

PGI Guidelines for preparing Ethical Considerations

I. Research proposals, Theses and Papers

The Ethical considerations constitute a critically important component of all theses, proposals and papers. The Faculty members are requested to carefully go through the protocols to incorporate the various issues in their submissions. **The Ethical Considerations of the Proposal should focus on the issues relevant to the proposal rather being general or broad as if picked from the web-sites**

The following issues are important to discuss under this heading:

- Essentiality and justification for the study
- Voluntariness, informed consent of study-subjects
- Non-exploitation of subjects- both patients and healthy people
- Privacy and confidentiality
- Safety, Precautions and Steps for risk minimization
- Costs of the tests- who to bear? Source of funding must be clearly defined.
- Appropriate involvement of investigators/ co-investigators from other departments with expertise or other stakes in the study.

It may be specifically pointed out that the facts of sponsorship especially with reference to the sponsored Clinical Trials by other sources must not be hidden. Surrogate ethical clearance sought from the Ethical Committee in itself is a bad practice.

Proposals for Retrospective studies/ analyses of pooled and stored data

It is a welcome idea to produce meaningful research from cumulative data. But the stored data in the hospital or in a laboratory generally belongs to multiple faculty members of one or more departments, at one or the other time. Each such proposal has its own characteristics and ownership issues. It is required that each such proposal should be prepared with a separate description of such issues. **A Resolution of agreement signed by the Investigator and 3-4 other Senior Faculty members including the Head of the Department/Units should be submitted.**

II. Guidelines on Authorship of papers, project reports (etc.)

Most good journals these days require clearance of the paper being submitted, by an Institute Review Board (IRB/Ethics Committee). Authorship is a very important issue on stored data, retrospective studies, pooled data from multiple sources, collaborative studies and those involving other conflicts of interest. It is therefore important to adhere to ethical practices and guidelines.

The various intellectual works produced at the institute include the papers, project reports, images and other products in the paper or electronic media which are either published or prepared for other uses. Authorship of all these works involves giving credit as well as assigning responsibilities. All the authors become jointly responsible for the contents, including the errors and the omissions. It may be pointed out that unnecessary inclusion of a name as a co-author does not really add to one's achievements or merits. On the other hand, it may sometimes become a liability.

All the three following fundamental principles should be met while considering authorship:

1. Substantial, intellectual contribution to the work. (Any other substantial contribution should be acknowledged).
2. Participation in the writing, reviewing the drafts and approval of the final version.
3. Precise contribution made to the work should be definable and justifiable.

What is intellectual contribution?

1. Conceptualization: Identifying the issues and hypothesis.
2. Performance of experiments and data collection.
3. Conducting analysis and interpreting data.
4. Reviewing the literature, assessing the accuracy and relevance of data and writing a significant part of the paper.
5. Involvement in data collection, verification, supervision and guidance, analysis and writing throughout the study or at least form most of the study period.

The following participations/contributions do not necessarily constitute a right to authorship, unless there is specific agreement to the contrary:

1. Work done by an employee in course of his/her employment for a specific purpose.
2. Laboratory data: Routine diagnostic or treatment, investigations in a laboratory for patients, unless: i, the tests are carried out for purpose of the study; ii, a significant laboratory data is being analysed and reported; iii, the laboratory data constitutes or forms the subject of the study; iv, Multiple laboratory data from a single laboratory are taken and highlighted; v, Even single data highlighted in case report.

3. Clinical data Routine registration of a patient/s in an OPD/Clinic/ward does not constitute the right to authorship, unless i, the work is based on one or more of these patients or from the material from these patients including the stored samples ii, or a study is being done with reference to a clinical issue. (eg. on clinical patterns, therapy, prognosis and natural history).
4. Mere provision of funds, facilities or administrative supports
5. Sole participation in data collection.
6. Being Head of Department, does not qualify to be author. Scientific contribution is required for authorship.
7. Authorship distribution should not be a charity, it should be earned.
8. Preservation of raw data is the responsibility of the primary author in the department.

Order of authorship

The lead author is generally the person who took the lead and contributed maximally. The subsequent order does usually not speak of the respective contribution of individual authors. This could be either alphabetical in order or as agreed upon by all the co-authors.

Authors should specify in their manuscript a description of the contributions of each author.

Multi centre group or collaborative studies The group should identify the individual/s who accept direct responsibility for the manuscript. These individuals should fully meet the three principle criteria defined above.

Guidelines

1. The issue of authorship should be frankly discussed very early in the course of the work and an mutual decision should be made in writing.
2. The first or the senior author should generally communicate with the journal, editor and others related to the publication. He/she will take all the responsibility as the primary author. In case the first author is a student in the department, the corresponding author could be the leader of the group performing the study.
3. The first or the corresponding author should be able to speak on and defend the paper.
4. **Students theses:**

M D/M S/M Sc: The student is the primary author of paper on his work. Sometimes a student's work is only a component of a larger work being done by an investigator.

In those situations, each student, whose significant work has been included, may qualify as a co-author.

As per current practice, if the student fails to write and submit his work within a year after completion, the supervisor is free to write the same and include the student as a co-author.

PhD theses The student retains his/her right over work "as the first author". In case, he/she fails to write even after one year of completion, the supervisor can write himself/herself or assign the writing to some one else, (but keep the student as the first author).

5. Dispute over authorship should be best settled at the local level by the authors themselves or with the help of the department head. If local efforts fail, the Dean of the Institute should be informed. It does no good by directly writing to the journal's office/editor.
6. If any complaint is to be sent to any Editor of a journal, it might bring down the reputation of the institution. The person should consult first the Dean/Director before writing to the Editor.

Source documents

1. Morris R et al. International society for medical professionals position statement: the role of the professional medical writer. *Current Medical Research & Opinions* 2007, 23: 1837-1840.
2. Smith R. Authorship is dying: long live contributorship. *BMJ* 1997; 314: 992.
3. Davidoff F et al. Sponsorship, authorship and accountability (ed). *Ann Int Med* 2001; 135: 463.
4. Canadian Alliance for Health Research Authorship Guidelines (June 2004).
5. Authorship guidelines Faculty of Medicine, Harvard University (www.hm.harvard.edu).
6. Laine C et al. Clinical trial registration: looking back and moving ahead (ed) *Ann Intern Med* (Sept 2001).
7. Bates et al. Authorship criteria and disclosure of contributions. *JAMA* 2004; 292: 86-88.
8. Uniform requirements for manuscripts submitted to biomedical journals writing and editing for biomedical publications (www.icmje.org).

(Circulated on behalf of the Chair, Institute Ethics Committee for Institutional Proposals)