

# The topic of research integrity in Latin America<sup>a</sup>

*La Cuestión de la integridad de la investigación en América Latina*

*A Questão da integridade da pesquisa na América Latina*

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**ABSTRACT:** Bioethical thinking, initiated as against well-known cases of disregard of human dignity and rights in research involving human beings, became institutionalized in the US and Europe in the form of norms, regulations, and corporate bodies, such as commissions and committees entrusted with their interpretation and application. A constructive contribution of Latin America requires sound oversight systems and science of high quality. Due to this, the discrepancy between knowledge and action must be reduced not by imitation but through realization of the social consequences of research. Research integrity depends both on the researcher moral character and on external pressures, such as competition with other researchers, career improvement exigencies and/or access to funding. A retrospective look to what have happened in the last years in research ethics issues at Latin America through the experience of the 50 trainees, has shown that there is great diversity among countries, with some advancement in ethics of research oversight regulations, but at the same time with problems on research integrity mechanisms of supervision. The paper emphasizes respect to subject's rights and a true commitment in the research process by researchers, sponsors, subjects and scientific ethical review committees as well as establishing high standards of research integrity and monitoring systems at Latin America as a constructive way to support health and development policies.

**KEYWORDS:** Interdisciplinary Research. Latin America. Bioethics.

**RESUMEN:** El pensamiento bioético, iniciado en contraposición a casos bien conocidos de indiferencia a la dignidad y los derechos humanos en la investigación en seres humanos, se institucionalizó en los Estados Unidos y la Europa bajo la forma de normas, regulaciones, y organismos tales como comisiones y comités encargados de con su interpretación y uso. Una contribución constructiva de América Latina requiere sólidos sistemas de supervisión y ciencia de alta calidad. Debido a esto, la discrepancia entre el conocimiento y la acción debe ser reducido no por la imitación sino promedio la percepción de las consecuencias sociales de la investigación. La integridad de la investigación depende del carácter moral del investigador y de presiones externas, tales como competición con otros investigadores, exigencias de mejora en la carrera y/o acceso a financiación. Una mirada retrospectiva a lo que ha sucedido en los años pasados en cuestiones de ética de la investigación en América Latina promedio la experiencia de 50 aprendices, ha demostrado que hay gran diversidad entre países, con algún adelanto en procedimientos de supervisión de las regulaciones ética de investigación, pero al mismo tiempo problemas en mecanismos referentes a la supervisión de la integridad de la investigación. Este artículo acentúa el respecto a los derechos de los sujetos y un verdadero compromiso con el proceso de investigación de parte los investigadores, los patrocinadores, los sujetos y los comités éticos científicos de revisión así bien el establecimiento de mayores niveles de integridad de la investigación y de sistemas de acompañamiento en América Latina como manera constructiva de apoyar políticas de la salud y de desarrollo.

**PALABRAS-LLAVE:** Investigación Interdisciplinaria. América Latina. Bioética.

**RESUMO:** O pensamento bioético, iniciado como reação a casos conhecidos de negligência quanto à dignidade e aos direitos humanos na pesquisa que envolve seres humanos, tornou-se institucionalizado nos Estados Unidos e na Europa sob a forma das normas, regulamentos e organismos como as comissões e os comitês a que é confiada sua interpretação e aplicação. Uma contribuição construtiva de América Latina exige sólidos sistemas de supervisão e ciência de alta qualidade. Devido a isso, a discrepância entre o conhecimento e à ação deve ser reduzida não pela imitação, mas com a percepção das consequências sociais da pesquisa. A integridade da pesquisa depende do caráter moral do investigador e de pressões externas, tais como a concorrência com outros investigadores, exigências de melhoria da carreira e/ou acesso ao financiamento. Um olhar retrospectivo e ao que aconteceu nos últimos anos em questões de éticas de pesquisa na América Latina, com a experiência de 50 estagiários, mostrou que há uma grande diversidade entre países, com algum avanço nos regulamentos éticos de supervisão da pesquisa, mas ao mesmo tempo com problemas nos mecanismos de supervisão da integridade da pesquisa. O artigo enfatiza o respeito aos direitos dos sujeitos e um real compromisso com o processo da pesquisa da parte dos investigadores, patrocinadores, sujeitos e comitês de ética científica, bem como o estabelecimento de altos padrões de integridade da pesquisa e de sistemas de monitoração na América Latina como uma maneira construtiva de apoiar políticas de saúde e de desenvolvimento.

**PALAVRAS-CHAVE:** Pesquisa Interdisciplinar. América Latina. Bioética.

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a. This article represents the experience of trainees who have participated in the ethics of biomedical and psychosocial research program of the Interdisciplinary Center for Studies on Bioethics, University of Chile, Fogarty Grant R25TW6056.

## INTRODUCTION

Bioethical thinking, initiated by well-known cases of disregard of human dignity and rights in relation to research involving human beings, became institutionalized in the US and Europe in the form of norms, regulations, and corporate bodies (commissions and committees, IRBs) entrusted with their interpretation and application. A constructive contribution of Latin America requires sound oversight systems and science of high quality. Research quality depends on integrity and responsible conduct, but different conceptualizations between countries may affect collaboration. Translation of research evidence into public policies demands that researchers be aware of their role in a globalized scientific community and interact with their peers internationally at a comparable level of ethical competency. The “know-do gap”, the discrepancy between knowledge and action, must be reduced not by imitation but through realization of the social consequences of research.

Research integrity depends both on the researcher moral character and on external pressures, such as competency with other researchers, career improvement exigencies and/or access to funding. In order to prevent scientific misconduct such as plagiarism, fabrication and falsification, researchers must build professional honesty and a sense of social responsibility; institutions must create an environment promoting responsible conduct of research with norms, oversight and support mechanisms. In order to make this a reality it is necessary both train professionals on responsible conduct of research and to have mechanisms of ethics oversight in the institutions.

In the U.S., the problem with research integrity is recognized for a long time. Recently, a study questionnaire sent to NIH-funded PIs proved there is a very real problem with research misconduct. It revealed that if the 167 scientists who had observed misconduct in the study were multiplied by the entire mass of scientific researchers the NIH supports, “the number of scientists observing incidents of suspected research misconduct in that population would be about 4,650 incidents per year<sup>1</sup>”.

There are holes in the efficacy of the review process. Biomedical and psychosocial research is required to undergo ethical review, either through national laws, professional codes of conduct or as a condition of sponsors, institutions, research agencies, or publishers. However, according

to *JNCI* editor Barnett Kramer, ethical review and referees for journals typically examine study design and treatment of subjects, but it is difficult to determine whether the primary and raw data initially used in research studies is true<sup>2</sup>.

In the past in the international setting, the alarm about scientific misconduct of cases such as the Tuskegee study of syphilis paid attention to the inhuman treatment of research subjects in the name of scientific knowledge advancement, but the *modus operandi* of many current cases of intentional misconduct seems to point rather to personal reasons, such as reactions to a negative work environment<sup>1,3,4</sup>, or personal gain, either for reputation or financial gain<sup>1</sup>. As suggested by Miller, et al, professional integrity in research is intimately linked to the kind of moral identity professionals embrace, highlighting the conflicts in clinical research between the roles of the “investigator as clinician and the investigator as scientist.” Studies involving human subjects are often neither completely therapeutic nor completely scientific with such dilemmas as the problems of “therapeutic misconception”<sup>5,6</sup> in which subjects participate only because they believe are receiving therapy.

The individual character of researches may influence ethical decision making<sup>7</sup>. According to Antes and collaborators, most studies that link individual factors to ethical decision are related to financial gaining<sup>7</sup>, but there are also other psychological needs involved such as seeking personal prestige<sup>2</sup>. Some examples of this are psychosocial research studies where social inequalities are used as resource to select study populations, due to their easiest access and management, without taking into consideration that the studies may damage the populations, with the only goal to publish and gain financing<sup>8</sup>.

The ethics of biomedical and psychosocial research program of the Interdisciplinary Center for studies on bioethics (CIEB) of the university of Chile over the last ten years has train Latin American professionals (50 trainees) to assume active leadership in teaching, evaluating, designing and conducting ethically sustainable research, collaborating in the formulation of ethics of research regulations and the formation of scientific ethical review committees. Besides implementing institutional programs on responsible conduct of research, one of the fruits of such activities has been to collect data related to research integrity at Latin America, which we convey in this article.

## RESEARCH INTEGRITY IN LATIN AMERICA

A retrospective look to what have happened in the last years in research ethics issues at Latin America through the experience of the 50 trainees, has shown that there is great diversity among countries, with some advancement in ethics of research oversight regulations, but at the same time with problems on research integrity mechanisms of supervision. In one hand, ethics of research programs and scientific ethical research committees has been incorporated in many research institutions, but on the other hand the visibility of research misconduct is increasing. One example is the value given to informed consent, which although accepted as essential for research involving human beings, in practice is reduced in many cases to signing a document internationally required, but without regarding to respect in the process that the subject truly understands the study. This situation is favored by the lack of adequate oversight mechanisms. Often researchers have little understanding on what is necessary to include in informed consent: risks and benefits are poorly defined, inclusion and exclusion criteria for subjects are not defined, language is too technical.

Currently, the capacity of self regulation by the scientific community and that of regulatory agencies has come into question. Some authors have denounced research corruption<sup>9</sup>. In the academic world, fabrication, falsification and plagiarism are increasing in a culture where there are many pressures due to seeking prestige and ambition to scale positions and to the pressure to publish<sup>10</sup>.

Without responsible participation with reflection and deliberation is not possible to define scientific and health policies according to Latin American needs, reason why some trainees try to contribute with new proposals in order to define public policies. But, the problem is that the prevalence of scientific misconduct is difficult to evaluate due to the difficulty of diagnosis and the lack of mechanisms to report them. Moreover, when some cases are denounced, institutional directors minimize the facts or hide them to avoid discredit. There are also limits related to lack of policies to safeguard ethical issues by many Latin American journals editorial committees and the information about these topics is very limited<sup>11</sup>. In the case of plagiarism there are only sporadic reports with editors retracting a publication<sup>12,13,14</sup>.

In developed countries there are “offices of research integrity” and institutional committees where denounces can be made for scientific misconduct, but these organisms are lacking in most Latin American countries, although in some countries they are emerging, such as in Colombia, where there is a Commission for intellectual property and a government agency for denounces.

In the following, we describe some conditions which merit the need to conform research integrity offices in Latin American countries.

## PUBLICATIONS

Many Latin American scientific journals are not integrated into the science citation index system, they do not contain guidelines for ethical considerations and they do not follow international uniform recommendations, such as the International Committee of Medical Journals Editors. Thus, for example, in an analysis of scientific Brazilian journals, only 21 % contained instructions about the use of informed consent, ethical principles and the requirement to be approved by a scientific ethical review committee<sup>15</sup>. In an attempt to correct this situation several journals have elaborated Editorial ethical codes<sup>16</sup>.

### Public Based Registration of Protocols

The obligation to register clinical trials is fulfilled in Latin America since 2003 by incorporating them into LATINREC of the Cochrane web (<http://www.latinrec.org>), Pharmaceutical trials register phase II and III trials carried out in Latin America in the U.S national web (<http://www.clinicaltrials.gov>). But, this type of data base in many occasions is not used by scientific ethical review committee members to know if protocols were previously presented and rejected in other countries before approving a new trial.

### Scientific Ethical Review Committees Limitations

The following problems have been identified:

- Lack of monitoring mechanisms due to lack of time of members and lack of funding;
- Lack of infrastructure and funding to carry out activities and excessive work load;

- Some committees do not count with all require members, such as the member representing the community or the legal advisor;
- In some countries committees have no authority to interrupt a clinical trial that present serious adverse events and lack guidelines to correct error in protocols;
- Scientific ethical review committees oversight does not reach the conversation between researcher and patient volunteers during informed consent disclosure and negotiation before forms are signed<sup>17</sup>. A system to **guarantee legibility, understanding** by subjects and lack of pressure to consent is not implemented in many cases;
- In some academic institutions, thesis protocols presented by students are not evaluated by a scientific ethical review committee, due to the fact that the procedure is considered more an academic exercise supervise by professors than research, but human subjects are intervened with little ethical supervision.

## **PROBLEMS WITH SCIENTIFIC MISCONDUCT REPORTING**

When scientific misconduct is revealed by colleagues, many times they do not denounce them due to the lack of clear mechanisms to solve these issues both for denouncing and judging them; in the case of Colombia, even though there are mechanisms, there is reticence to denounce due to fear of reprisals<sup>18</sup>. Furthermore, the regulatory agency INVIMA (National Institute for Drugs and Food Surveillance) has tried to regulate clinical research, but does not count with the necessary structure and financing to carry out this task. In Ecuador, there is an Honor Tribunal for presenting denounces, but its decisions are not binding.

There are cases of corruption denounced publicly related to the management of health care service and research. In Argentina there have been for several years cases of violations to norms without punishment to the responsible persons<sup>19</sup>. These have been corrected currently with the creation of the regulatory agency ANMAT (National Administration of Drugs, Food and Medical Technology). A case with international impact oc-

curred at Hospital Naval Pedro Mallo in Buenos Aires with physician Luis Garre, who carried out a clinical trial with the experimental drug Cariporide of Aventis Pharma. Garre falsified informed consent documents and electrocardiograms with the aim to include patients in the research protocol, thus receiving the money paid by Pharma for each patient participating in the protocol. The physician was discovered after an investigation when some patients died because of receiving the drug for a condition they do not had, but Dr. Garre was not punished<sup>20</sup>.

A case denounced in the Dominican Republic by one of the trainees reflect the little experience some countries have in dealing with research integrity. The National Bioethics Committee CONABIOS approved a study using UV light irradiation as therapy for patients living with HIV/AIDS, when researches did not have experience in this type of therapy both in animals and humans, nor they were to be trained and there was no safety tests and quality control. Another case in Dominican Republic reveals that sometimes the obligation that protocols involving human beings be reviewed by scientific ethical review committees is not fulfilled. In 2007, Dr. Baez Acosta declared to have probed finding a cure for AIDS without having submitted his research protocol to CONABIOS as is requested by the General Health Law. The Public Health Secretary confiscated the experimental drug which was not registered in the Agency for Dugs and Pharmacy (SESPAS), close the laboratory and punish the physician<sup>21</sup>.

In Ecuador, the drug ivermectina was used to eradicate oncocercosis, with the Ministry of Health sponsorship, but without FDA approval for use in human beings, it only was approved for horses and donated by the Pharmaceutical MSP. After a few tests with endemic patients the results were presented for approval by the FDA.

Although infrequent, there is a case denounced in Chile of not fulfilling with the norm of approval of protocols by a scientific ethical review committee, an international study carried out without informed consent. The project GENADIO, a collaboration of Universities of Glasgow (Scotland), Chile and Concepcion, Chile, had the aim to find causal relations between health state and nutrition, life styles and environment. As part of the methodology, blood samples were taken from per-

sons of the indigenous community Mapuche to study the prevalence of obesity and diabetes. The Mapuche Parliament Koz Koz rejected the Project for lack of approval by regional authorities and for lack of guarantee of prohibiting genetic manipulations<sup>22</sup>.

In Guatemala, there are cases of researches that carry out the same research with different sponsors with few changes, with the only purpose of having a salary. Often patients are coerced offering them free treatment with the experimental drug, knowing that they do not have access to regular treatment because of poor economic condition.

### **PROBLEMS WITH DEFINITIONS**

Ambiguity is a problem in definitions of research integrity. Such standard definitions of misconduct – fabrication, falsification and plagiarism (ORI) or integrity – “the fundamental principle that scientists be truthful and fair in the conduct of research and the dissemination of research results” (CRI) – do not cover miscellaneous examples such as reporting experiments as one’s own in published articles that were never carried out<sup>23</sup>. Broad definitions of research misconduct need to be narrowed to include conducts “that are not generally part of normal practice in science, where a single performance of this act is sufficient to label as misconduct, and that the intent to deceive is implicit in the act itself”<sup>24</sup>. Conflict of interest is another example of an ambiguous area in research ethics. Thus, there is a problem with interpretation and application of definitions of integrity, which is exacerbated in different cultural settings with distinct views and customs, such as Latin America.

### **INCREASE OF MULTI-CENTRIC INTERNATIONAL RESEARCH**

As science grows, research is increasingly performed in international networks<sup>25</sup>. Multi-site research and international collaboration offer multiple advantages, but the process of ethical oversight has become more complex due to differing views on its meaning and importance. International collaborative research often means limited personal contact among researchers and ethical review boards in developing countries might not have the same rigorous standards of developed countries due to “poor

funding and lack of properly trained staff”<sup>26</sup>. The trend of globalization in clinical and psychosocial research implies that sponsors in economically advanced countries outsource trials and research to poor communities within developed countries or, most frequently, to resource-poor nations<sup>27</sup>. The cost of conducting research is less than in advanced countries. Poor countries offer large patient pools for diseases, thus ensuring rapid recruitment and reduction of time for completing trials. Regulations are weak or nonexistent, and lack of qualified policymakers and scientists create an imbalance between what is offered to communities and the actual benefits in terms of manpower development or economic support<sup>28</sup>. While issues of human subject protection, such as consent, placebo, risk-benefit ratio and vulnerable populations, have been addressed, issues of research integrity, such as conflicts of interest, data management, publication and authorship, have not<sup>29,30,31</sup>. In the study of Hyder et al. there was more preoccupation for confidentiality on part of the U.S. IRBs than the host country IRBs<sup>32</sup>. There is confusion with exact meanings of terms and procedures derives from an insufficient consideration of cultural diversity, and their distinct work environments and organizational structures. Cultural factors as obstacles to identify adverse events have been found in developing countries for accurate pharmaco-surveillance<sup>33</sup>.

### **PROBLEMS WITH NORMS FOR SCIENTIFIC INTEGRITY AND ETHICAL OVERSIGHT**

Some countries in Latin America show deficiencies in developing and implementing regulations for health research and lack professionals qualified for conducting ethical evaluation.

Countries like Argentina, Brazil, Chile, Colombia, Costa Rica, Mexico, Nicaragua, Peru and Venezuela count with norms, codes and policies for research integrity and promote research in academic centers, but in many cases norms point to research results and ethical review before starting research, more than to the research process. The following problems have been identified:

In some countries scientific ethical review committees are created for approving or rejecting research protocols but there are not laws supporting them and no system for their accreditation;

- Many regulatory agencies lack funding for monitoring activities and Latin American physicians are reluctant to inform “adverse events” involving trial patients. Even with a commitment to Good Clinical Practices, on many occasions these are not implemented<sup>34</sup>;
- Many countries lack regulatory agencies and those that do have, lack sufficient infrastructure to guarantee norm fulfillment;
- There is lack of communication between scientific ethical review committees and lack of public national registers of research undergone in the countries;
- In some countries there are national bioethics commissions, but there is confusion in their role and conformation and lack of agreement in how to proceed.

## Challenges

The importance of oversight to guarantee integrity in research practices cannot be overstated as trust is the keystone of public support of science and in areas like health research lack of confidence in the scientific enterprise may damage progress in medicine and public health. It could be said that scientific research on health faces a “normative polyphony” with competing rules, expectations, and needs impacting individuals, groups, institutions, and public or private donors. While written norms are important, their interpretation, applicability and enforcement are subject to competing interests and different interpretations in distinct cultural contexts. Misconduct in clinical research carries especially grave consequences and ultimately serious ramifications for it deals with the health of human beings. Flawed studies can lead to the applications of treatments which do not do what they claim, or worse. Scientific progress is a spiral, built on previous studies and research designs, and when these

are found to be inaccurate, the whole process of scientific progress unravels. Therefore, it is very important to establish high standards of research integrity and monitoring systems at Latin America in order to support health and development policies

Some future challenges are:

- To design transparency indicators of research integrity in research institutions;
- To establish a methodology for evaluating these indicators;
- To promote a culture that allows minimizing scientific misconduct risks in research development;
- To design and implement courses and workshops for training researchers and students in university curricula about ethical issues and the practice of good research habits;
- To develop monitoring mechanisms by scientific ethical review committees;
- To create networks for disseminating ethics of research programs;
- To promote interest on researchers about ethics of research issues.

Research in Latin American requires not only ethical codes and guidelines, but mainly to respect subject’s rights and a true commitment in the research process by researchers, sponsors, subjects and scientific ethical review committees. Research integrity only will become alive with public debate and reflection about scientific advances, while preserving human dignity and autonomy.

### Acknowledgements

The authors thank the contribution with data to this paper to the following trainees: María Rita Garbi-Novaes, Carmen Alicia Cardozo, Julieta Ivone Castro, Katia Rodríguez, Elsa Díaz, Lilian P. Moncayo, Liliana Mondragón and Hilda Elena Valencia-Marroquín.

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Recebido em: 13 de junho de 2011

Aprovado em: 26 de julho de 2011