

Role and Responsibility of Research Stakeholders in Promoting Ethical Health

Research in Ethiopia

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With the objective of development of quality and consistency in the ethical review system for biomedical research, complement existing laws regulations and practices to serve as bases upon which Ethics Committees (ECs) could develop their own written procedures, the use the guideline in developing, evaluating, and progressively refining Standard Operational procedures for Ethical review of the biomedical research is mandatory. Hence the role of stake holders at various levels of participation in the research should contribute to safe guarding the dignity, rights, safety and well being of all actual or potential research participants. The goals of research while important should never be permitted to over ride the health well being and care of research participant. Hence stakeholders at all levels of responsibility and research implementation should take into account the principles justice create awareness on research Ethics Guideline among Stakeholders and research collaborators.

ECs should provide independent, competent, and timely review of the ethical considerations of proposed studies, need to have independence from political institutional and professional and market influences and need to demonstrate competence and efficiency in their work. The review system should check on if the proposed research qualifies for scientific merit and ethical standards before the commencement of the research and ensure the regular evaluation of the ethics of ongoing studies that receives a position decision. Establish system of ethical review to ensure broadest possible coverage of protection for potential research participants and maintain highest quality of science and ethics in biomedical research. To this effect system of ethical review should be strengthened through establishment of ECs at all levels (national, institutional and local levels) and should be independent, multidisciplinary multi-sect oral and pluralistic in nature requiring administrative and financial support to ensure efficient communication mechanisms in place between national, institutional and local ECs. To this effect, investigators stakeholders, investigators, host institutions and donors /sponsors monitor through ECs at various levels accountable and have to ensure that study design is

scientific and ethical high ethical requirements are met pre during and post implementations of the study. Experiences from a number of health/ biomedical research have shown that “quite often as investigators we feel our obligations end when the study is over and the same often applies to study sponsors but what is most important is post-trial obligations to participations, investigators, communities health and other, research institutions, peers scientific community and sponsors at the end of the study. Who should bear these obligations is most important. Hence investigators need to adhere to basic principles of Ethics & International Guidelines) this including the question of authorship, authority, adaptation law, implementation including proper dissemination of study results to beneficiaries of the study. If a study has to meet appropriate scientific and human ethical standards. Hence, stakeholders need to adherence to basic principles of Ethics & International Guidelines) this includes question of authorship, authority, adaptation law, and implementation.

In Summary, "Beyond (and before) international guidelines on health research lies ethical principles formulated in terms of human dignity. Disease and suffering are fundamentally and essentially an affront to dignity of persons. Ethics in biomedical research is not a question of asserting the right principles but the question of recognizing and addressing the moral dilemma's inherent in our practices". The way forward with regard to role /responsibility of stakeholders is to ensure that the study results are properly disseminated, ensure that guidelines, principles of and related materials sent by the secretariat of NERC reach end users and are expected to report any breach of ethics to the National, Regional of Local/Institutional ERCs for action if they do not comply with Nationally/internationally recognized ethical guidelines principles and legal requirements Popularization of National Guideline and awareness by stakeholders at all levels on the elements of ethical review through workshops, training of trainers on ethics and eventually train all stakeholder involved in health research and capacity building of Ethical Review Committees is the way forward.

Int.Guidelines...

1. Nuremberg code of Human rights (1997)
2. The World Association Declaration of Helsinki (2000)
3. CIOMS. Int. guidelines for Biomedical research Involving Human Subjects (2001),
4. The WHO (1995) and ICH (1996) guidelines
5. The WHO 2000 Operational guidelines for ECs2000BMR
6. The WHO 2000 Operational guidelines for Surveying and Evaluating Review practices