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Original article

Promotion of research integrity in Latin American institutions

Promoción de la integridad en investigación en instituciones latinoamericanas

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Abstract

Most Latin American Research Institutions do not have an establish system to detect and denounce research misconduct This article reflects on the need to establish high standards in research integrity and monitoring mechanisms in Latin American Research Institutions in order to have an accurate science and for transferring research results to public policies, health promotion and social progress. Based on the experience of developed countries, we propose the following mechanisms to promote research integrity: to promote a culture to enhance good research practices; to establish norms to maintain responsible conduct of research; to establish monitoring proceedings; and to establish mechanisms of support to affront demands of research misconduct.

Keywords: Research integrity; Research misconduct; Responsible conduct of research; Monitoring; Research ethic

Resumen

La mayoría de las Instituciones Latinoamericanas de Investigación no tienen un sistema establecido para detectar y denunciar faltas en la conducta de investigación. Este artículo reflexio-

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na sobre la necesidad de establecer altos estándares de integridad científica y mecanismos de monitoreo en Instituciones Latinoamericanas de Investigación para lograr una ciencia válida y para transferir los resultados de investigación a políticas públicas, promoción de la salud y progreso social. Basándose en la experiencia de países desarrollados, proponemos los siguientes mecanismos para promover la integridad científica: promover una cultura que mejore las prácticas de investigación; establecer normas de conducta responsable de investigación; establecer procedimientos de monitoreo; y establecer mecanismos de apoyo para enfrentar las denuncias de faltas en conducta de investigación.

Palabras clave: Integridad científica; Faltas en la conducta de investigación; Conducta responsable de investigación; Monitoreo; Ética de la investigación

Introduction

For many years, problems in research integrity have been discussed and detected throughout the world, for which there is need to promote research good practices in order to improve research quality. The numerous examples of research misconduct reported globally questioned the efficacy of the scientific community to self-regulation and the ability of regulatory agencies to guaranty research integrity (Aultman, 2013). This is paramount, since precise and credible data are necessary in order to transfer scientific evidence to public policies.

Research integrity is influenced by the moral character of scientists and by the way in which external pressures are managed at institutional and individual level deriving in research misconduct. Researchers may be influenced, for example, by financial interests (Antes et al., 2007) or by looking for personal prestige (Vastag, 2006).

A study questionnaire sent to NIH-funded PIs proved there is a very real problem with research misconduct revealing 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 4650 incidents per year." (ORI, 2008).

On the other hand, most Latin American countries do not have an establish system to detect and denounce research misconduct, for which it is difficult to know the frequency and scope of research misconduct in Latin American research Institutions. But, there is

a growing concern and mistrust on scientific enterprise among the population due to the denounce of abuses and lack of ethical supervision in clinical research (Aultman, 2013). Therefore, there is need to establish mechanisms to guaranty research integrity.

Research misconduct

There is research misconduct when a person doing or publishing research intents to deceive others making belief that a scientific result is true, when in reality it is not. Therefore, research misconduct involves not only an omission or an act, but also a deliberate intention to deceive (Committee on Publication Ethics, 2000; Jaffer & Cameron, 2006). Typically research misconduct includes fabrication, plagiarism and falsification when proposing, carrying out or reporting research results (U.S. Department of Health and Human Services, Office of Research Integrity, Fed.Reg.76262).

Fabrication consists in reporting invented (partially or completely) data not obtained by experimentation (Pimple, 2002).

Falsification refers to the manipulation of research data, equipment or processes, or changing or omitting research results which affect the accuracy of the study (Pimple, 2002).

Plagiarism refers to appropriating ideas, processes, results or words of others without giving appropriate credit.

Besides these flagrant research faults, there is growing concern over the existence of conflict of interests in the research enterprise which may introduce biases in presenting and analyzing results. There is conflict of interest when a secondary interest (money, prestige, family care, social promotion, political or religious beliefs) may prevail over what is considered primary interest (knowledge, teaching, research, promoting health care and subject wellbeing) compromising moral conduct when carrying out a study or when disseminating results (Thompson, 1993).

Furthermore, there is a long list of research misconduct practices which there is need to pay attention to for a precise and exact science, such as:

- Not fulfilling protocol steps approved by a scientific ethical review committee.
- Negligence in preventing evitable risk or damages to humans, experimental animals or environment.

- Breaking confidentiality without authorization.
- Lack of credit to research data of others which contradict own results.
- Not including or giving appropriate credit to authorship.
- Hiding methodology or results details so that others will not be able to repeat the experiment.
- Inadequate research design.
- Inadequate records keeping.
- Giving false information to public.
- Getting advantage of peer review process to put obstacles to the research of a competitor.
- Ignoring specific vulnerabilities due to cultural factors of studied population.
- Circumventing certain minor aspects of human-subject requirements.
- Overlooking others' use of flawed data or questionable interpretation of data.

In the academic world there are many pressures due to ambition to scale positions, to have prestige or the pressure to publish. In Latin America, it is difficult to evaluate the scope of research misconduct due to the lack of organized mechanisms to denounce and judge the veracity of demands. In most countries there is no governmental office of research integrity, nor a place at institutional level to evaluate allegations. When some cases are denounced, often institutional directors minimize or hide the facts to avoid discredit and many researchers have reticence to denounce fearing reprisals (Rodriguez & Lolas, 2011). There are also limits related to the lack of norms to safeguard ethical topics by editorial committees of Latin American journals (Rodriguez & Lolas, 2011). Nevertheless, some allegations have been made public. There are sporadic claims of plagiarism which journal editors retract the publication (Guillen Fonseca, 2006; Reyes, Palma, & Andersen, 2007; Silva Hernandez, Llanes Cuevas, & Rodriguez Silva, 2007). Clinical trials are more prompt to be denounced when there is damage to patients. One case that has world repercussions was the physician Luis Garre of Pedro Mallo Navy Hospital in Argentine: when carrying out a clinical trial with the experimental drug cariporide for Aventis Pharma in 1997 and 1998, he falsified informed consent documents of patients and their electrocardiograms with the only aim to include them into the research protocol and receive the money allocated by the Pharmaceutic. Due to this deceive, some patients died due to being assigned an inadequate prescription (Deyoung & Nelson, 2000). Something similar occurred in year 2000 with the clinical trial of drug Ketek (Telithromycin) from Sanofi-Aventis for infections in the respiratory tract. Researchers falsified data to include patients in the trial. Even though, the drug was approved for public distribution using Latin American data, eventually its use was prohibited in

2007 after the occurrence of 12 death related to the drug used (Weyzig & Schipper, 2008).

Some studies use social inequalities as resource to select study populations base on easy access and management, without taking into consideration the damage produced due to their vulnerability, with the only purpose to publish and obtain financing (Mondragon, 2007). In Chile, in 2003, a study in Pascua Island did not respect informed consent by not revealing the true research aim, to find genetic markers for macular degeneration. This was a vulnerable of native elders, from which blood samples were taken with the excuse of health reasons (Fajreldin, 2010). In 2006, the project GENADIO, a collaboration between the University of Glasgow (Scotland) with the Chilean Universities of Chile and Concepcion, extracted blood samples from mapuche indigenous community to study the prevalence of obesity and diabetes, but the project was not approved by regional authorities and there was not an adequate informed consent procedure, without the guaranty to prohibit genetic manipulations of Mapuche DNA. This fact was denounced by the Mapuche Parliament (Parlamento de Koz Koz, Panguipulli February 20, 2008).

Mechanisms to promote research integrity

Promoting a culture to enhance good research practices

Training in research ethics should be required for scientists carrying out research in order to safeguard from research misconduct and affirm the values of accuracy and objectivity, avoiding biases. In order to prevent from research misconduct scientists must be train in honesty and social responsibility, while institutions must promote an environment or culture adequate for responsible conduct of research. When there is no culture of transparency or of confronting moral misbehaviors research misconduct tent not to be reported. In general, honesty, efficiency and objectivity are highly valued by scientists (Steneck, 2006), but institutional pressures for publishing and the ambition to scale positions may influence research misconduct.

A culture promoting research integrity must show honesty, accuracy, respect for research participants and environment, respect for the different roles in research, care in the use of public resources for research, precise and responsible information of research results including those contrary to own hypothesis, information on possible risks and adverse events. Furthermore, researchers must develop a culture of social responsibility in attitudes and values taking into consideration the implica-

tions of their research for society and environment, especially when there is risk of bad use of information, products or technology generated, which could produce damage instead of progress. Researchers must accept their responsibilities and to practice and promote safe procedures.

The development of this culture depends on educational, social and political factors, such as: values and attitudes transmitted, enough financing and support for ethics of research training, a system for monitoring, regulations to protect research subjects, transparency and accuracy in reporting research results, a positive work environment (Rodriguez-Yunta, 2005).

Norms to maintain responsible conduct of research

Institutional management norms can promote responsible conduct of research, minimizing the risk for damage. Every research Institution should have norms for staff establishing a management structure according to National laws, regulations and guidelines to guaranty quality, security, privacy, risk management, resources management and respect for research subjects. The structure must specify roles, responsibilities and liabilities of all involved in research, with provisions about data and research materials retention.

In order to consider how much time data and research materials must be maintained, researchers must take into account the professional standards, legal requirements and contractual agreements. Other researchers or institutions may need the data or materials or it may occur a demand for research misconduct or be available for auditing. In general, research data must be available for other researchers upon request unless they are protected by confidentiality or privacy rules.

In collaborative research between Institutions there must be norms for agreements on financial management issues, intellectual property, authorship and publications, scientific ethical review approval, property of data and equipment.

Institutions must have norms to protect intellectual property rights and for assigning these rights appropriately, be the Institutions, researchers, trainees or sponsors. Furthermore, there must be institutional norms to guide researchers and institutional staff in data and primary materials management, including storing, access property, confidentiality agreements and restrictions. In order to guaranty confidentiality, Institutions most count with safe facilities to store research data and keep records. Confidential information must only be used in ways ac-

cepted by agreements. Computer systems must be safe, managed by staff that knows safe procedures in the web and access control measures. Electronic data must be kept indexed in a way that data could be recovered to avoid data missing. These norms must cover all possible situations in research management, including data transfer to other researchers or Institutions or abroad. Property depends on financial agreements, but in general research results are the property of the Institution who carried out the study, unless there are agreements with sponsors or other institutions.

Institutions must have written norms about the management of conflict of interest to prevent biases in research results. Full disclosure of conflicts of interest must be requested. Generally, withdrawing from the process which may be influenced by conflicts of interest is recommended, but supervision is also an option.

Monitoring proceedings

Institutions must count with ethical supervision mechanisms. One way consists in empowering ethical review committees to carry out monitoring activities, which requires capacitation of the members and some budget for expenses incurred. Another way is to hire specialized groups for monitoring. Currently, most institutional ethical review committees do not carry out monitoring visits due to lack of financing and lack of time and capacitation of members; they only carry out ethical review of proposals before the initiation of the study and receive information on adverse events and of changes in research procedures (Leon-Correa, 2011). There is need for professionalization and accreditation of scientific ethical review committees. In the countries where there is regulatory agency, this only audit a few clinical trials, but there is no auditing for other type of research.

Monitoring activities include:

- To supervise the progress of the study.
- To guaranty that research staff knows their obligations and the regulations applied to the study.
- To guaranty that research staff fulfills research protocol.
- To guaranty that research site has the necessary equipment and materials to carry out the study.
- To supervise the process of informed consent and appropriate respect for research subjects.
- To guaranty the accuracy of data and their safety to safeguard confidentiality.

Mechanisms of support to affront demands of research misconduct

In order to promote research integrity in Latin American Institutions, institutional support mechanisms must be provided so that allegations be managed in a fair way. Misconduct allegations must be verified and integrated into institutional mechanisms with written norms of procedures to present and verified them. The example of developed countries which count with norms may serve to develop a local model. Specifically, the United States has a well developed system. The Health and Human Services Department developed in 1992 the Office of Research Integrity (ORI) to manage research misconduct demands and to promote integrity and responsible conduct of research. ORI provided guidelines for norms and procedures to respond to allegations to help research Institutions (http://ori.hhs.gov/html/policies/model.asp). The National Institute of Health requires training in protection of research subjects to all researchers that present protocols. Regulations provide norms for reporting research misconduct and for disclosing conflicts of interest.

Latin American Institutions should create offices where allegations could be presented with staff to verify them and for maintaining records of processes carried out, as well as counting with a legal advisor to help prepare necessary evidence and for questioning witnesses. The officer designed for verification must not have conflicts of interest and have authority to obtain relevant documents having experience on different types of denounces. There must be a mechanism for disciplinary actions in case allegations are verified. The person denounced must have the opportunity to defend himself and the possibility of appealing. The allegation, the findings of officers when verifying the claim and the reasons to take disciplinary actions must be stated by writing. Disciplinary actions must be taken in agreement with institutional requirements for employees. Disciplinary actions may vary from simple fines to expulsion from the Institution. It is possible that public records of research findings disseminated, including publications, may need to be corrected if research misconduct affect them. If there is not found a base for the allegation, the Institutions must work in restoring the good reputation of the denounced researcher.

Furthermore, Institutions may appoint advisers in research integrity to help staff members to decide whether a particular conduct merits to make an allegation. Advisers must have familiarity with accepted research practices, knowledge on institutional policies and management structure and analytical skills. An adviser may recommend whether an allegation may be made to an Office of Research Integrity, refer it directly to the person denounced or refer it to an institutional authority or

consider it a problem not related to research misconduct. Advisors may help to write the claim if it is necessary.

Conclusion

Clearly, to compromise with research integrity requires to build an institutional framework non existing in most Latin American Institutions today, which needs financing in order to avoid depending only in the good will of researchers. The need to finance ethical supervision is a difficult decision to encompass, but in the long rate it may be argued that a framework which guarantees accuracy in science save time and money and increase credibility, avoiding to repeat flaw experiments. This is a reality which must convinced institutional and governmental authorities.

It is paramount to establish high standards in research integrity and monitoring mechanisms in Latin American Institutions to have an accurate science and for transferring research results to public policies, health promotion and social progress. Some challenges which must be focused in order to promote research integrity are:

- To design transparency indicators on research integrity in research Institutions and a methodology to evaluate those indicators.
- To introduce a training curricula for researchers and university students in topics of responsible conduct of research.
- To promote a culture which allows to minimize risks of research misconduct.
- To develop monitoring mechanisms.
- To create webs for disseminating ethics of research programs.

Research in Latin America requires not only ethical guidelines and codes, but mainly a true compromise with accurate science, where subjects, researchers, sponsors and scientific ethical review committees are respected.

References

Aultman, J. M. (2013). Abuses and apologies: Irresponsible conduct of human subjects research in Latin America. *Journal of Law, Medicine and Ethics, 41*(1), 353–368.

Committee on Publication Ethics (COPE) (2000). Guidelines on good publication practice. *Clinical Oncology, 12*(4), 206–12.

Deyoung, K., & Nelson, D. (2000). Latin America is ripe for Clinical Trials and Fraud. *The Body Hunters Washington Post.* December, p. A01 [accessed May 2015]. Retrieved from http://www.washingtonpost.com/ac2/wp-dyn/A31027

Fajreldin, V. (2010). Bioethical issues in biomedical research involving Chilean indigenous populations. Acta Bioethica, 16(2). Retrieved from http://www.revistatrabajo.uchile.cl/index.php/AB/article/view/15626/16096

Guillen Fonseca, M. (2006). Información. *Revista Cubana Enfermeria* [online], 22(1), 0 [accessed 28 Aug 2013]. Retrieved from http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S0864-03192006000100002&lng=es&nrm=iso

Jaffer, U., & Cameron, A. E. (2006). Deceit and fraud in medical research. *International Journal of Surgery, 4*(2), 122–126.

Leon-Correa, F. J. (2011). *Ética clínica y comités de ética en Latinoamérica* (pp. 1–327). Santiago de Chile: FELAIBE, Fundación Ciencia y Vida [accessed Jun 2016]. Retrieved from http://www.bioeticachile.cl/felaibe/documentos/libros/congreso/FELAIBE%20Comites.pdf

Mondragon, L. (2007). Ética de la investigación psicosocial. *Salud Mental, 30*(6), 25–31 [accessed Sep 2015]. Retrieved from http://redalyc.uaemex.mex

ORI, Gallup Organization (2008). Final report: Observing and reporting suspected misconduct in biomedical research [online; accessed 16 Aug 2016]. Retrieved from http://ori.hhs.gov/sites/default/files/gallup_finalreport.pdf

Pimple, K. D. (2002). Six domains of research ethics. A heuristic framework for the responsible conduct of research. *Sci Eng Ethics, 8*(2), 191–205.

Reyes, H., Palma, J., & Andersen, M. (2007). Ética de las publicaciones en revistas medicas. *Revista Médica de Chile, 135*(4), 529–533 [online; accessed 28 Aug 2013]. Retrieved form http://www.scielo.cl/scielo.php?script=sci_arttext&pid=S0034-98872007000400017&lng=es&nrm=iso

Rodriguez, E, & Lolas, F. (2011). The topic of research integrity in Latin America. *Bioethikos, 5*(4), 362–368.

Rodriguez Yunta, E. (2005). Cultura ética e investigación en salud. *Acta Bioethica, 11*(1), 11–22 [online; accessed 27 Aug 2013]. Retrieved from http://www.scielo.cl/scielo.php?script=sci_arttext&pid=S1726-569X2005000100002&lng=es&nrm=iso

Silva Hernandez, D., Llanes Cuevas, R., & Rodriguez Silva, A. (2007) Manifestaciones impropias en la publicación científica. *Revista Cubana Salud Publica, 33*(4) [online; accessed 28 Aug 2013]. Retrieved from http://scielo.sld.cu/scielo.php?script=sci_arttext&pid=S0864-34662007000400009&lng=es&nrm=iso

Stenek, N. H. (2006). *Introduction to the responsible conduct of research* [accessed May 2015]. Retrieved from http:/ori.hss.gov/education/products/RCRintro/

Thompson, D. F. (1993). Understanding financial conflicts of interest. *New England Journal of Medicine, 329*, 573–576.

Vastag, B. (2006). Cancer fraud case stuns research community, prompts reflection on peer review process. *Journal of the National Cancer Institute, 9*(6), 373–376.

Weyzig, F., & Schipper, I. (2008). SOMO in collaboration with Wemos Foundation, briefing paper on ethics in clinical trials. *Examples of Unethical Trials,* 1–16.