



LITERATURE REVIEW:

Evolution of Regulatory Governance for Human Research in Costa Rica

Evolución de la gobernanza regulatoria para la investigación con seres humanos en Costa Rica

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ABSTRACT: Regulatory governance of human research derives from historical abuses of people participating in health related and non-health related studies. Costa Rica was no exception and nowadays counts with a Regulatory Law of Biomedical Research (Law 9234) that guarantees the protection of research participants' human rights. The aim of this narrative review is to overview the gradual development and state of the art of protections and oversight of research with humans in Costa Rica. A recapitulation of why regulatory governance for biomedical human research was enacted in 2014 will be discussed. Even so, there is no legal requirement in Costa Rica, as in other developing nations, for non-health related protocols with human participants, to undergo the scrutiny of research boards. Nonetheless, even before Law 9234 was passed, the University of Costa Rica made efforts to compel compliance with research ethics when studying humans. Therefore, another objective is to review the current ethical guidelines dictated by the University of Costa Rica and Scientific Ethics Committee of the University of Costa Rica to conduct responsible human research. The University of Costa Rica's institutional regulatory framework on human research, can serve as a model to other national and international institutions from developing nations, where ethical assessment of sociocultural research is relatively neglected, compared to the review of biomedical and clinical studies.

KEYWORDS: Biomedical research; Ethical guidelines; Ethical review; Human research; Human research ethics; Sociocultural research.



RESUMEN: La gobernanza regulatoria de la investigación en humanos se deriva de abusos históricos a personas que participaron en estudios relacionados y no relacionados con la salud. Costa Rica no fue la excepción, y hoy cuenta con una Ley Reguladora de la Investigación Biomédica (Ley 9234) que garantiza la protección de los derechos humanos de las personas participantes de investigaciones. El objetivo de esta revisión narrativa es recorrer el paulatino desarrollo y el estado del arte, de la protección y supervisión de la investigación con humanos en Costa Rica. Se hará una recapitulación de por qué se promulgó en 2014 una ley para la gobernanza regulatoria de investigación biomédica en humanos. Aun así, no existe ningún requisito legal en Costa Rica, ni en otros países en desarrollo, para que los protocolos no relacionados con la salud con participantes humanos se sometan al escrutinio de comités de ética. Sin embargo, incluso antes de que se aprobara la Ley 9234, la Universidad de Costa Rica hizo esfuerzos para garantizar el cumplimiento de ética en investigación al estudiar seres humanos. Por lo tanto, otro objetivo, es revisar los lineamientos éticos vigentes dictados por la Universidad de Costa Rica y el Comité Ético Científico de la Universidad de Costa Rica para realizar investigaciones responsables en seres humanos. El marco regulatorio institucional de la Universidad de Costa Rica sobre la investigación en seres humanos podría servir de modelo para otras instituciones nacionales e internacionales de países en desarrollo, donde la evaluación ética de la investigación sociocultural está relativamente ignorada, en comparación con la revisión de estudios biomédicos y clínicos.

PALABRAS CLAVE: Investigación biomédica; Lineamientos éticos; Evaluación ética; Investigación en humanos; Ética en investigación con humanos; Investigación sociocultural.

INTRODUCTION

Foreign institutions and transnational pharmaceutical companies have considered Costa Rica an ideal setting to conduct research with human participants. For context, Costa Rica is an upper middle-income and developing country in Central America (1). Most part of the country has access to potable water and electricity. Public and private education are available, and literacy is almost universal. The nation abolished its army in 1949 and since then, national resources are destined to a highly rated and affordable healthcare system, the Costa Rican Social Security Fund (CCSS). Since 1941, the CCSS has been a cornerstone of an effective health care system, of universal coverage. In fact, the Costa Rica health outcomes produced historically, can be compared to those of industrialized nations (2). For this reason, Costa Rica's public hospitals were the first investigation settings in Latin America to attract foreign clinical research

sponsors (3). Forbye, the national health system used to provide easy access to study participants and its systematic and organized keeping of health records. In addition, Costa Rica has had a commitment to respect and defend human rights, guided by international ethical standards, and a culture to resist and report foreign exploitation (4).

Substantial improvements in the oversight of biomedical research with human participants has been implemented during the last years in Latin American and Caribbean countries (5). However, in Costa Rica, as in other developing countries, existing formal legal regulations and oversight of research apply exclusively to health-related studies or biomedical research. Biomedical studies, involve systematic investigation of biological processes and the cause of disease through observation or experimentation. This includes, but is not limited to, basic science studies and clinical trials (6).

There is still debate in the region, whether review by an Institutional Review Board or Ethics Review Committee, is required for sociocultural research protocols that study humans (7). In what follows, sociocultural research, involves studying human participants and their cultures to gain insights into various aspects of their lives. Sociocultural research includes exploration of a problem, through systematic methods such as: observation, ethnography, interviews, surveys, focus groups, experiments, life stories action research, among others. In addition, sociocultural investigations refer to research projects oriented to study social, economic, political, historical, cultural, or psychological variables or dimensions and their relationships, that are not part of the definition of biomedical studies.

Additionally, ethical review processes are still not formally established in many national institutions that perform sociocultural research, since there is no legislation in Costa Rica that mandates committees to overview these types of studies. Thus, many times the only ethical control over non-health-related research is the good will and integrity of investigators. For example, the University of Costa Rica (UCR) and National University are the only two of five public universities that execute research with human participants, with accredited ethics review committees. This is gradually changing; since more often, it is impossible to publish a research paper involving human participants in a respectable journal, without prior evaluation and approval by a research ethics committee.

Therefore, the aim of this report is to outline ethical guidelines to develop both, health-related and non-health human research in Costa Rica, based on lessons learned from the Scientific Ethics Committee of the University of Costa Rica (CEC-UCR). These procedures must be followed nowadays by all actors involved in research

with human subjects within the institution, from students to professors or international collaborators. Since this is a regulation that was set by the UCR, it can serve as a model for other institutions, for responsible conduct of health related and non-health related research in Costa Rica, and other developing countries in the region.

It is important to first address the initial stages of research with human participants in Costa Rica to think about why and how human research protections were developed in this country to execute biomedical studies, and how progressively, Costa Rica can move forward as a leader in human research ethics if review of sociocultural studies with humans is promoted, as accomplished by the CEC-UCR.

INITIAL STAGE OF RESEARCH WITH HUMAN PARTICIPANTS IN COSTA RICA

In Costa Rica, the first clinical trials dated back to 1962 (8). Ten years later, in 1972, the supervision of medical research involving human beings began (9), still much earlier than in other Latin American countries. Then, the Ministry of Health established an Ethics Review Committee, responsible to advise on human research and experimentation, and to evaluate and approve clinical trials (10). In 1974, the Legislative Assembly (legislative branch of the Costa Rican government), passed the General Law of Health in which several fundamental principles of the Declaration of Helsinki were contained, including the requirement of informed consent from participants of investigations (4). One year later, the Ministry of Health issued a Decree which created the first interinstitutional scientific ethics committee to review all proposals for human research. However, regulatory ambiguities and conflict of interest existed between the CCSS and the Ministry of Health, affecting human research protections compliance

(3). Several decrees were promulgated to regulate clinical trials; nonetheless, decrees were subjected to change as governments changed.

Despite having a regulatory framework at that time, Costa Rica failed to prevent the violation of the rights of some participants in clinical trials. It has been revealed that a disproportionate number of improperly-regulated clinical trials were conducted in CCSS facilities, especially in the pediatric population (3). In many studies, informed consent was not requested to parents or legal guardians, and some clinical investigations were approved without even passing ethical review. In one study carried out by a foreign university in collaboration with the Ministry of Health, an influenza vaccine formulated for adults was administered to children without parents' consent (3). In another trial that was approved by the Ministry of Health, children from low socioeconomical status, were given an experimental vaccine for respiratory syncytial virus, again without parents' consent (4). In these ways, foreign-sponsored private companies spearheaded their research activity in public hospital facilities without proper regulations.

Unfortunately, one of the deficiencies of the past emitted regulations was the lack of sanctions for transgressors. For example, the National Children's Trust got acquainted of the violations in these experiments and sued the foreign research sponsor institution. However, the national court did not spell any penalties for not complying with the executive decree. Besides, principal investigators of these projects were usually prominent physicians, most of whom worked simultaneously in the social security administration, and in the private sector, and whose reputation and political connections escaped public scrutiny. These physicians viewed clinical research, as a pathway to promotion (9).

A legal crisis prompted in the mid-1990s when deficient human research regulations and

oversight, due to lack of financial resources to monitor clinical research, was exposed by the local media. According to reports, studies were conducted with vulnerable populations and participants were experiencing adverse events (10). To make matters worse, sponsors were not legally bound to take financial responsibility (11). Consequently, the Ministry of Health and CCSS made efforts to ensure rules for research and protection policies. For instance, the Ministry of Health created the National Council for Health Research (CONIS, for its acronym in Spanish) and required that all institutions that carried out clinical trials to create CONIS-accredited scientific ethics committees. Simultaneously, the CCSS created an internal scientific ethics council and three supporting committees to monitor research with vulnerable populations (3).

During this epoch in Costa Rica, started an epidemiological study, in one of the countries' poorest rural regions, studying the natural history of cervical cancer. Later, a clinical trial, testing vaccines against Human papillomavirus serotypes, was executed, in this population of women. This clinical study was sponsored by the U.S. National Cancer Institute in collaboration with the Epidemiology Project of Guanacaste, a private research entity. According to literature, employees from the Ministry of Health recruited participants, and CCSS's clinics and hospitals served as research settings, where participants' screenings, check-ups and follow-ups took place, without institutional approval (12). Thus, goods and services provided by the government were used to benefit non-government parties. These breach of regulations, led to internal audits at the CCSS, concurrently, with an investigation conducted by the Legislative Assembly, revealing irregularities such as conflicts of interests between administrators of the CCSS, researchers and oversight authorities (3). To aggravate the situation, informed consent procedures could not be accessed by CCSS's auditors (13).

In 2003, politician José Miguel Corrales Bolaños filed a claim before the Constitutional Chamber of the Supreme court to act for violation of human rights, arguing, the government did not make much to enforce regulations governing biomedical research. For the next seven years, the Ministry of Health, the CCSS, and the Legislative Assembly brought up new initiatives and new regulations. For example, the CCSS created local bioethics committees and the Ministry of Health issued new decree with more specific regulations for clinical research (4).

Then, in 2004, the Epidemiology Project of Guanacaste in partnership with a transnational pharmaceutical company, initiated the Phase III trial of the Human papillomavirus 16/18 vaccine. This time, with the collaboration of a private foundation affiliated to the Ministry of Health. Even though this project had the approval of three Scientific Ethics Committees, again, facilities of the CCSS were used for the study, without the authorization of neither the institution nor its ethic committee (14).

It was not until 2010, that the Costa Rican Supreme Court imposed a national moratorium that prohibited all biomedical research involving humans. A total of three hundred and fifty biomedical research protocols were suspended (15), among these, epidemiological studies, and clinical trials. This event had serious consequences on the country's economy. As an example, multinational pharmaceutical companies left Costa Rica, investing in other Latin American countries for research purposes. Panama, Guatemala, and Dominican Republic were new targets, offering better conditions for research development (16). As a result, two hundred people lost their jobs, twenty clinical research centers were closed, and more than fourteen thousand patients lost their possibility to participate in clinical studies (17).

REGULATORY LAW OF BIOMEDICAL RESEARCH (LAW 9234)

In 2014, the Legislative Assembly of Costa Rica enacted the Regulatory Law of Biomedical Research, Law 9234, (18) which allowed biomedical studies on human beings after a four-year ban. The objective of the law is to regulate biomedical research with human beings in public and private sectors. Research with human participants that draws upon different theoretical approaches to better understand factors that may influence health and well-being, are classified as biomedical research and are subject to Law 9234.

Law 9234 is one of the most important efforts in the history of clinical research in Costa Rica, aimed to establish clear and rigorous protection regulations for study participants. In this matter, Law 9234 stresses the requirement that the design and implementation of the project must attain the basic principles of research: respect for persons, non-maleficence, beneficence, and justice. It clearly states, research ethics and good practices should guide responsible conduct of biomedical research, and that the dignity and well-being of research participants, precede scientific and economical benefit.

Among the greatest assets of Law 9234, is a regulatory framework that describes research participants' rights and duties, protection of confidentiality, expense reimbursement for participation in research protocols, compensation for damage, and post-trial access to products that have been tested in the country and have been proven effective. In this matter, Costa Rica is the only country that requires companies to provide perpetual access, if the trial demonstrated the tested products are beneficial to the participants of the study.

As well, research with vulnerable populations is regulated and controlled by Law 9234, declaring vulnerable individuals and groups require additional protections as participants. In the same line, Law 9234 delineates working with vulnerable populations is justified when the focus of research is on alignment to the health needs or priorities of this group, and the participants of the study will get benefited.

Law 9234 establishes the guidelines that must be followed to use biological samples of human origin with research purposes. Namely, specimens can only be used if the participant has given a specific informed consent. Participants may not be remunerated or compensated for donation of samples for research. This law prohibits to use specimens with other purposes than those established in the informed consent. It also states that the participant can retract their consent, at any timepoint of the study. Regarding storage of samples, these may only be stored for the research purposes stated in the informed consent document. In case biological samples will be used in future research projects, participants must be acquainted about possible subsequent uses, where and how the samples are going to be stored and preserved. Sale of donated biological samples is prohibited by Law 9234.

The duties and responsibilities of individuals involved in biomedical research are also delineated in Law 9234. With the highest rank of authority is the Ministry of Health, in charge of defining procedures to biomedical research. CONIS is ascribed to the Ministry of Health and oversees all biomedical research regulatory processes. CONIS is also in charge of having a registry of all biomedical protocols performed in the country. Law 9234 mandates Scientific Ethics Committees to be CONIS-accredited. The latter reviews, supervises and audits biomedical research projects. In addition, researchers are required to be CONIS-accredited.

The accreditation process involves getting trained in research ethics by taking a CONIS-accredited Good Clinical Practice Course, and following regulations established in Law 9234. Sponsors are required governance of the research study, including quality throughout all stages of the investigation. Unlike previous regulations, sanctions for scientific misconduct, bribery, conflicts of interest or for not conducting research projects responsibly, are delineated in Law 9234. Penalties include fines to months/years in prison.

Even though, Costa Rica is only of the few developing countries in Latin America, that have a biomedical research law, the legislation has been criticized. For example, defenders of vulnerable populations allege, they were never included drafting the document. An omission of Law 9234 is that it does not regulate the use of placebo. Additionally, there is ambiguity in what insurance policies cover. Nonetheless, as stated, an insurance policy must be provided to the participant through the duration of study, and two additional more years once the study terminates. Another contradiction is that the law leaves the door open for the CCSS to continue paying for the restoration of the health of participants who have suffered adverse reactions. A major flaw is that the law regulates exclusively biomedical research, it fails to look after other kinds of research with human beings, such as humanities and social sciences research. This has led to many researchers in the humanities and social sciences resisting ethics review. Despite gaps, no person conducting biomedical research in Costa Rica can claim to be unaware of the existence of the law and its implications.

A year later after Law 9234 was passed, a Regulation was emitted, Decree NO.39061-S, (19), to comply with the responsibility of adequately supervising research processes in human beings in Costa Rica. This regulation supports and clarifies articles and sections of Law 9234.

Currently, the government of Costa Rica is committed in promoting biomedical research in the country. According to data from CONIS, a total of 1,596 researchers are fully accredited principal investigators. CONIS has also accredited nineteen Scientific Ethical Committees. A recent decree has been signed recently, to establish the Ministry of Health Ethics Review Committee which will be the only collegial body that will exclusively have the task of reviewing and approving Phase 1 trials, as well as bioequivalence studies, conducted in national territory.

LESSONS LEARNED FROM A SCIENTIFICAL ETHICS COMMITTEE IN COSTA RICA

The UCR is the oldest and largest public university in the Republic of Costa Rica. Also, the most important research university in the country, in Central and Latin America, according to international ranks. For many years, health research projects of the UCR were evaluated by the Ministry of Health Ethics Review Committee. In the early 1990s, the university began receiving research funds from the National Institutes of Health (NIH), the primary agency of the United States government responsible for biomedical and public health research. The NIH required that all funded projects had to be evaluated and approved by an IRB. Therefore, a group of professors, among them, biomedical investigators, and philosophers, created an ad hoc committee to evaluate research proposals with human participants. That was the beginning of the UCR's first IRB, following NIH guidelines (20). Another determining aspect was the interest of this group in strengthening research ethics, which led them to continue with the work of reviewing protocols. By 1994, the meetings were held at the Vice Rector's Office for Research. This group, with some variations among its original members, assumed the review and discussion of health-related research protocols with human participants, especially those with external funding. In this way,

a de facto ethics committee acted at the university, until the passing in June 2000, of the Scientific Ethical Regulation of the UCR for Research Involving Human Beings (21). This document, which describes ethical and scientific rules for research with human participants, officially established the figure of the current Ethical Scientific Committee of the UCR (CEC-UCR, for its acronym in Spanish). This board was later accredited by CONIS, in March 2001. This regulation is currently being updated, to act in accordance with Law 9234. Additionally, the students are being included in the drafting of the proposal, since nowadays, many conduct research involving human participants as part of their degree requirement.

It is important to highlight that the current Scientific Ethical Regulation of the UCR for Research Involving Human Beings alludes not only to biomedical research, but also to non-related health research. The latter is the most common type of research studies executed at the institution. Thus, the UCR incorporated non-medical research into its regulations since the beginning. Herein, any systematic investigation with human beings, designated to develop or contribute to generalizable knowledge, executed by faculty or students, is subject to review by the CEC-UCR, to ensure that the participants in the proposed research are not harmed.

Historically, the CEC-UCR has consisted of members from different academic units, with different backgrounds, in areas related to human rights and law, philosophy and bioethics, health education, health research, social sciences, representatives of the post-graduate programs, and a spokesperson of the community. Members' term is four years long, with the possibility of reelection. Under UCR's regulation, this group has been formally designated to review and monitor research involving human participants. The CEC-UCR has the authority to approve, request modifications of proposals, or disapprove research projects.

The committee is responsible also to disseminate bioethical knowledge and train researchers and students on research ethics.

One issue that generates doubts in the UCR's scientific community and researchers that come from abroad and collaborate in research projects with the institution, is about the types of projects that require review by the CEC-UCR. In 2016, guidelines were developed by the CEC-UCR, with the aim of guiding research commissions, researchers that work or collaborate with the UCR, and students, to inform them about the committee's working procedures. Basically, biomedical (health-related) and nonbiomedical research projects involving contemporary human populations must be presented for review by CEC-UCR. Additionally, all projects working with vulnerable populations. Based on complexities and variable contexts, proposals are reviewed on a case-by-case basis. For biomedical proposals, the CEC-UCR ensures that projects are carried out in accordance with universal bioethical principles, national regulations, and applicable institutional policies. Review of non-biomedical projects is required when private, confidential information, sensitive data from participants is obtained in accordance with Law on the protection of individuals against the processing of their personal data, Law 8968 (22). This legislation dictates personal data protection and contains all the regulatory information referring to both public or private automated or manual databases. Law 8968 establishes that databases with personal information, such as health records, must guarantee the security, integrity, and confidentiality of people.

SOCIOCULTURAL RESEARCH

Ethical considerations are paramount in sociocultural research, as it involves most of the time, interacting with individuals and communities. In relation to sociocultural research with human beings, the CEC-UCR makes decisions based on the legal basis of the Scientific Ethical Regulation

of the UCR for Research Involving Human Beings (21). In situations of omission or lack of clarity regarding ethical criteria in research, the use and interpretation of other regulations such as Law 9234 and others pertinent to the matter are used. In what has not been regulated by the respective regulation and if pertinent, the following normative sources are applied: the Political Constitution of the Republic, the Civil Code, the Penal Code, the General Health Law, the Law on Authorization for Organ Transplants, Human Anatomical Materials and its Regulations, and any other legal regulation related to the subject (23).

Review of sociocultural proposals by the CEC-UCR is oriented to be commensurate with the level of risk of harms, the potential benefits to the population of study, or to the advancement of scientific knowledge. Each project is examined on its own merits by the ethics committee. Nonetheless as general aspects, before initiating research in which human beings participate, the proposing researchers must consider the following points in their research project: a) likelihood or probability of harm, the severity of harm, and in this case duration of harm (24) b) the anticipated benefit to the participants (25), c) the importance of knowledge that can be expected as a result of the investigation (26), d) the procedure for obtaining informed consent (27), e) containment measures to avoid or address adverse effects on people participants, d) the provisions that will be taken to ensure the privacy of the participants and the final destination of the information, data and documentation collected (18).

SOCIOCULTURAL RESEARCH WITH VULNERABLE POPULATIONS

Much of social science research involves inclusion of vulnerable individuals and groups. For instance, studies with ethnic minorities, victims of violence, and refugees are some examples of this. In most cases, the object of study is intrinsi-

cally linked to vulnerable individuals and groups. For this reason, it is impossible to avoid including these individuals in the investigations, since the object of study is a particular problem that may affect this group of people (28).

Several factors make a person vulnerable, therefore the CEC-UCR relies on the categorical and contextual approach when determining vulnerability participants (29). Namely, children and teenagers, senior citizens, people without volitional and cognitive capacity, people highly dependent on health care, with a potentially stigmatizing illness such as HIV/AIDS, people who were recently discharged from the intensive care unit or who depend on medication provided by the health system, are categorized as vulnerable. Also, indigenous communities, migrants, and collectives particularly vulnerable, subordinate groups, pregnant or lactating women, and people deprived of liberty are considered as vulnerable populations. It's crucial to also consider the contextual approach, and identify degrees of vulnerability within a group, based on individual characteristics and situations in which individuals might be considered susceptible. For instance, individuals engaged in illegal activities, sex workers, drug use, illegal immigrants, or individuals whose civil rights have been compromised. Of relevance is to address potential vulnerability, to illustrate in this scenario, people with history of attempted self-elimination. Any review board should ensure additional safeguards to protect the rights and welfare of participants who are likely to be vulnerable and are included in the study under review (30).

Nowadays, many tribes in Costa Rica are active in investigations and approach the University of Costa Rica to work on questions they have themselves defined. Since indigenous people are among the most vulnerable groups, correspondingly, there are a series of norms when working with indigenous communities. Researchers must ensure the protection of members of indigenous

communities and consider the political, economic, social, and cultural impact that the investigation may have on these groups. Also, it is fundamental to respect cultural, political, and social norms, as well as the dignity of individuals and groups when doing research on indigenous communities or those belonging to various ethnic groups. Previous consultation of the proposal must be carried out with the community as stipulated in Convention 169 (31), and the specific protocols and guides of each town, if any, must be followed before starting any type of investigation. Since Costa Rica has eight indigenous groups, the country ratified Convention 169 in 1993, and added recognition of its multicultural nature to the Political Constitution of the Republic in 2015.

EXPEDITED REVIEW AND EXEMPTION OF REVIEW BY THE CEC-UCR

Some projects working with human participants may qualify for expedited review by the CEC-UCR. An expedited review may be rendered if the proposal poses minimal risk. Expedited revision is performed by two members of the CEC-UCR rather than by the full board. For instance, in the social sciences field, ethnographic research mostly qualifies for expedited review, since normally it involves the observation and interaction of the researcher with adult participants in ordinary life and poses minimal risks. However, if the ethnographer records or takes pictures of public behavior and if the identity of the participant is disclosed or revealed, this may involve a significant risk, according to local regulations.

Certain research projects working with contemporary human populations are exempted from review. Exempt is an agreement equivalent to not requiring review and refers to projects and investigations that by their nature, in the perspective of the CEC-UCR and based on the applicable regulations, do not imply any danger to, or compromise the participants. Neither Law 9234 nor its

regulations specify who can make determinations on exemptions. Some examples of proposals that may not require review are, but not limited to: a) course activities that provide educational training in research that include research methodologies and data collection, but do not constitute research, b) proposals for quality assurance or control, professional practices, in which knowledge already acquired from the respective disciplines is applied, and of which a report is made at the end of the course, and c) when the data being collected in the study is about institutional or social processes, and not about the lives of the informants. In summary, research on social institutions or processes, to create generalizable knowledge about attitudes, beliefs, or behaviors of individuals or groups (for example, voters, prisoners, employees, teachers) as representatives of these institutions or social processes, is research that demands review by the CEC-UCR (23).

CONCLUSIONS

Ethical and scientific evaluation of research projects with human beings, regardless of whether they are related to health or not, is an international standard criterion. It derives from historical abuses of people participating in investigations. It is the obligation of any instance in which research with human beings is carried out, to be a guarantor of the protection of the participants' human rights. Ethical review boards should protect not only human participants, but also serve as advisory boards and guide researchers on ethical dilemmas that may arise before, during and after the execution of the research project. Additionally, any ethics committee must verify that in all the reasoning of the project, from the beginning to the

end, there is guarantee that the principles of doing good science are met.

In Costa Rica, research ethics education to perform biomedical research is enforced by law. However, no regulatory legal framework exists to stimulate researchers and student researchers, to attend a good clinical practices course to perform social and behavioral studies in humans. In summary, local ethical guidelines, standard operating procedures, and accreditation processes to promote ethical conduct of non-biomedical investigations in humans, is a task pending in the region. Nonetheless, the University of Costa Rica has made efforts to compel compliance with research ethics when studying humans. The ethical guidelines dictated by the University of Costa Rica and Scientific Ethics Committee of the University of Costa Rica (CEC-UCR), can serve as a framework for other national and international institutions from developing nations, to enhance responsible conduct of human research, where ethical assessment of sociocultural research is relatively neglected, compared to the review of biomedical and clinical studies.

Ethical codes and principles have been developed to aid researchers to critically evaluate ethical viewpoints, attitudes, and to develop skills to make well-informed decisions when studying humans. These regulations don't serve the same purposes as laws. Instead, these codes and guidelines norm existing legal standards. Since the rule of law is upheld, scientists are subject to the law just like other members of society. Therefore, research ethics obligations include the application of fundamental ethical principles to the process of investigation, and responsibility over the conse-

quences derived from it. From this viewpoint, ethical review is justified before any research with humans is performed. This is a lesson learned from the CEC-UCR.

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CONFLICT OF INTEREST

None to declare.

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