

Contextual challenges in research ethics and quality of research

Gehanath Baral

Professor of Obstetrics and Gynecology, Clinical Research Associate
Nobel Medical College, Kathmandu University, Nepal

Received: Sep 1, 2020

Accepted: October 16, 2020

ABSTRACT

Context, issues and challenges are different in different set up globally. Research and ethics appear to be challenged by ignorance, scarcity, formality and business. Non-research beaurocratic planning and management results in ethically challenged substandard product as the ethics and procedures are not legally binding. Structured training, capacity build up and resource mobilization would be the preliminary solutions.

Keywords: challenge, ethics, issues, research

Citation: Baral G. Contextual challenges in research ethics and quality of research. Nep J Obstet Gynecol. 2020;15(31):6–7. DOI: <https://doi.org/10.3126/njog.v15i2.32894>

CONTEXT

Biomedical researches are expensive and require strict regulation to protect the rights of research participants at the study site. Research regulations may not be well developed or are in an initial phase in the low income countries. Research culture as well as the expertise is at a low level.

ISSUES

To persuade authorities the value of research will be the first barrier to start and to help people by research only may not be convincing if there is no direct advantage to them as they have some degree of deprivation even in the basic health facility. If the research outcome is not reasonably beneficial to the population at the study site in future that would be mere exploitation of the unprotected people. For example, if an expensive anticancer drug is on trial and that drug would not be available at an affordable cost to that population even if the outcome was good, that type of research is not justifiable. There will usually be blame from ignorant people and yellow journalists projecting even good work as an experiment for nothing; this happens not only in research but in usual clinical treatment as well.

The strength of ethical committees and technical reviewers is at beginners' level that predisposes the participants in vulnerable states and the quality research compromised. There will be a risk of biased and inconclusive outcome despite reasonable effort that makes people purchase risk unknowingly. Inappropriate use of ethical principles and substandard reviewing processes would be detrimental. The hierarchical relation to the research participants, lack of controlling confounders, incoherent research design with the objective, ill-defined sampling frame and conceptual framework, and use of un-validated research tools are the areas to address by the global research community.

National regulatory authority owns its own research guideline based on and copied from the global resources.¹⁻⁴ The problem arises as the regulatory post is appointed disregarding the expertise and the undue pressure by position or ignorance outweighs the scientific decision making. Business driven projects and programs make public deprived of research benefit and it extracts benefit to outsiders. Undue privilege taken by authority by putting pressure on regulatory procedure has become the political dynamics.⁵ Then the end result would degenerate to the documentable formalities. For the public interest,

CORRESPONDENCE

Gehanath Baral MD
Editor-in-chief, NJOG
Email: njogeditor@gmail.com; Mobile: +977-9851131860
Email: gehanath@gmail.com; Mobile: +977-9841228829

the science and research should get rid of those obstacles for the benefit of people and society.

SOLUTION

Awareness, training, lobbying and scientific capacity building would be the solution. The mechanism should be ascertained to keep the ethics committee practically independent with full scientific authority. There should be a systematic program for training a technical reviewer for the review process; to researchers on ethical principles, research design, good clinical/manufacturing/laboratory practices and relation of research to people and society. Awareness and orientation program to be set for

community leader and authorities on biomedical research and development. Enabling researchers, sponsors and regulatory authorities answerable to people and society in every aspect of participants' right, societal need and human value is the need of the day. Incorporate research ethics and moral values in school/college curricula.

CONCLUSION

Research is the scientific process which can be a complex business as well as a simplified product to the society. Research ethics should be institutionalized for the benefit of society and people.

REFERENCES

1. Bhatt A. International Council for Harmonisation E6(R2) addendum: Challenges of implementation. *Perspect Clin Res.* 2017;8:162-6.
2. Hamrell MR, Mostek K, Goldsmith L. Monitoring of clinical trials -Are remote activities helpful in controlling quality? *Clin Res.* 2016;18-21.
3. International Council for Harmonisation Harmonised Tripartite Guideline. The extent of population exposure to assess clinical safety for drugs intended for long-term treatment of non-life-threatening conditions E1. 1994;version 4. [Updated 27 october 1994]
4. NHRC. National Ethical Guidelines for Health Research in Nepal. Kathmandu. Nepal Health Research Council (NHRC), Ramshah Path, Kathmandu, Nepal; 2019.
5. Helmke G, Levitsky S. Informal Institutions and Comparative Politics: A Research Agenda. *Perspectives on Politics* 2004;2(4):725-40.