

International Collaborative Research

A Guide for Ethics Review Committees

1. Concerns

As globalisation increases, so does international collaborative research. Concerns have been expressed about the ethics of this, particularly of clinical research being performed in developing countries under protocols originated in a developed country and the application of different ethical standards. Safeguarding the intellectual property rights (IPR) of indigenous peoples is another concern.

*Collaborative research could be research carried out by researchers of a number of institutions or independent researchers within one country or from a number of countries. In such a situation one researcher or institution will play a lead role and others a subordinate one (See #3 for definitions). These guidelines are drawn up especially for **international collaborative research** between a lead researcher elsewhere and workers in Sri Lanka. However, the provisions of these guidelines could be usefully applied to the conduct of collaborative research in Sri Lanka itself.*

2. Biomedical ethical principles

In international collaborative research, as in any other research, the four principles of ethics apply. These are autonomy, beneficence, non-maleficence and justice.

3. Collaborators

Those taking part in international collaborative research are **host country researchers**, by whom the data for research is collected; **collaborating country researchers**, from whom the research proposal originates, research participants (the subjects of the research) and their communities.

3.1 Prior agreements

Before submission of a collaborative research proposal to a Research Ethics Committee, a clear agreement on all aspects of the research between the host and collaborating country researchers must be in place. These include intellectual property sharing, management of the research process, data management, research outputs, division of responsibilities, finances, spreading of benefits and burdens, and any other appropriate aspects. Particular attention should be paid to the following points:

- i. The fate of data must be agreed.
- ii. The fate of any research specimens must be agreed.
- iii. Publication strategy must be agreed.
- iv. An ombudsman to settle disputes should be acceptable to all parties.
- v. There should be agreement on the nature of all benefits and their distribution.

i & iii: Ownership of data and right of publication should lie with the researcher/s who collect that data. In a collaborative multicenter study the data will necessarily have to be pooled for publication of that study. Notwithstanding such publication, there should be no bar for a researcher from Sri Lanka to publish data collected by him that is of relevance to this country. This right of publication exists even if a research study is initiated or sponsored by a commercial organization on a collaborative basis.

ii: *When specimens are sent to a researcher in the collaborating country as part of a research study, there must be a clear understanding that those specimens should be used only for the purpose described in the research proposal for which approval was granted.*

iv: *There is no compulsion to have an ombudsman for all studies.*

4. Principles

4.1 Commencement of research

- i. No research shall be undertaken until Research Ethics Committees of all collaborating institutions (or independent committees where there are no institutional committees) have given ethical approval to the research. Before granting ethical approval, such a Research Ethics Committee shall:
- consider whether the study findings can, and will be incorporated into the local healthcare system;
 - ensure that the proposed research is benevolent; and
 - consider the newness of the proposed research.

It may not always be possible for the study findings to be incorporated at once into the local healthcare system on account of expense, lack of facilities or other factors. The Committee should ensure that research of potential benefit to mankind is not hindered for this reason, provided it is satisfied that the research participants are not being exploited by a study that excludes participants from the collaborating country without valid reasons.

- ii. No research shall be undertaken after ethics approval of a protocol by a Research Ethics Committee until there is proper informed consent from participants, their families and communities according to local customs. This consent shall:
- be obtained in a manner that can be understood by the participants;
 - include full disclosure of the aims and methods of the study, benefits and risks, confidentiality methods and commercial implications;
 - be in written form.

It is essential that information sheets and consent forms be in a language understood by the research participants. It is also essential that the information be couched in words and phrases that they are able to comprehend. Information sheets (in English) designed for distribution to participants in developed countries, when translated into Sinhala and Tamil may be too technical or detailed for many Sri Lankan people. In such instances, these should be reworded and simplified to make them intelligible in a local setting.

4.2 Exploitation

- i. There shall be no exploitation by one institution of another, or of any investigator, research participant or community.
- ii. Intellectual property rights of institutions, investigators, participants and communities shall be respected, shared and acknowledged according to clear agreements before commencement of research.
- iii. There shall be equitable compensation of institutions, investigators, participants and communities. This shall be beyond pure financial compensation.

- iv. Institutions and investigators have a moral obligation to assist indigenous peoples, traditional societies and local communities to protect their knowledge and resources.
- v. Institutions and investigators have a moral obligation to respect what is sacred and secret by tradition.
- vi. No research shall be performed in a host country without local research collaboration in the design and conduct of that research.
- vii. Biological samples should only be used for the purpose stated in the research proposal and not for any other purpose.
- viii. Such samples **may** be stored **provided** such intention was declared in the research proposal together with reasons and ethical approval was given.

The subjects of biorepositories and the ethics of tissue storage and trans-boundary transfer of genetic material in the Sri Lankan context are still being discussed. Until guidelines are defined and accepted, Ethical Review Committees should act with caution to safeguard the interests of local individuals and communities, and at the same time ensure that research is not hindered.

4.3 Justification

- i. There must be clear justification of why Sri Lanka was chosen as a host country and also why the particular institution(s), researchers, research participants, community etc were selected.

Ethical Review Committees should satisfy themselves that the research proposal under consideration has not been designed to exploit any actual or perceived difference in national or institutional laws or ethical standards between the collaborating and host countries. They should also satisfy themselves that the institutions are adequately equipped and researchers qualified to undertake the work and that the communities in which the research will be undertaken will not be adversely affected or disadvantaged by that research being done.

- ii. Unless there are compelling and acceptable reasons, no research shall be done in a host country that could just as easily be done in a collaborating country.

*In multicenter collaborative studies where data is collected in the collaborating country as well, this caution will not apply. However studies, whether multicenter or not, where **no** data collection is made in the collaborating country should be scrutinized to justify the reasons for this.*

- iii. If there are no potential benefits to the community being researched, ethical approval should be withheld **unless** the ERC is satisfied that the potential advance in scientific knowledge outweighs any burden or hardship (e.g. pain and discomfort of venepuncture) that the research participants may experience.
- iv. Those who are involved in international research should have some understanding of, and be sensitive to, the social, economic, and political milieu in which the research is taking place. This will include protection for research participants who are subject to systematic deprivations through poverty and other threats to freedom.

4.4 Benefit to host country

- i. No research shall commence without agreement between the host researchers and the collaborating researchers. In this agreement the development of material and human research capacity in the host country should be addressed.

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- ii. Coercion and inducement of research participants are unacceptable.
- iii. There should be benefits where relevant - other than pure financial gain - to the community in which research is undertaken, such as access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.
- iv. There must be a clear and fair system of compensation for research injury with clear lines of responsibility and guidelines on how to obtain this. GCP Guidelines for South Africa give these.
- v. Participants should continue to be provided with the best possible available care/treatment. Care must be taken to ensure that any existing disparities are not more deeply entrenched by inappropriate deflection of local human or material resources away from the healthcare system during, or connected with, the research project.

References:

Guidelines on Medical Ethics for Research General Principles, Health Knowledge Network (SAHealthInfor). SAHealthInfor is a Government initiated project of the South African Department of Arts, Culture, Science and Technology.
www.SAHealthinfo.org

History

Draft 2: MF Start: 9.8.03

Draft 3: Amendments of Ethical Review Committees' Forum of 29.8.03

Draft 4: Final version accepted ERCF 5.12.03

Amendments:

#1 19.2.2004. Proposed by Eugene Corea. To clause 2 (title); 4.1 (i) add bullet; 4.4 (v) amend wording.

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