

Research Ethics Committees and scientific publications

The United Nations' General Assembly adopted and proclaimed the Universal Declaration of Human Rights once the Second World War and its concomitant horrors had ended, stating in article 27 that, "Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits," and, "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." The World Medical Association's Declaration of Helsinki may be added to the foregoing; it stated that a research proposal's protocol should be submitted to an independent organ for its, "consideration, comment, guidance and approval," thereby giving birth to what is known today as a "Research Ethics Committee" (REC).

Such declarations made it implicit that doctors, health care professionals and scientists are obliged to place any type of scientific or technological process at the service of the people. As this topic is of interest for our authors, reviewers, readers and researchers, we have decided to dedicate this issue's editorial to this crucial aspect regarding research, hoping that it will be of great help to all. A complementary bibliography has been included at the end of this editorial for those interested in a broader approach to the topic.

Most United Nations Organisation for Education Science and Culture's (UNESCO) member states have welcomed the creation of bioethics committee at national, regional and/or local level, followed by institutional level; today, universities, hospitals, research centres have formed their respective bioethics committees, these being responsible for an ongoing, systematic approach to ethics in all its dimensions, as well as formulating policy for future implementation. Their interdisciplinary formation involves experts in different areas working towards resolving certain moral dilemmas related to bioethics.

UNESCO has divided bioethics committees into 4 types: regulatory and advisory, health care professionals' associations, health care ethics and REC (UNESCO, 2006). The first two provide guidance and orientation for public functionaries and participate in adopting scientific and health care policy within a national context, health care ethics committees deal with clinical practice and associated problems whilst REC examine experimental protocols involving human beings and animals' participation.

An activity so dynamic and changing as research requires that the regulations governing its development should be clearly understood, thereby forming the basis for REC committees to perform their functions. The main objective for such committees is to protect those participating in biomedical research, whether they be humans or animals, in turn leading to biomedical, behavioural, biological and epidemiological knowledge being acquired which could be extrapolated regarding pharmaceutical products, vaccines and instruments.

REC operability has played a great part in influencing what has become known as good research practice (GRP), having great importance in experimental protocols gaining approval and then becoming accepted or rejected by a scientific publication. Journals today, whether in their printed or electronic version, orientate researchers concerning the need to ensure GRP; some have gone further by demanding that an article be accompanied by the number of the particular REC minutes approving an experiment protocol when such article is being sent for consideration for publication. One of the responsibilities which an REC is duly qualified to undertake concerns acting with respect concerning a regulatory framework and current legislation, as well as acting in good faith regarding applicants and the community.

Each country has been adjusting its regulatory framework in the light of the above. Colombia is no exception; decree 1101/2001 created an inter-sector bioethics committee and named its members, resolution 008430/1993 established scientific, technical and administrative regulations for health-related research and



Law 84/1989 led to the Colombian statute for the Protection of Animals becoming adopted, some contraven-
tions being created/defined and regulating that referring to pertinent procedures and competency. Resolution
2378/2008 led to GCP being adopted by institutions engaged in research into drugs involving human beings.

It should be stated that all researchers are bound (by law) to be aware of current regulations and any new
modifications made to them, as their knowledge will depend on publications arising from their research having
a greater or lesser chance of being accepted. Consequently, *Orinoquia* is committed to promoting GRP and
expects to raise the level of its articles in the future.

Bibliography

Council of Europe. The Guide for Research Ethics Committee Members. Reviewed 12/03/2013 at http://www.coe.int/t/dg3/health-bioethic/activities/02_biomedical_research_en/Guide/default_en.asp

Manzini JL. Declaración de Helsinki: Principios éticos para la investigación médica sobre sujetos humanos. *Acta Bioethica*, 2000; 6, 2:321-334

World Health Organisation. Operational Guidelines for Ethics Committees evaluating Biomedical Research. Translated in to Spanish by DafnaFeinholz-Klip, IN Per, México 2000.

Ripollés SA. Comités de Bioética: Nuevos desafíos para la Inclusión de la Diversidad Funcional. *Rev Medicina y Humanidades*, 2011; 3:1,2:59-75

UNESCO, Guía No 1 Creación de los Comité de Bioética, 2005

UNESCO, Guía No 2. Funcionamiento de los Comité de Bioética: Procedimientos y Políticas, 2006.

Agustín Góngora Orjuela
MV. MSc. Dr.Sci, Editor *Orinoquia*

