The official estimate is about 0.3 % among the adult population, mainly through heterosexual transmission. HIV incidence is increasing, with an estimated 1096 cases of new infections in 2015, up from 957 new cases in 2014 and 617 new cases in 2012. HIV prevalence is also increasing in subgroups of key populations such as sex workers; people who inject drugs; and men who have sex with men (MSM), identified as transgender persons who reported selling sex. Heterosexual (88%) and MSM (8%) contact accounted for the majority of HIV transmission from 1990 to 2013. Transmission from mother to child (4%) and injected drug use (less than 1%) account for only a small proportion of cases.[9] HIV cases due to mother-to-child transmission increased from 2% in 2003 to nearly 5% in 2010.[10] According to a 2016 National AIDS Control Committee report, the cumulative number of pregnant women with pre-counseling and testing was 25,456; among these, 24,487 received blood tests and 23,957 received post-HIV-test counseling. Of these pregnant women, 68 mothers tested positive for HIV and were put on ART. However, in rural areas where PMTCT services are rarely available, many pregnant women deliver without being tested for HIV.

Recent studies indicate that many Laotians still know little about HIV prevention and treatment. People, such as housewives or youth who are not primarily identified as among the “most-at-risk groups” (sex workers, drug addicts, etc.) are nevertheless at risk of being infected by HIV. For example, during their investigation in Luangnamtha province, in Northern Laos, Sychareun et al.[11,12] documented the alarming rate of sexual risk behaviors among younger adolescents. The study showed that these risks were related to their curiosity and taste for experimentation, their use of alcohol, and traditional sexual customs.

---

7. Dozon, J-P. (1997). L’anthropologie à l’épreuve de l’implication et de la réflexion éthique. In Agier, Michel (Ed.), *Anthropologues en dangers : l’engagement sur le terrain, Cahiers de Gradhiva, 30*, 109–21. Paris: J.-M. Place.
8. Fassin, D. (2006). *Quand les corps se souviennent. Expériences et politiques du sida en Afrique du Sud*. Paris: La Découverte.
9. CHAS, National AIDS Control Committee, Lao PDR. (2016). *Lao PDR country progress report: Global AIDS response progress country report*, 2016
10. National AIDS Control Committee. (2010). *Lao PDR’s UNGASS 2010 country progress report 2010*.
11. Sychareun, V., Faxelid, E., Thomsen, S., Somphet, V., & Popenoe, R. (2011). Customary adolescent sexual practices among the Akha of northern Lao PDR: considerations for public health. *Culture, Health & Sexuality*, 13 Suppl 2 (December), S249–62. doi:10.1080/13691058.2011.634924
12. Sychareun, V., Thomsen, S., Chaleunvong, K., & Faxelid, E. (2013). Risk perceptions of STIs/HIV and sexual risk behaviours among sexually experienced adolescents in the Northern part of Lao PDR. *BMC Public Health*, *13*(1), 1126. doi: 10.1186/1471-2458-13-1126

Many young Laotians begin exploring their sexuality and gain sexual experience at an early age. Nearly two decades ago, the 2000 Lao Adolescent Reproductive Health Survey[13] found that adolescents increasingly engaged in sex before marriage, that many resort to unsafe abortion, and that many contract sexually transmitted infections (STIs).

Our intensive data collection, in both urban and rural health care settings over four years, has shed light on the situation. Fearing stigma and discrimination, many people do not want to be tested for HIV in Laos, and many die of HIV-related diseases because they arrive to antiretroviral treatment centers too late. The HIV epidemic remains a sensitive subject. However, similar to other parts of the world, Laos has also acknowledged that all HIV-positive people should be treated to break the transmission chain and hopefully see an end to the epidemic. The Center for HIV/AIDS/STIs (CHAS), working under the Ministry of Health in partnership with donors and international organizations, has implemented various activities in this area,[14] but access to HIV testing, prevention, and care services remains limited, especially in rural areas.

What ethical issues are raised by producing knowledge related to the prevention of mother-to-child transmission of HIV in such a context? We answer this question by considering the ethical rules governing access to data collection, HIV disclosure among couples, the management of confidentiality in health care settings, and personal ethical conduct.

As always when collecting scientific data, we also had to take various steps to gain access to information. Conducting research means first negotiating one’s presence in various spaces. After obtaining authorization from the National Ethical Research Committee, we had to request authorizations at the district and village levels. For observations and interviews at the hospital level, we sought authorization at each hospital department in charge of the prevention and treatment of mother-to-child HIV transmission (antenatal care, obstetrics, pediatrics, and infectious diseases departments). While such requirements represent the basic ethical standard for any scientific research, other demands were quite challenging. For example, before interviewing caregivers, we were requested to also ask permission from their supervisors. Interviews could rarely exceed 45 minutes, and no second interviews were allowed. This constraint raised various questions in terms of classical anthropological methods that require prolonged immersion and floating observation.[15] Although the informants did

---

[13] Lao Youth Union, Japanese Organisation for International Cooperation in Family Planning & UNFPA. (2001). Adolescent Reproductive Health Survey 2000.

[14] CHAS, National AIDS Control Committee, Lao PDR. (2016). Lao PDR country progress report: Global AIDS response progress country report, 2016

[15] Hancart Petitet, P. (2008). Dimension éthique de la recherche en Inde du Sud. A propos d’une étude anthropologique d’un programme de prévention de la

their best to “provide accurate answers,” the hospital staff tended to state that everyone followed the official rules and medical protocols with no hurdles, questions, or doubts regarding their daily activities. The counseling team in the antenatal care department rarely admitted to any difficulties when giving HIV test results to pregnant women or when convincing those women’s husbands or partners to also get tested. At the end, we were left in an uncomfortable position when asking people questions that they felt were unfair or inappropriate.

In retrospect, our frustration during the fieldwork became an opportunity to observe *locally* how social and cultural norms influence the management of the epidemics, in terms of generation gaps, social status, gender, hierarchy, and ethnicity. It helped us to understand the development of the HIV epidemic in Lao PDR, long after its emergence in Europe and the United States. Finally, because of our work through IRD’s collaboration with the University of Health Sciences research team and our partnership with Médecins du Monde in Champassak province, we were able to better document the perceptions of various stakeholders, caregivers, and patients involved in HIV prevention and care programs in both urban and rural settings as well as the local interpretation of medical protocols.

We observed that in rural areas many women were delivering at home and received no HIV tests. Only a few pregnant women attending antenatal consultations in NGO-subsidized health care centers were tested since HIV tests were only available at provincial hospitals. However, testing raised various issues for them. Some women who were prescribed an HIV test did not go to the laboratory to be tested, others did not return to get their test results. When investigating the process caregivers followed when providing HIV test results to these women, we also felt that caregivers did not fully grasp the basic rules for managing confidentiality. For example, with no private space set up so that caregivers could return HIV test results to patients confidentially, patients feared that their result would not remain confidential because other caregivers or patients would overhear it. Also, although some women understood that they could receive treatment and limit the risk of HIV transmission to their babies during pregnancy, delivery, and breastfeeding, they found it very difficult to bear the responsibility of disclosing their HIV status to their partners and families all alone.

To comprehend the social context of HIV infection as it relates to reproductive health issues, we also had to understand the common social representations of HIV sexual risks. What do people know about HIV? Do they consider themselves at risk of getting HIV infection? How do they deal with prevention measures? We interviewed people in non-health care settings and encouraged them to share their own perceptions of HIV/STI

---

transmission mère-enfant du VIH. ethnographiques.org. Retrieved at http://www.ethnographiques.org/ 2008/Hancart-Petitet.html risks. For example, one married housewife told us that she observed that since getting a smartphone, her husband frequently contacted his friends on WhatsApp. Every night they invited him out to have fun and drink in entertainment venues. Based on her friends' stories, this woman feared that her husband may be having intimate relationships with other women. The presence of a regular mistress, a *mia noy*, in her husband's life was unacceptable, but she said she could understand and accepted the fact that her husband may want to experiment sexually with other women since they had already been married for many years. She knew about HIV; however, she did not dare to discuss infectious risks with her husband, and she wondered how to protect herself from being infected.

Another ethnographic case raises additional questions about ethical and responsible conduct.

*Jon (a pseudonym) is an 18-year-old man we met in Vientiane. He defined himself as a playboy. He is very smart, plays music with his band at weddings and events, and is successful with young women. Regarding HIV risks he stated: "I have read books at the school library. I learned that if one loses weight and has a fever and spots on the tongue, that means that he has HIV/AIDS. I don't have any of these, so I don't have HIV. Condoms? Oh no! You know, right then, it's urgent, and I'm often very drunk. If you stop and wonder about condoms, then it's over! I only have sex with very young, pretty women. I also follow them on Facebook to be sure that I'm their only one!"*

At this stage, we felt that we could not wait to complete the usually long process to publish research results. While data collection and analysis continued, we started sharing some of our results during locally held HIV meetings. We provided information that we felt could be useful for improving the delivery of PMTCT services and explaining why housewives and youth should also be targeted as at-risk populations in the public health program. We raised an ethical question shared by all researchers involved in applied research programs: how can we make the research results useful for others? How can we shape them in such a way that everyone—the general population, caregivers, and stakeholders—can learn from them? And given the extremely slow process to share results, how do we make research findings accessible faster?

After one year of negotiations, we began sharing our results on radio programs that reach 80% of Lao territory. In May 2015, with the help of Mrs. Souk Prasay Sithimolada, an expert consultant at Radio National Loa and at the Ministry of Information, Culture, and Tourism, we started a collaborative project with a team from Radio National Lao. This weekly radio program in Lao language was called "Health for You/Soukapap peua tan." These broadcasts openly addressed various themes related to our study using simple language. During the 15 30-minute radio shows, scientific data, interview extracts, and a diverse range of testimonies from lay men and women and health professionals were woven together around a chosen topic (HIV basics, mother and child mortality, young people and HIV, risk taking, how to live with HIV, PMTCT, and children living with HIV).

Through this program we provide basic information on reproductive issues and HIV, and share the experiences and perceptions of stakeholders, caregivers, and patients involved in HIV/MTCT prevention and care programs. We also talk about prevention, stigma, and gender issues. The radio program made these research results accessible and understandable for a wide audience (the general public; public health, development, and media actors; researchers; and decision makers). Each broadcast was also linked to several digital platforms and Facebook pages (in Lao and in English) and a website (https://healthforyouinlao.wordpress.com/), which also posts summaries and photos from the field as well as communication materials in Lao produced by the Ministry of Health and international institutions. Through our collaboration with the organization I Care Benefits, a social enterprise based in Vietnam and active in Laos since 2012, our program has also been broadcasted in eight garment factories in Vientiane, reaching an audience of 8000 workers.

## Conclusion

This chapter presented issues related to the ethical aspects of research that arose during fieldwork conducted during prevention programs for mother-to-child transmission of HIV in Laos. First, we employed a reflexive approach to describe the initial conditions of data collection and the process used to obtain research authorization. Second, we described the steps taken by researchers while conducting the various phases of the study and the steps to meet ethical research requirements. Next, our ethnographic examples raised additional ethical questions. Our results raised confidentiality issues in health care settings and weighed people’s individual responsibility to prevent HIV/AIDS transmission.

Further analysis of these findings also suggests that issues related to ethical aspects of research, professional deontology, and what meanings researchers give to knowledge production are inseparable. Once the research has begun, maintaining ethical concern for the involved actors cannot be limited to fulfilling administrative formalities or avoiding the unfortunate consequences of possible misconduct. This constant concern for “the Other” represents a challenging imperative whose raison d’être lies beyond a formal requirement, underlying the epistemology of our scientific discipline and how we give meaning to knowledge production.

* * *

# Ethics, or a Dialogue of Knowledge. The Case of Tuberculosis Surveillance in Elephants in Laos

**Nicolas LAINÉ[*] in collaboration with**
**Khamphan MAHAVONGSANANH[**]**

## Human-animal relations

We conducted research in Laos on representations of the disease-causing agents that circulate between animals and human beings in an effort to compare different societal and cultural spheres. The information gathered through this anthropological research can help to better understand and prevent zoonotic diseases (those transferred between humans and animals), which are a significant medical threat in the world today.

We have long known that humans and animals share many diseases, and that these can be passed from one to the other during our interactions with other species. The discovery of the genetic mechanisms of cells has deepened our understanding of this relationship and of the links between population health and the diversity of species in the natural world. The “One Health” initiative, a tripartite collaboration launched in 2009 between the World Health Organization (WHO), the World Organisation for Animal Health (OIE), and the Food and Agriculture Organization of the United Nations (FAO), advocates a rapprochement between human and veterinary medicine so that we can better understand the diseases that exist in all species and how they interact in the environment. This all-encompassing perspective requires renewed appreciation of local populations’ knowledge of their environments and its risks to their health and practices, which is traditionally the realm of anthropologists. An extension of the 1992 International Convention on Biological Diversity signed in Rio, the Nagoya Protocol, has governed access to genetic resources (animal, human, and microbial genomes) since taking effect in 2014. This protocol emphasizes the need to involve local populations in research so that they have access to scientific knowledge, participate in building such knowledge, and share in its benefits.

---

[*] Laboratory of Social Anthropology, Collège de France. Affiliated with EFEO Center (École Française d’Extrême-Orient) in Vientiane, Laos.

[**] Research Assistant to Nicolas Lainé for the duration of the survey (September to December 2015).

This is an undeniable ethical requirement for research that must be followed in all contexts, so that dialogue between scientists, decision-makers, and populations can support the development of policies on health and biodiversity conservation.

Although we have seen progress, international health agencies still often overlook local understanding of diseases, both human and animal, or even consider this perspective to be an impediment to their interventions. Yet the specific understanding that local populations have of their environment makes them "cultural nodes" that are key to communicating within global-scale networks.[1] How can we integrate "the science of the concrete" [2] with other forms of knowledge to better anticipate unknown environmental and health crises?

Our research in Laos[3] examined the local perception and management of risks associated with tuberculosis (TB) in elephants. TB is a human disease that affects all organs, especially the lungs, and is caused by a microbe first identified in 1883. Animals can also be afflicted with TB, particularly bovines such as cows and water buffalo. In fact, the vaccine that is still given today to combat TB—Bacillus Calmette–Guérin (BCG)—comes from an attenuated bovine microbe.

TB in humans remains a serious public health issue in Laos[4] that now threatens the living symbols of the country: elephants. Only some 900 elephants live in that country today, half of them in villages alongside local populations.[5] Most of the nation-states in Asia with pachyderm populations have faced the issue of human contamination from these animals. Laos launched a national elephant seroprevalence survey,[6] limited by the difficulty

---

1. Lowenhaupt Tsing, A. (2003). Agrarian Allegory and Global Futures. In P. Greenough & A. L. Tsing (Eds.), *Nature in the Global South: environmental projects in South and Southeast Asia* (pp. 124–170). Durham: Duke University Press.
2. Lévi-Strauss, C. (1962). *La pensée sauvage*, Paris: Plon. Claude Lévi-Strauss (1908–2009) was a French anthropologist who argued that diverse cultures share universal reasoning.
3. As part of the project entitled "*Représentations sociales des pathogènes à la frontière entre les espèces" (Social representations of pathogens at the boundary between species)*, coordinated by Frédéric Keck (CNRS/Musée du Quai Branly, Paris, France).
4. World Health Organization (2016). *Global Tuberculosis Report 2016*. Retrieved from http://apps.who.int/iris/bitstream/10665/250441/1/9789241565394-eng.pdf
5. Khoubouline, K. (2011). Current status of Asian elephants in Lao PDR. *Gajah* (35): 62–66.
6. Tuberculosis has reappeared in pachyderms across the world in the past 20 years, resulting in several disease surveys and targeted surveillance campaigns in Asia (Maslow, J. N., & Mikota, S. K., (2015). Tuberculosis in elephants: a reeemergent disease: diagnostic dilemmas, the natural history of infection, and new immunological tools. *Veterinary Pathology*, 52(3): 437–440.

of diagnosing the disease,[7] which found a 34% infection rate in the animals tested.[8] Concern about TB transmission to both human and domestic animal populations, as well as to other species, led to the establishment of a surveillance campaign in that country in 2013.

We explored local knowledge and its role in the surveillance of this zoonotic disease, which is considered a “reverse” zoonosis[9] because humans can be the source of the contamination. We surveyed villages in the communities of Tai Lao Tai Lue, and in an elephant camp in the Sayabouli province (northwest Laos) in the Hongsa and Meung Ngeun districts. The Sayabouli province is currently home to three-quarters of the country’s domestic elephants.

## Procedure and outcomes

We surveyed mahouts and elephant owners about how they perceive and treat diseases that affect these animals as well as about TB-related risks. They described elephant TB as a recent phenomenon associated with the “modern medicine” that was brought in with elephant conservation efforts in the country in the early 2000s.[10] They expressed a lack of trust in modern veterinary science and the changes made to elephant management, such as the creation of camps or conservation centers where their animals become “patients” treated by the veterinarians and they themselves are demoted to mere animal drivers.

Epidemiologists, however, consider mahouts and elephant owners to be “sentinels” who provide information on the animals’ health. Elephants are screened on a regular basis, and infections in that population can be used to alert authorities to risks for human populations. Yet the people living in these areas find it hard to fathom that diseases can be transmitted between people and animals.[11] How can surveillance work when it is meaningless to those involved? We decided to explore the human-animal boundary with them. We observed several daily rituals that involved ceremonial specialists

---

[7] The blood test marketed immediately following the disease alert, Stat-Pak, was found to be defective by many epidemiologists, who faulted it for being overly sensitive. Often elephants tested positive when in fact they did not have the disease.

[8] Lassaussaie J., Bret A., Bouapao X. Chanthavong V., Castonguay-Vanier J., Quet F., Mikota S. K., Théorêt C., Buisson Y., Bouchard B. (2014). Tuberculosis in Laos, who is at risk: the mahouts or their elephants? *Epidemiol Infect*, *143*(5), 922–31.

[9] Suterhimshony, A. (2008). Tuberculosis in elephants: a reverse zoonosis. Infectious Disease News, December 2008, DVM Retrieved from http://www.healio.com/infectious-disease/zoonotic-infections/news/print/infectious-disease-news/%7B193d8ef8-75be-4476-a39c-92b22d0b10d8%7D/tuberculosis-in-elephants-a-reverse-zoonosis

[10] Suter, I. (2000). ElefantAsia in the Lao PDR – An Overview. *Gajah* (33), 53–57.

[11] Known as “crossing the species barrier” in biology.

and evoked invisible entities known as spirits, or *phi*, which can be both benevolent or malevolent. These entities are important in the relationships owners and mahouts have with their elephants and can be compared to the importance biologists place on microbes to biologists, which of course are also invisible entities to most mortals.

Our survey was based on dialogue and exchanges, and provided pertinent information on pachyderm health and any treatments they were given. The data showed that mahouts are highly attuned to the signs and symptoms exhibited by their animals. They describe causality systems for elephant diseases[12] that combine both visible and invisible signs that are not considered by experts in disease surveillance. Veterinarians rely solely on so-called clinical signs, an analogy with human medicine: only visible, external signs are considered in detecting the presence of pathogens in animals.

For example, when veterinarians visit villages they ask the mahouts if they have noticed any significant nasal discharge from the trunks of their animals, or if the elephants have lost weight (signs comparable to those seen in human TB infection). The mahouts reply that it is not unusual for their elephants to lose weight, especially after several days of work in the forest, so they do not view it as a potential sign of disease. After returning from logging work in the forest, the elephants need only be allowed to roam freely around the outskirts of the village for several days to return to a healthy weight. Both mahouts and herbal medicine specialists (*mo ya*) in the village use a variety of plant-based therapies/compositions to treat the animals, but they also trust another important factor: the elephants' own knowledge of how to maintain their health and well-being. If mahouts provide the necessary elements for a healthy diet, the elephants know to select the plants they need, thanks to the abundance and diversity of biological species they encounter in their environment.[13]

In an effort to conserve the species and out of a concern that owners may sell their animals if they receive alarming health news, veterinarians have not wanted to share all of the findings of the national prevalence survey with the owners. We were often asked about this during our survey by owners and mahouts who had not been informed of the results of tests performed on their animals.

---

12. Lainé, N. (2017a). Surveiller les animaux, conserver l'espèce. Enjeux et défis de la surveillance de la tuberculose des éléphants au Laos. *Revue d'anthropologie des connaissances*, 11(1), 23–44.
13. Lainé, N. (2017b). Travail interespèces et conservation. Le cas de l'éléphant d'Asie. *Écologie et Politique*, (54), 45–65.

## Conclusion: Better global health

This research raised a variety of questions, both scientific and ethical.

The ethnographic survey of mahouts and elephant owners illustrated a system of knowledge and understanding that they develop over time and apply daily in their interactions with pachyderms.[14] Those who live and work with elephants are key to assessing the risks of TB emergence in elephants and its spread to surrounding populations, and are well positioned to monitor the disease effectively. Their knowledge is a partial yet essential component to addressing the issues of global public health, species conservation, and biodiversity being discussed in international arenas. Unfortunately our survey shows that in the current system there are several layers of misunderstanding and a lack of dialogue between those with different backgrounds and experience with elephants. Rather than facilitating exchanges, disease surveillance appears to be exacerbating existing tensions between the various field actors.

The scientific issues include the scope of TB infection in elephant populations, how contagious the disease is for humans who are in contact with them and vice versa, and the possibility of transmission between wild and domestic animals (e.g., when domestic elephants encounter their wild cousins while working in the forest).

The ethical issue relates to the need to provide information to individuals who work with elephants, and to the validity and relevance of incorporating their experience in diagnosing and caring for these animals, regardless of the theoretical and socio-cultural context of this experience.

In Laos, knowledge created jointly with local specialists would improve the effectiveness of both the TB detection and elephant conservation efforts sought by government agencies. Mahouts would also benefit from a more in-depth understanding of the diseases that affect their animals and from being integrated into modern thinking about biodiversity conservation, which for them is an awareness of their precious natural resources. Research ethics is thus enriched by local know-how, folklore on the verge of disappearing.

In today’s “globalized disease environment,”[15] characterized by the emergence and re-emergence of diseases circulating between humans and animals and by the rapid disappearance of many species, there is no single “one size fits all” solution to the health and environmental risks that threaten our entire planet. Case-based contextual studies must be conducted in

---

[14] This system draws from two types of medicine: remedies and rituals (cf. Pottier, R. (2007). *Yû dî mî hèng “Être bien, avoir de la force” : essai sur les pratiques thérapeutiques lao*. Paris: EFEO Monograph, 192).

[15] Morand, S. (2016). *La prochaine peste : une histoire globale des maladies infectieuses*. Paris: Fayard.

collaboration with local partners to incorporate their understanding of the environments they know so well.

Anthropology research in Laos, conducted in immersion with local populations, has revealed and taught us much about the various perspectives on biological phenomena like the transmission of diseases from humans to animals and from domestic to wild animals. One of the roles of a social science researcher, in this case an anthropologist, is to apply knowledge gained in the field to mediate between scientists, decision-makers, and local populations. In this case the research can be applied with the two-fold aim of improving public health and conserving biodiversity while contributing to local development.

***

# Research Ethics in Health and Social Sciences: Unpacking Key Issues and Controversies from Field Study Experience in South China

**Évelyne MICOLLIER**[*]

Principles and ethical rules in the humanities and social sciences are basically drawn from research ethics in biomedical sciences[1] and from a North-American globalized approach of good practices.[2] Unsurprisingly this genealogy raises epistemological and practical issues in actual local situations. For instance, obtaining informed consent from research participants is a vital procedure covered in all good practices guidelines. However, applying them in specific contexts may prove difficult.

In China and in the Mekong region, when shifting from collective principles of behavior to actual practice, the individual may not be able to make a health-related decision when family members play an *active* role in the decision-making process, whether it is to prevent or treat an ailment. These collective principles may contradict international research ethics guidelines, which are based on supposed individual rights, drawn from the individual's legal status. Collective ethical principles, termed ethno-ethics or local ethics when related to the local culture and society, are rooted, both implicitly and explicitly, in local social norms, thought, and lifeworld: these have to be taken into account in the complex negotiation of health care decisions.[3,4]

---

[*] Anthropologist, IRD UMI 233, Inserm 1175, University of Montpellier, IRD Laos, Vientiane

1. Desclaux, A. (2008). L'éthique médicale appliquée aux sciences humaines et sociales : pertinence, limites, enjeux, et ajustements nécessaires. *Bull Soc Pathol Exot*, 101(2), 77–84.
2. Fassin, D. (2008). L'éthique, au-delà de la règle. Réflexions autour d'une enquête ethnographique sur les pratiques de soins en Afrique du Sud. *Sociétés contemporaines*, 71, 117–136.
3. Micollier, É. (2012). Réflexion transculturelle en bioéthique à partir d'une expérience en Chine : construire un cadre théorique et méthodologique pour de futures coopérations de recherche. *Journal international de bioéthique*, 23 (2), 105–116.
4. Desclaux, A., & Sarradon-Eck, A. (2009). Introduction au dossier "L'éthique en anthropologie de la santé : conflits, pratiques, valeur heuristique."

In the Chinese context, these sets of principles are grounded in either scientific, lay, or inherited scholarly knowledge.[5,6]

In 2000s' China, issues related to research ethics first arose in biology and medicine, followed by social sciences and policy research at the institutional level and were openly discussed mainly in academic circles and the news media. Ethics committees designed to review biomedical research on humans and animals that met international recommendations, regulations, and norms insofar as possible, were created in a short period. Although less so than in health research, research ethics issues have also been addressed in the social sciences and in policy research, two closely related fields in China and in most low- and middle-income countries.

Drawn on case studies investigating HIV, reproductive health, gender, and sexuality in multi-ethnic, low income, and mobile living conditions, my experience in China shows that people's vulnerability, culture, and development are closely linked. These links are also acknowledged in Southeast Asia's bordering regions, which share cultural, social, and environmental features with Southwest China. Today, these links are even more salient in times of intensifying cultural and material exchanges and circulation in the Greater Mekong Subregion (GMS). The GMS draws its name from a development project initiated by the Asian Development Bank (ADB) in 1992 to promote closer economic regional integration; approximately 326 million people live across this natural area bound together by the Mekong River. China's Guangxi (bordering Vietnam) and Yunnan (bordering Lao PDR and Myanmar) provinces are part of the GMS.

In Southwest China, the two GMS provinces, along with Hainan Island province, share many cultural, linguistic, and economic features with Southeast Asian countries. For example, the social dynamics specific to trans-border exchanges and inter-ethnic relations demonstrate one reason why linking China and the Association of Southeast Asian Nations (ASEAN) in the GSM project produces a consistent regional perspective. Based on self-declared ethnic affiliation, some 55 "official" ethnic groups account for approximately 8.49% of Mainland China's total population (over 1.3 billion).[7] Yunnan is the most diverse province in terms of ethnic identities, with at least 25 registered groups. Its ecosystem diversity boasts landscapes

---

*Ethnographiques* 17. http://www.ethnographiques.org/2008/Desclaux-Sarradon-Eck

[5] Micollier, É. (2015). Medical ethics and therapeutic knowledge from China: contested knowledge in times of globalization? *Chiang Mai University Journal of Humanities and Social Sciences,* 2(2), 91–101.

[6] Micollier, É. (2015). (Ethno-)medical ethics in globalizing China: tracing local knowledge and adaptation of biomedicine. *Journal international de bioéthique,* 26(4), 101–116.

[7] National Bureau of Statistics of China. (2010) The Sixth National Population Census of the People's Republic of China, 第六次全国人口普查. Beijing.

ranging from tropical plains to the high mountains near Tibet, the source of the Mekong River. In the two GMS provinces, the Zhuang, a large Thai group from Guangxi, account for 16 million, currently the most numerous minority group in China, while the Miao (called Hmong in Southeast Asia,) account for 9 million. The Thai people, all groups included, and the Hmong people are well represented in the Mekong region; and the Dai, another Thai group (called Tai Lüe in Southeast Asia) account for one million. Guangxi and Yunnan are still poor Chinese provinces with socio-demographic data showing living standards below the national average. These specificities partly explain transnational mobilities; migrations are a key factor for macro- and micro-social analysis of living conditions and social dynamics in this region, considered as a highly diverse though relatively integrated territory sharing common features including its diversity and spreading beyond the borders of nation-states. This region reveals an ethnic mosaic and a natural heritage including various ecosystems.

## Medical research ethics in China: issues and controversies[8]

Current Chinese guidelines and regulations show similarities and differences with international regulations in terms of principles.[9] However, when implementing studies, the situation must be investigated case by case, and the situation may diverge from one research site to another.

The early 2000s saw a surge in the establishment of ethics committees, primarily to promote international-level research in partnership with foreign research institutes. These committees were designed to provide research ethics clearance at local, provincial, and national levels for scientific research projects. However, some key guidelines were not followed. For instance, many committee members did not grasp the concept that independent expertise must exclude conflicts of interest. For example, hospital directors were often the presidents of the newly created committees. Issues related to the ethical governance of national ethics committees, specifically the management of interactions between committees at various administrative levels such as universities or hospitals, were neglected. Accordingly, the committees' legitimacy and authority were problematic: Qiu Renzong, an ethicist and philosopher of science, referred to them as "cosmetic committees."

In the context of *biomedical research with human subjects*, patients hardly differentiate between clinical treatment and clinical research trials.

---

[8] Project on Ethics in Research, Treatment and Care, Center for Bioethics, Department of Humanities and Social Sciences, IRD UMI 233/PUMC (Peking Union Medical College)-CAMS (Chinese Academy of Medical Sciences), Tsinghua University, Beijing, 2009–2011, Micollier, É., & Zhai, X. M., Principal Investigators.

[9] See the main Chinese Guidelines and Regulations (translated from Chinese) (2009). *China-UK CURE Committee Report.* Appendix I, 45–51.

The risks and benefits of participating in a trial have not been properly explained to them. In most observed situations, the patient cannot provide genuine "informed consent": he or she usually lacks consistent information about the associated risks while "choosing" to participate in a trial involving an innovative treatment instead of one that has already been tested and approved. Hence, actors working in research and health institutions compromise on the issue of *therapeutic misconception* since they are aware of their failure to provide sufficient information to the patient. They frequently claim that some patients cannot understand their explanations about available treatments. This jeopardizes the funding principle in research ethics, which depends on the patient's correct assessment of the risk/benefit balance.

There is no clear line between adapting a well-known clinical treatment and testing an innovative one. This poses a confusion for the patient at the cognitive level. Furthermore, it may serve the interests of various actors, particularly those in low-income countries, who are more specialized and skilled than most patients, namely academic researchers, clinicians, officials, and actors from private laboratories and pharmaceutical companies.[10]

Poor training of health personnel was also part of the problem. However, there has been greater discussion on the necessity for research planning to respond more appropriately to local needs. The debate surrounding public health policies when choosing between policies that genuinely benefit patients and those that reflect positively on a State that is engaged in international research unveils diverging voices among healthcare providers, research staff, and officials.[11] Choosing between a study on the development of an HIV vaccine versus increasing the quality of and access to HIV treatment and care is a paradigmatic example of such ongoing controversies.[12] Basic research development for innovative treatments could be detrimental to clinical research that aims to optimize adaptation of current treatments.[13]

The issue of *biomedical research with animals* was raised in the late 2000s with some questions addressed in international conferences and in the context of booming research cooperation between China and foreign countries in biology and medicine. Did the research questions and therapeutic perspectives justify developing the experimental process with animals? From an ethical lens, this is the key question: it should be clearly

---

10. Micollier, É. (2012). *Op. cit.*
11. Micollier, É. (2012). *Op. cit*.
12. Micollier, É. (2009). Management of the AIDS epidemic and local/global use of Chinese medicine: treatment and research issues. *China Perspectives*, 77, 67–78.
13. Micollier, É. (2009). Experimenting on innovative scientific vs traditional treatments: the case of AIDS medical research in China. In C. Glymour & Wei Wang, D. Westerstahl (Eds.), *Logic, methodology and philosophy of science* (pp. 639–644). University of London, King's College.

raised before implementing any research protocol including experimenting with animals.

The debate on the relevant social and cultural factors influences the ethics of animal research. This debate addresses the local lifeworld underlying the concept of animal, life, and of its position in the universe, and has far-reaching consequences for knowledge production in ethno-sciences and in life sciences. Moreover, it also focuses on changing perceptions of relations and inter-relations between animals, humans, and the environment; the transition from rural to urban societies; social movements for animal welfare and environmental protection; and the overall ethical governance process involving a whole range of stakeholders.

## Reproductive and sexual health in Southwest China

In the 1990s, long before the HIV and AIDS National Program was launched in 2004, the Yunnan provincial government[14] designed and implemented specific policies, such as targeting vulnerable groups that were either socially or ethnically marginalized. Health personnel, students, and volunteers were trained in Thailand; academic exchanges and exchanges between civilian and official actors were encouraged. Research projects brought together officials, academic institutions, local social organizations, international non-governmental organizations, and foundations. The Yunnan provincial government, Kunming Medical University, and the Ford Foundation became partners in a long-term comprehensive research program in reproductive health. Teams conducted research about family planning issues, contraception and childbirth methods in a multi-ethnic context, youth vulnerability to sexually transmitted infections (STIs), access to health facilities, and treatment acceptance. Based on the results, several policies were redesigned to better consider local specificities.

Following the gradual implementation of the national HIV program, national policies to improve access to family planning services were revised at the central level. The former policy scheme only covered people who were engaged or already married and registered in their municipalities and therefore excluded teen-agers, unmarried individuals, and mobile populations. According to field studies[15] in Beihai, a coastal town in Guangxi province, “beach girls” who provide erotic and sexual services on the beach, including many Vietnamese women, could not receive family planning and STI/HIV-related services. The same situation occurred in the central

---

[14] In the 1990s, Yunnan province went through a dramatic HIV epidemic outbreak. The majority of people living with HIV in China were reported as living in this province, with most of them in poor, rural, and border districts.

[15] Studies on STIs (including HIV) and gendered youth vulnerability in Guangxi and Hainan province, Social Sciences Program (2006–2011), IRD UMI 233-PUMC-CAMS, Tsinghua University, Beijing, Micollier, E. & Liao, S. S., Principal investigators.

province of Hainan Island in mountainous multi-ethnic districts populated by Li (an ethnic Thai group), Miao-Yao, and ethnic Chinese people. The same study acknowledged the HIV vulnerability of teen-aged and unmarried young Li women. Premarital sexual relations and sex work are widespread. Premarital sex among teenagers or young adults from neighboring villages is practiced as a ritualized prelude to courtship in order to select an appropriate marriage partner. In this cultural context coupled with booming economic development, a new social condition emerged for many young women and their families seeking economic opportunities. Hainan Island became a province in 1988 and was granted the privileged status of "Special Economic Zone." Consequently, numerous young women migrated to beach towns or the capital city, Haikou, and entered the sex industry.

## Concluding remarks: a quiz on ethical issues

### *a) What are the main ethical issues in medical research?*

Our experience in the South of China highlights the following points: independent expertise is in demand, ethics committees have not established legitimacy, and patients are easily confused about the difference between clinical treatment and research trials. Higher quality and widespread access to common treatment for more patients may be a better option than the development of cutting-edge research.

In medical research development, a *pragmatic adaptation* of research and administrative institutions has been observed over the years: ethics committees to review protocols designed to comply with international recommendations emerged in a *short time* and with *insufficient human resources and poorly trained staff*. Within the framework of the *research context* in China, civilian voices are rarely heard and their agency is very limited. Subsequent tensions are related to conflicting national and global economic interests, either public, private, or mixed. These include economic constraints, such as the case of vulnerable individuals who have no other choice than to register as research subjects. These people are usually excluded from local regular health care services due to poverty and/or mobile living conditions.

### *b) What ethical issues are related to biomedical research with animals?*

*Firstly*, the main issue concerns the relevance of the research question and therapeutic prospects: do they warrant experimenting on animals?

*Secondly*, the animal's suffering and living conditions in the laboratory context should be taken into account in all phases of the experimental process.

### *c) What are the main ethical issues regarding policy and governance?*

Reproductive and sexual health in South-China was detailed as an example.

Local cultural and socio-economic conditions need to be accounted for as a whole. Policy changes ignite tensions and invite negotiations at the local, national, or international levels, unveiling ethical implications that must be tackled. As we observed, the implementation of these changes was very uneven. Moreover, it should be monitored in context at each administrative level. In some cases, health officials and personnel were not even informed that an ethical review was required. As pointed out in this article, social, ethnic, or age-related vulnerabilities—involving both cultural context and socio-economic conditions—need to be unpacked in order to frame an appropriate project, along with a policy designed to monitor the intervention phase.

* * *

# *Conclusion*

# Using this Guide

## Anne Marie MOULIN[*]

The existence of so many texts on ethics, like those mentionned at the end of the book, might tempt us to believe that everything has been accounted for, so all that remains for a student or researcher is to mechanically apply the protocols using a checklist, like pilots before a flight or surgeons before a procedure. However, no manual or guideline can provide for every possibility, so researchers must rely on their own sensibilities and culture when deciding what methods to use and how to interpret their results. For example, Article 37 of the 2015 Lao Health Care Law states that professionals must listen to patients' opinions, suggestions, and decisions. This is both laudable and revolutionary, yet is of course more a guideline than an enforceable requirement, and remains to be proven in practice. The doctor-patient relationship is not a relationship between equals in any country; the passage of this law should be interpreted as indicating the need for two-way communication in a common language understood by everyone concerned, which itself remains somewhat elusive.

We decided to call this book *The Paths of Ethics in Research* to indicate our desire to guide the reader along paths that may branch off in different directions, or others that may not yet be laid out. The purpose is to instruct, using illustrative scenarios and situations that require the reader to engage in ethical reflection. The goal is to inspire, not compel, such reflection.

In other words, like a textbook, the teachers and students who use this volume must discuss it, comment on it, and even mark it up if they see fit.

Written as a partnership between researchers in the Mekong region and elsewhere, it suggests a dialogue, with Buddhism for example, taking a long-term view of human destiny. Buddhism views sentient beings with cool distance as a combination of physical and mental elements that exist as temporary, discontinuous forms. Transient beings who believe themselves to be permanent, we are like bursts of fireworks that think they are true sources of light. This coolness, which requires monks and renunciants to

---

[*] Philosopher, Physician, Director Emeritus of Research at the CNRS (UMR SPHERE), Chair of the IRD Advisory Committee on Deontology and Ethics, France.

withdraw from productive society, is balanced by the compassion that is required from us all by the spectacle of beings, steered by their desires, committing acts (*karma*) that stupidly keep them mired in unhappiness and suffering. Observing the workings of karma can itself be an invitation to continually check our ethical compass.

In engaging in varying degrees of ethical reflection and then comparing our findings between countries, we are limited by mutual ignorance of our intellectual resources, beliefs, and experiences. In our so-called global world, information and people circulate with previously unimaginable speed, yet communication remains chaotic and unequal. Some have called it a Babel world, alluding to the Bible passage in which an ambitious king constructs the Tower of Babel in an attempt to reach heaven. As punishment for this impudence, God destroyed the tower and scattered the people so they no longer understood each other, leading to disaster and war. Many cultures have mythic tales describing a similar curse to explain the difficulty of communicating, rather than appreciating the wealth of languages and cultures that surround us all. Social sciences address this challenge head-on, further testament to their ethical vocation as described herein.

This book is merely a springboard—a project more than a manual—to be translated into Lao and other languages so that it can be further discussed and enriched by research experiences around the world.

* * *

# Postface

## Paul BREY*

There was a time, not so long ago, when ethical assessments of biomedical research in developing countries, like Lao PDR, were largely ignored or at most considered a necessary "ill" to get people to sign a consent form to obtain their biological sample. Often times subjects involved in biomedical research protocols were not treated as autonomous individuals, and getting a "signature" for the group from the village head was a means to an end. We all have heard of studies being carried out without a rigorous evaluation of subject respect, beneficence, or justice during research projects. However, over the past decades and especially during the past 10 years the situation has tremendously improved with the creation or reinforcement of National Research Ethics Review Committees. These committees have greatly ameliorated the requirements and standards to guarantee as best as possible the protection of participants. Furthermore, the generalized setting-up of Institutional Review Boards (IRBs) within research institutions locally and in developed countries carrying out biomedical research in developing countries, such as Laos, have provided an additional analysis to improve research protocols from an ethical point of view prior to submission to the National Committees. The various presentations and abstracts presented in this Pedagogical Manual following the colloquium on *Ethics in research in health, environment, and social sciences* held in October 2015 sponsored by the Institut de Recherche pour le Développement (IRD) and the University of Health Sciences (UHS) in Vientiane, Laos, underline the vast progress made and provide concrete examples of case situations to guide others, including students, to structure their research protocols in the most ethical way possible. Furthermore, the international nature of a colloquium with participants from Lao PDR, France, Vietnam, United Kingdom, Brazil, Switzerland, etc. also emphasizes the need to work together on ethical issues facing medicine and biomedical research as this multicultural approach brings greater depth and clarity of the issues at hand. Hopefully the colloquium on *Ethics in research in health, environment, and social sciences* will set the example for other colloquiums like this and could spawn new initiatives in the region.

Even though the examples in this manual serve as a useful guide, challenges remain in finding the most ethical way to carry out biomedical

---

* Entomologist, Director of Institut Pasteur of Laos.

research in Lao PDR and other developing countries, especially in remote areas. Perhaps at the forefront is the over emphasis placed on the "signing" of a consent form rather than on the extensive exchange of information and clearest possible understanding between the researcher and potential participants. If the study objectives, design, and protocol information are properly explained using an understandable vocabulary, the volunteer can assign his or her consent to participate in the study fully understanding what they are consenting to. Hence, information should be culturally adjusted to include local factors, such as degrees of literacy, native dialects of ethnic minorities, and a suitable vocabulary to express complex investigative concepts. Furthermore, in some communities there is a preference for communal decision-making rather than individual decision-making, so this too needs to be taken into consideration to avoid misunderstanding or stigmatization. The researcher needs to work with local authorities and village heads or leaders (school teachers, elders, women's union members, etc.) and spiritual leaders to find the way to best communicate: (1) why the researcher needs their biological samples; (2) what the sample will be used for; (3) what information can be derived from the sample; and (4) what is the benefit or useful information that will come back to the volunteer sample donor or his or her community. Indeed, multiple visits and interactions with the community of future study participants, to explain these above-mentioned points, increase their understanding and lead to a more "fully" informed consent.

Another area that was highlighted in the colloquium was a new and emerging domain of environmental ethics that also has repercussions in social sciences. This subject area takes on special importance in the developing world where hydro-electric dam projects, mining, logging, land clearance for mass monocultures, etc. are driven strongly by economic forces. Governments often agree to these sometimes-controversial projects because they need to raise country GDP and provide employment; furthermore, such projects can also bring attractive revenue and incentives to cash strapped economies. Environmental impact statements are becoming requisite for such projects but, more often than not, important ethical and related societal issues are still not sufficiently considered with regard to these projects. Sometimes these environmental projects can adversely affect the welfare and livelihood of local populations by introducing new vector-borne diseases, modifying land use so farmers can no longer grow crops to assure the food security of their villages, bringing unwanted pesticides into the environment, etc. These are indeed complex issues because development projects are necessary to boost economies, but this needs to be balanced with an ethically viable approach with regard to the welfare and livelihoods of local populations in the long term.

As mentioned, the colloquium was aimed at a very wide range of researchers, but also students, who very actively participated in discussions and breakout sessions. This student participation should be considered an investment in the future, as these students will grow to be the leaders in medicine and in biomedical, environmental, and social sciences research in Lao PDR and will remember this colloquium and the important messages conveyed there. This manual will serve as an excellent long-lasting guide for their future work. Finally, this colloquium attests that Lao PDR has become a regional leader in ethics for research in health, environment, and social sciences, which is indeed a necessary and just endeavor.

* * *

# Selection of Key Texts on Ethics and Deontology in France and Worldwide

Marie BAUDRY de VAUX*

## Major International Documents

• The ***Nuremberg Code*** is a list of 10 criteria formulated during the Nuremberg Doctor's Trial (1946–1947). These criteria identify the conditions that must be met when experimenting on human subjects in order for the research to be considered "acceptable."
https://en.wikipedia.org/wiki/Nuremberg_Code
The Nuremberg Code, 1947:
The *Nuremberg Code* in English is accessible at:
https://history.nih.gov/research/downloads/nuremberg.pdf
The *Nuremberg Code* in French is accessible at:
http://www.frqs.gouv.qc.ca/documents/10191/186011/Code_Nuremberg_1947.pdf/d29861b8-30a7-456e-9a83-508f14f4e6d5

• The ***Belmont Report*** is considered the foundation of medical ethics. This report, published in 1979 by the United States Department of Health, Education, and Social Services advocates for respect for persons, beneficence, and justice as fundamental principles when conducting ethical research on human beings.
The report identifies the three fundamental ethical principles: respect for persons through their free and informed consent, an assessment of risks-benefits related to the research, and justice to ensure fair selection of research subjects.
***Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.*** Issued on 30 September 1978, published in 1979:
The Belmont Report in English is accessible at:
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
The Belmont Report in French is accessible at:
http://www.frqsc.gouv.qc.ca/documents/10191/186011/Rapport_Belmont_1974.pdf/511806ff-69c4-4520-a8f8-7d7f432a47ff

---

* Chargée de Mission, Advisory Committee on Deontology and Ethics at the Institut de Recherche pour le Développement.

- The ***Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine***, known as the "***Oviedo Convention***," dated 4 April 1997, entered into force on 1 December 1999, was ratified by 29 countries in 2017.

This convention is the only binding international legal instrument to protect the rights and freedoms of human beings from any misuse of innovations in biomedicine.

This document is a framework convention aimed at protecting the dignity and identity of all human beings and guaranteeing "everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."

The Oviedo Convention is supplemented by four additional protocols:

- Additional Protocol on the Prohibition of Cloning Human Beings
- Additional Protocol concerning Transplantation of Organs and Tissues of Human Origin
- Additional Protocol concerning Biomedical Research
- Additional Protocol concerning Genetic Testing for Health Purposes

*The **Oviedo Convention*** in English:
https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98
*The **Oviedo Convention*** in French:
https://www.coe.int/fr/web/conventions/full-list/-/conventions/rms/090000168007cf99

## World Medical Association (WMA)

Since its founding in 1947, the WMA aims to establish and promote the highest standards of ethical behavior and care by physicians. Four major declarations have been published under the auspices of the WMA.

- The ***Declaration* of *Helsinki*** of the World Medical Association provides guidelines for medical research on humans. It aims to promote ethical conduct in clinical research and to protect human subjects from associated risks. *The Declaration of Helsinki* provided, for the first time, a series of guidelines for research at the international level that requires research participants to provide *informed consent*.

***Declaration of Helsinki: International Ethical Guidelines for Biomedical Research Involving Human Subjects****.* Developed by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), adopted by the 18th WMA General Assembly, Helsinki, June 1964, amended by the 29th WMA General Assembly, Tokyo, October 1975; the 35th, Venice, October 1983; the 41st, Hong Kong, September 1989; the 48th, Somerset West, October 1996; the 52nd, Edinburgh, October 2000; the 53rd, Washington, DC, October 2002

(1st Note of Clarification); the 55th, Tokyo, October 2004 (2nd Note of Clarification); the 59th, Seoul, October 2008; and the 64th, Fortaleza, October 2013.
In French: https://www.wma.net/fr/ce-que-nous-faisons/ethique/declaration-dhelsinki/
In English: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

- The ***Declaration of Taipei*** addresses ***Ethical Considerations Regarding Health Databases and Biobanks***:
French version: https://www.wma.net/fr/policies-post/declaration-de-lamm-sur-les-considerations-ethiques-concernant-les-bases-de-donnees-de-sante-et-les-biobanques/
English version: https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/

- The ***Declaration of Geneva*** or "***The Physician's Pledge***" was adopted in Geneva in 1947. It is based on the same principles as the Hippocratic Oath and is considered a modern version of that famous—albeit obsolete—pledge.
The French version can be consulted at:
https://www.wma.net/fr/policies-post/declaration-de-geneve/
And the English version at:
ttps://www.wma.net/policies-post/wma-declaration-of-geneva/

- The ***Declaration of Tokyo*** on the guidelines for physicians to prevent torture (last revision in 2016)
In French: https://www.wma.net/fr/policies-post/declaration-de-tokyo-de-lamm-directives-a-lintention-des-medecins-en-ce-qui-concerne-la-torture-et-autres-peines-ou-traitements-cruels-inhumains-ou-degradants-en-relation-avec-la-detention-ou-l/
In English: https://www.wma.net/policies-post/wma-declaration-of-tokyo-guidelines-for-physicians-concerning-torture-and-other-cruel-inhuman-or-degrading-treatment-or-punishment-in-relation-to-detention-and-imprisonment/

## WHO

- ***WHO Guidelines on Ethical Issues in Public Health Surveillance, published in 2017:***
French version:
https://www.wma.net/fr/policies-post/declaration-de-geneve/
English version:
https://www.wma.net/policies-post/wma-declaration-of-geneva/

• ***International Ethical Guidelines for Health-related Research Involving Humans***, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva, 2016
In English: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
In French: https://cioms.ch/shop/product/lignes-directrices-internationales-dethique-pour-la-recherche-en-matiere-de-sante-impliquant-des-participants-humains/

• ***Module for Teaching of Medical Ethics to Undergraduates***, published by WHO. The English version can be consulted at:
http://www.searo.who.int/entity/human_resources/documents/Module_Medical_Ethics/en/

• ***Facilitators' Guide for Teaching Medical Ethics to Undergraduate Students in Medical Colleges in the South-East Asia Region***
English version: http://apps.searo.who.int/PDS_DOCS/B4477.pdf

## UNESCO

• ***Universal Declaration on Bioethics and Human Rights***, adopted by UNESCO in 2005:
The French version can be consulted at:
http://www.unesco.org/new/fr/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/
And the English version can be consulted at:
http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/

• The ***Recommendation on Science and Scientific Researchers***, adopted by the General Conference of UNESCO, meeting in Paris on 13 November 2017. The online French and English versions can be consulted at:
http://www.unesco.org/new/fr/social-and-human-sciences/themes/bioethics/1974-recommendation/
http://unesdoc.unesco.org/images/0025/002592/259256e.pdf

## National and international charters

• The ***French National Charter for Research Integrity*** was signed on 29 January 2015 in Paris by universities and major French research organizations (CNRS, Inserm, Inra, Inria, IRD, Cirad, and Institut Curie).
The charter is accessible in French and English at the IRD website:
http://www.ird.fr/l-ird/ethique-et-parite/ethique/charte-des-metiers-de-la-recherche-janvier-2015

This charter is a national version of the main international texts in this area: the ***European Charter for Researchers*** (2005); the ***Singapore Statement on Research Integrity*** (2010); and the ***European Code of Conduct for Research Integrity*** (ESF-ALLEA, 2017). The charter is part of the European HORIZON 2020 - Framework Programme for Research and Innovation. These international texts can be consulted online:

• The ***European Charter for Researchers and Code of Conduct for the Recruitment of Researchers*** (2005)
In French:
https://cdn2.euraxess.org/sites/default/files/brochures/eur_21620_en-fr.pdf
In English:
https://euraxess.ec.europa.eu/sites/default/files/am509774cee_en_e4.pdf

• The **Singapore Statement on Research Integrity** (2010)
In English:
http://www.singaporestatement.org/
In French:
http://www.cnrs.fr/comets/IMG/pdf/121030-singapour.pdf

• The ***European Code of Conduct for Research Integrity (2017)***
Available only in English:
https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

• The *Ethics Charter for Research in Developing Countries*, published in 2002, by the l’Agence nationale de la recherche sur le sida, revised in 2008 and in 2017 by the ANRS (France Recherche Nord & sud Sida-hiv hépatites),
In French:
http://www.anrs.fr/sites/default/files/2017-07/charte%20e%CC%81thique%20F%202017.BD-1.pdf
In English:
http://www.anrs.fr/sites/default/files/2017-07/charte%20e%CC%81thique%20A%202017.BD__0.pdf

• The ***Charte de l’Éthique des Facultés de Médecine d’expression française*** [French Ethics Charter for Faculties of Medicine], published by the Conférence Internationale des Doyens et des Facultés de Médecine d’Expression Française [International Conference of Deans of French-Speaking Faculties of Medicine] (CIDMEF) in 2012:
http://www.cidmef.u-bordeaux2.fr/sites/cidmef/files/ethic_fr.pdf

• The ***Charte éthique*** [Ethics Charter], published in 2012 by the ***Institut Pasteur***: https://www.pasteur.fr/fr/file/2625/download?token=BoPhwjAF

- ***Guidelines for Good Clinical Practice***, published in 1996 by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

“Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.”
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

## Access and benefit sharing (ABS)

- The ***Nagoya Protocol*** on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity, published in 2012 by the Secretariat of the Convention on Biological Diversity of the United Nations Environmental Programme.

The full version of the protocol and its annex is available:
In French:
https://www.cbd.int/abs/doc/protocol/nagoya-protocol-fr.pdf
And in English:
https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

For the ***Background Document*** on the implementation of the Nagoya Protocol on access and benefit-sharing provisions in the European Union, commissioned by the French Ministry of Higher Education and Research, through the Fondation pour la Recherche sur la Biodiversité, with input from Cirad, CNRS, Ifremer, Institut Pasteur, IRD, INRA, and MNHN, published in November 2015, see:
Entrée en vigueur de la règlementation européenne sur les activités de recherche et de développement sur les ressources génétiques et les connaissances traditionnelles [Entry into force of the European regulation on research and development activities on genetic resources and traditional knowledge]:
http://www.fondationbiodiversite.fr/images/documents/APA/Note_FRB_reglement_EU.pdf

***

# Contributors

**Paul BREY,** PhD, is a Medical Entomologist and has worked at the Institut Pasteur for 36 years, specializing in insect immunity and host–parasite interactions. Brey was also involved in the *Anopheles gambiae* genome project. Since 2008, Paul Brey has been Director General and Head of the Medical Entomology Lab of the Institut Pasteur of Laos in Vientiane.

**Audrey DUBOT PERES** is a virologist at IRD working on the emergence of viral diseases, UMR190, at the Faculty of Medicine in Marseille. Since 2008, she has been supervising the virology team at LOMWRU (Laos – Oxford – Mahosot – Wellcome Research unit), within the Microbiology Laboratory of Mahosot Hospital, Vientiane, Laos. Her main activities consist of training for technical and research staff, supporting medical diagnosis, and conducting research projects on central nervous system infections, dengue fever, enterovirus disease, and respiratory infections.

**Guillaume DUTEURTRE** is a researcher working for CIRAD (France). He holds a Master's degree and a PhD in agro-economics, and is currently posted in the SELMET Joint Research Unit in Montpellier (France). For about 20 years, he has been in charge of conducting research projects on animal products marketing and livestock development policies in various African and Asian countries. From 2009 to 2015, he was posted in Vietnam, were he coordinated research projects in partnership with other research institutions and development partners.

**Louis GABAUDE**, Professor Emeritus at the École Française d'Extrême-Orient, studied the history of Buddhist ideas in Thailand and now lives in Chiang Mai. His articles can be found at: https://efeo.academia.edu/LouisGabaude. A recent interview is available at: http://www.viverealtrimenti.com/glimpses-of-theravada-buddhism-interview-to-louis-gabaude/

**Pascale HANCART PETITET**, MSC PhD, is an anthropologist and research scientist at IRD (International Research Unit UMI 233, INSERM U 1175: Local Cultures and Global Health Team, University of Montpellier I). She is the IRD representative in Laos, and has been assigned at the IRD office in Laos since 2013. She conducts research that documents the intersections of human reproduction politics, policies, and history; global flows of medical technologies; and social forms and outcomes of inequalities (India, Cambodia, Laos). More recently she has conducted a new multidisciplinary research program on migration paths in Laos.

**Damien HAUSWIRTH** is a tropical agronomist. He holds a PhD in ecosystems and agronomy at the University of Montpellier (France). As a member of the "Climate Resilience and Ecological Intensification of Agroecosystems in the Sahel" initiative, he is currently based at AGRHYMET regional center (Niamey, Niger). He has worked on sustainability of agricultural systems in French Guyana and Chad and later in Northern Vietnam. His research has included the design and assessment of conservation agriculture cropping systems in the mountainous regions of Northern Vietnam for five years.

**Damien JOURDAIN** has a degree in Agricultural Science and a PhD in Agricultural, Agro-Food, and Rural Development Economics at the University of Montpellier (France). He is currently a researcher in Natural and Agricultural Resources Economics (UMR Water Management, Utilities, and Actors, CIRAD) and is seconded to the University of Pretoria (GovInn/CEEPA). His research themes focus on economic and institutional instruments leading to more sustainable agriculture. He has worked in collaboration with research and teaching institutions in Thailand, Mexico, Vietnam, and South Africa.

**Gonzague JOURDAIN**, MD, PhD, is a medical epidemiologist trained in France and the director of the PHPT Clinical Research Unit in Thailand, currently focusing on HBV- and HIV-related public health issues.

**Cheeraya KANABKAEW** was a research nurse at the IRD174/PHPT unit in Chiang Mai, Thailand. She holds a Master's degree in Community Medicine from Chiang Mai University. She was the coordinator of the TEEWA study (Teens Living with Antiretrovirals) on adolescents born with HIV in Thailand.

**Woottichai KHAMDUANG**, PhD, is a virologist, lecturer at the Faculty of Associated Medical Sciences, Chiang Mai University (CMU), Thailand who earned his PhD degree at University of Tours and CMU. His research investigates HBV prevention and transmission.

**Nicolas LAINÉ** holds a PhD in Ethnology from University of Paris West (2014). He is affiliated with the Laboratoire d'anthropologie sociale (Paris). Specializing in human-animal relations, his research is at the crossroads of the anthropology of nature and conservation. He has published several articles on the human/elephant interspecies community in South and Southeast Asia, and has co-edited the collective volume *Nature, Environment and Society* (2012). Nicolas Lainé is currently pursuing his research interest on the issues of health and environment, and the relationship between biodiversity and cultural diversity.

**Claire LAJAUNIE** is a legal researcher who investigates the relationships between biodiversity and health through the study of Global Environmental Law, multi-level governance, and related ethical issues. She is currently involved in research projects in this area, focusing on Southeast Asia (PI of the ANR project, Future Health SEA (2017–2021) with Serge Morand, CNRS).

**Vatthanaphone LATTHAPHASAVANG**, MD, is a physician at Mahosot Hospital, Vientiane. She was trained in Medicine and Infectious Disease in Vientiane and Paris, and in Public Health in Brussels. She is currently a PhD candidate at University of Lyon 1, France.

**Sophie LE CŒUR** is a medical doctor and epidemiologist. She is a Senior Researcher at the Institut national d'études démographiques (INED) in France and a Visiting Scientist at the Harvard TH Chan School of Public Health in the United States. Her research investigated the epidemiology of mother-to-child transmission of HIV. She is currently the principal investigator of a study in Thailand on the situation of adolescents born with HIV and their outcomes as they enter into adulthood (funded by Sidaction, France).

**Éva LELIEVRE,** PhD is a senior researcher at the Institut national d'études démographiques (INED) in France, where she has coordinated the activities of the Working Group on Life Event History Approach (GRAB) since its creation. Her field of expertise covers the dynamics of individual trajectories, intergenerational relationships, and family networks, with a special interest in the interactions that play out in the course of individuals' lives between family, work, residential mobility, and health.

**Tereza MACIEL LYRA**, MD, PhD in Public Health, is a researcher at the Aggeu Magalhaes Institute (IAM), (Fiocruz Pernambuco), Brazil and a professor at the University of Pernambuco. As a member of the CCDE, she coordinated the symposium "Health, Ethics and Sustainable Development: Challenges for a World in Crisis," co-organized with the CCDE in Recife, Brazil, in May 2013. She is the local coordinator of research on the socioeconomic impacts of the Zika epidemic on the lives of women (general coordination of the London School).

**Khamphan MAHAVONGSAVAN** graduated in accounting and French from the National University of Laos and the University of Paris Sorbonne. In 2000 he founded the Elephant Lodge in Hongsa, the first institution dedicated to elephant tourism in the district. In 2008, he became director and site manager at Pakbeng Lodge, and then at the Elephant Conservation Center (Nam Tien, Xagnabouli, Laos). Since 2015, he has been a research-assistant to Nicolas Lainé during his ethnographic missions on local knowledge related to the domestication of elephants.

**Oumarou MALAM ISSA** is a university Professor of Geosciences and has been an IRD representative in Niger since 1 January 2013. On 1 June 2017, he joined IRD as a senior soil scientist and member of UMR 242 iEES Paris on ecology and environmental sciences. He is a member of the CCDE of IRD. His main research topic is related to soil surface structure evolution and its origin. He has experience in biological soil crusts and their impacts on water/wind erosion and infiltration.

**Mayfong MAYXAY**, M.D., PhD, is an Associate Professor in Infectious Diseases and Tropical Medicine, the Vice-Dean for Research, and the President of the Research Promotion and Management Committee at the University of Health Sciences (UHS), Ministry of Health, Vientiane, Laos. He is the founder of the first Lao ethics committee for health research in the former Faculty of Medical Sciences, National University of Laos (currently UHS).

**Évelyne MICOLLIER**, PhD, social anthropologist at IRD since 2004, ran a research programme in Beijing and South-China (IRD-Peking Union Medical College/Chinese Academy of Medical Sciences partnership/Tsinghua University, 2006–2011) conducting medical research in Chinese medicine; research ethics; global health; issues related to gender and sexuality, governance in the context of HIV risk, and the surge of basic research and R&D in China. Stationed in Vientiane (2013–2017), she is developing projects in Lao PDR and Southeast Asia, and in the Chinese cultural sphere outside China.

**Anne Marie MOULIN** is the Director Emeritus of Research at CNRS (SPHERE Unit Paris 7) and has been the Chair of the Advisory Committee on Deontology and Ethics for the IRD since 2013. A former student at the École normale supérieure with a degree in philosophy, a physician specialized in tropical diseases, and a former hospital practitioner, Dr. Moulin's professional life has been divided between medicine, philosophy, and the social sciences. She has conducted numerous missions in Africa and in the Arab and Muslim world. From 1999 to 2002 she was the head of the IRD Department of Health and Social Sciences. She has published several works and many articles on the historical, epistemological, and ethical issues involved in international medicine and public health.

**Didier ORANGE** has a degree in Hydrogeology and a PhD in Geochemistry from the University of Strasbourg. He is a researcher in ecohydrology from IRD. He is currently posted in Montpellier in a research unit investigating the functional ecology of agrosystems (Eco&Sols UMR IRD 210) and an associate researcher of the USTH (Water Environment Oceanography Department) in charge of two teaching units (Advanced Hydrology and Ecological Engineering). He previously worked in Senegal, Guinea, Central Africa, Mali, and then 15 years in Vietnam in the Red River Basin. All of his research activities focus on the processes and management of water fluxes and matter fluxes from the watershed to the agro-ecosystem. In particular, he has worked on implementing the concept of Payments for Environmental Services.

**Bansa OUPATHANA** is Deputy Director in charge of Administration and International Cooperation in the Rector's Office of the University of Health Sciences in Vientiane, Lao PDR. He is also Vice Chairman of the Research Ethics Board of the University of Health Sciences and Coordinating Committee with the Agence universitaire de la Francophonie (AUF) in Vientiane. He is a member of the CCDE (2013–2018).

**Phimpha PABORIBOUNE** is the Scientific Director of the Rodolphe Mérieux Laboratory of Laos. She is a graduate of the University of Health Sciences of Laos and was awarded a Master's degree in Tropical Medicine and Epidemiology from the Institut de la Francophonie pour la médecine tropicale (IFMT) in 2005. She has participated in several training programs in laboratory techniques at the Laboratoire des pathogènes émergents in Lyon and at the Christophe Mérieux Center of Molecular Biology and Microsystems in Grenoble. She further studied laboratory techniques in French hospitals specifically for TB (Hôpital Lyon-Sud, Lyon), HIV (Hôpital Saint-Louis, Paris), and parasitology (Hôpital Croix-Rousse, Lyon). She is currently completing her PhD.

**Marie-Geneviève PINSART** is professor of philosophy and ethics at the Free University of Brussels (ULB), Belgium. Since 2005, she has been a member of the Belgian Bioethics Advisory Committee (its chairwoman twice and its vice-chairwomen for six years). In Brussels, she is also Chairwoman of the St-Jean Hospital Committee; member of the Iris Sud Hospital Ethical Committee and of the Federal Commission on medical and scientific research on in vitro embryo. She is an invited expert of the European Commission and of UNESCO. She is a member of the International Bioethics Committee (2016–2019). Marie-Geneviève Pinsart has been a member of the CCDE since October 2016.

**Jean-Daniel RAINHORN** is Professor Emeritus of International Health at the Institut de Hautes Études Internationales et du Développement (IHEID) in Geneva (Switzerland). He served as Director of the Centre de recherche et d'étude pour le développement de la Santé (CREDES) in Paris from 1984 to 1999, and was the head of a program in international health at Paris XI. Dr. Rainhorn was appointed as a professor with several institutions: CERDI (Clermont I); Hanoi University of Public Health (Vietnam); Senghor University of Alexandria, Egypt; and finally Professor of International Health and Humanitarian Action at IHEID, University of Geneva. Dr. Rainhorn was also a Takemi fellow at Harvard University (US) and held the chair of Social Inequalities, Health, and Humanitarian Action at the Collège d'études mondiales de la Maison des sciences de l'Homme in Paris. He is the author of a number of works, articles, and reports about issues of poverty and precarity, social health inequalities, and humanitarian action. He is a member of the CCDE (2013–2018).

**Florence RODHAIN** is a Professor at the University of Montpellier in France and head of MRM-SI. She has published over 180 papers in scientific journals, books, and conference proceedings. She has researched and taught for five years in several countries, including the United States, New Zealand, India, and China. Her main research focus areas are: Sustainable Development, Gender issues, the links between Ecology and Information Technologies, the ethical problems related to Information Systems, etc. Eight of her doctoral students have defended their dissertations (six received a national prize for the high quality of their exemplary dissertations).

**Didier SICARD** is a Professor of Medicine. After receiving his degree in 1973, Dr. Sicard was affiliated with the School of Medicine in Vientiane (Laos) from 1974 to 1978. Upon returning to France in 1978, he was named Associate Professor at the University of Paris Descartes. He served as the Chairman of the Commission consultative nationale de transfusion sanguine from 1989 to 1991, and as Chairman of the Comité Sida Paris Centre from 1990 to 1994. In 1995 he created the ethics section in the Assistance Publique - Hôpitaux de Paris. Dr. Sicard was the Chief of Internal Medicine at the Hôpital Cochin in Paris in 1993, Chair of the French National Consultative Ethics Committee (CCNE) from 1999 to 2008, and Chairman of the Comité d'experts de l'Institut des données de santé from 2008 to 2016.

**Manivanh SOUPHANTHONG**, Dean of Faculty of Basic Sciences, Associate Professor and President of the Research Ethics Committee at the University of Health Sciences of Laos. After completing her Doctorate Degree with Distinction in 1991 from Berlin (Germany), and specialist training in anatomy in 1993 in Berlin, Dr. Souphanthong was appointed as Head of the Department of Medicine at the university in Vientiane, Laos from 1996 to 2009. She was also a member of the University Academic Board in Laos from 1998 to 2009 and an Adjunct Assistant Professor of the University of Cleveland in Ohio for three years. Since 2009 she has been Dean of Basic Sciences in Laos. Dr. Souphanthong teaches anatomy-histology, medical terminology, and scientific research. She is author and co-author of 30 articles for publications and communications. She has written four manuals and has collaborated on seven others.

**Vanphanom SYCHAREUN**, Pediatrician, MPH, PhD, Dean of the Faculty Post-Graduate Studies at the University of Health Sciences in Laos. She obtained her PhD in Public Health from Chulalongkorn University, Thailand in 2005. She has extensive experience teaching research methodology, qualitative research methods, health behavior, and sexual reproductive health at UHS. In 2008 she was the Leadership Course Director for the consortium, which included participants from Cambodia,

China, Lao PDR, Indonesia, Philippines, Thailand, and Vietnam and advocates in the field of gender, sexuality, and health. She has published more than 40 scientific papers that document both the applied and theoretical dimensions of her research.
https://www.researchgate.net/profile/Vanphanom_Sychareun

**Bernard TAVERNE** is an anthropologist and physician, and a research fellow in the International Joint Unit "Recherches translationnelles sur le VIH et les maladies infectieuses" – TransVIHMI (UMI 233 IRD, U 1175 Inserm, University of Montpellier). His work in medical anthropology investigates social responses to HIV and treatment programs for people living with HIV in Burkina Faso (1993 to 1999) and in Senegal (2000 to 2018). Since 2004, his research has also focused on the anthropology of medical research and, since 2014, the Ebola virus epidemic in Conakry, Guinea. He was a member of the National Ethics Committee for Research in Health in Senegal from 2003 to 2006 and a member of the IRD CCDE (2009–2013, 2013–2018).

**Frédéric THOMAS** (IRD, Paloc) is an historian of science and technology, specializing in the history of environment and of the intellectual property rights regarding living forms. Based on the theory of the commons, he studies the various forms of ownership (private, public, and collective) of genetic resources and agrobiodiversity in developing countries. He is currently on assignment in Vietnam at an international laboratory studying the functional genomics approach in rice in Hanoi (IJL Rice, IRD-AGI-Usth).

**Christian VALENTIN**, agronomist by training, PhD in soil science, gained over 40 years' experience in conducting and coordinating interdisciplinary research at ORSTOM and IRD, in soil erosion, agronomy, hydrology, and ecology, mainly in West Africa and Southeast Asia. His publishing credits include more than 100 articles in refereed journals. He is currently Deputy Director of the Institute of Ecology and Environmental Sciences - Paris, and coordinates working groups on soils for the French Alliance for Environment and for the French Academy of Agriculture.

**Manivanh VONGSOUVATH** is a medical doctor, head of the Laboratory of Microbiology at Mahosot Hospital, Vientiane, Laos. She participated in implementing laboratory techniques and staff training to support the diagnostics department at Mahosot Hospital. She graduated with an MSc in Tropical Medicine from Mahidol University, Bangkok, Thailand. Her research topics are infections of the central nervous system, specifically Japanese *e*ncephalitis virus (JEV) and enteroviruses; arboviruses including dengue, chikungunya, and Zika surveillance; and acute respiratory infections.

***

# The Paths of Ethics in Research in Laos and the Mekong Countries

In an historic first, two ethics committees — one from Laos, the other from France — met in Vientiane in October 2015. Researchers examined a multitude of ethical issues related to health, the environment, and societies in countries in the Mekong region. Urgent, universal questions were discussed in local contexts; productive debates illustrated a complex array of possible solutions. This book, born out of that meeting, serves as a guide for those working across the spectrum of scientific fields on paths to promote justice and reduce suffering. Like the Mekong River, the field of research ethics does not run in a straight line; and like that river, everyone it touches discovers that what may initially appear to separate us ultimately serves to bring us together.

Work directed by:

***Anne Marie Moulin*** *philosopher and physician, has been Chair of the Advisory Committee on Deontology and Ethics (CCDE) for the IRD since 2013.*

***Bansa Oupathana*** *physician, has been a member of the CCDE for the IRD since 2013.*

***Manivanh Souphanthong*** *physician, is the President of the Ethical Research Committee of the University of Health Sciences of Laos.*

***Bernard Taverne*** *anthropologist and physician, has been a member of the CCDE for the IRD since 2009.*

Cover photograph: © Louis Gabaude