



PSG INSTITUTE OF MEDICAL SCIENCES AND RESEARCH
Department of Clinical Research and Bioethics
RESEARCH PROPOSAL FORMAT

Note

The Department of Clinical Research and Bioethics (DCRB) is aware of the fact that different funding agencies may have different guidelines/format requirements.

Where this is the case, the Principal Investigator should prepare the proposal in the required format, provided that the format used gives all or most of the details as contained in the PSGIMSR DCRB and IHEC Guidelines. The Principal Investigator must provide supportive evidence for the format used to the Secretariat.

Otherwise the PSGIMSR DCRB and IHEC guidelines and format should be followed.

The following is the recommended format for research proposals in which members of staff of PSGIMSR, Coimbatore are involved.

FIRST PAGE

[a] Title

This should be specific and precise. It should not be more than 2 to 3 lines long, and should indicate what one intends to do/find out.

(Type here)

[b] Investigators

- Full names, qualifications, academic titles of all the investigators, including trainees (Assistant lecturers or postgraduate students) and their institutional/departmental affiliation(s). The principal/main investigator (responsible for the work) should be the first one. If there are co-investigators these should be indicated as appropriate with their qualifications, academic titles and institutional affiliations.
- A brief (one side of an A4 sheet) up to date C.V. of each of the investigators and co-investigators should be provided.

Full Name	Qualifications	Academic title	Department	Institution

[c] Institution[s] under whose umbrella the research project will be conducted:

e.g. [i] The World Health Organization. [ii] PSGIMSR, Coimbatore. **or** [i] The Government of India. [ii] ICMR [iii] PSGIMSR, Coimbatore. Etc.

(Type here)



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SUMMARY DOCUMENT (please start on a fresh page; this may be compiled after the sections [e] onwards are completed.)

[d] Executive Summary

This MUST **NOT** BE MORE THAN TWO SIDED OF AN A 4 SHEET, and should include: -

1. **The type of research study**
(Type here)
2. **The problem [to be studied]**
(Type here)
3. **The objectives**
(Type here)
4. **Methodology**
(Type here)
5. **Expected findings and their dissemination.**
(Type here)



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RESEARCH PROPOSAL FORMAT

STUDY DETAILS (please start on a fresh page)

[e] Background information and introduction

This should include:-

- A review of the relevant literature. It should be most current. (Majority being in the past five to ten years at most).
- Locally available information - either published or not. It may include clinical or laboratory observations (e.g. increasing number of adult males presenting with head injuries at PSGIMSR during national holidays).

(Type here)

[f] Rationale/justification for the research project:

There should be a statement explaining why the researcher[s] feel the research project is important and therefore should be carried out, (Explain, defend, and/or prove that the current literature (if any) and current findings (if any) on the given problem are inadequate, outdated, and/or inaccurate).

(Type here)

[g] Objectives of the study

[i] Broad

The main issues that are being looked at/for. (E.g. to survey the socio-demographic and biometric profiles of patients with acute congestive glaucoma at PSGIMSR).

[ii] Specific

The specific issues that are being looked at/for. These must be measurable, either qualitatively or quantitatively and form a guide to the research methodology, data analysis and presentation of results.

Examples:-

1. To survey the age distribution of patients presenting with acute congestive glaucoma at PSGIMSR.
2. To survey the ocular biometry of such patients.

(Type here)

[h] Methodology

This should be very detailed as it is your guide on how the study will be done as well as the data analysis.

It should provide relevant information on the study design, e.g. case – control / prospective, descriptive / randomized clinical trial / double - blind clinical trial / cross sectional study, and should reflect exactly what the researchers intend to do.

(Type here)

ii] Study Place

Where the study is going to be conducted (e.g. ten secondary schools in Coimbatore District or PSGIMSR Hospital, Government Hospital, Coimbatore and PSG Vedapatti Health Centre). All the areas in/at which the survey/study will be carried out must be indicated.

(Type here)

iii] Study Population

- Who are to be included in the study or from which group[s] of people is the study group going to draw, e.g. Patients presenting with multiple pregnancy at PSGIMSR, in Coimbatore, India.
- Inclusion / exclusion criteria

(Type here)

iv] Study Period

The entire period of the study including preparation of the proposal, submission and approval, training (where necessary), pre-testing (of the questionnaire), data collection, data analysis, report preparation, and dissemination of the findings. If the study is in phases, each must be specified and the time for each given.

(Type here)

v] Sample Size

- There should be justification for sample size in both qualitative and quantitative research, and in the case of quantitative research, this should be supported by a statistical calculation with stated power and P value, and/or named expert statistical advice.
- Describe sample selection [e.g. every 10th client / randomized (and how so)] to demonstrate representativeness.

(Type here)

vi] Data Collection

Details on:-

- What information is going to be looked for / collected? (Include the pro forma/questionnaire).
- How that is going to be done (e.g. laboratory test, with provision of appropriate details).

Requirements for that, (e.g. reagents, culture media, blood samples and their relevant tests etc). It should include - who is going to do each of the aspects of data collection (e.g. who will draw blood, perform the tests, do the physical examination, interview the study group, etc).

(Type here)



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RESEARCH PROPOSAL FORMAT

vii] Data Management and Analysis

- Details should be provided on how the collected data is going to be managed, (e.g. coding)
- Details on data analysis, including the statistical tests to be used (e.g. regression analysis / student 't' test of significance) for specific associations.
- The computer package to be used in data entry and analysis (e.g. SPSS / EPI - INFO 6.0, etc), if any.

(Type here)

viii] Results Presentation

- What are the primary and secondary outcomes being assessed through this study?
- A brief explanation of the format of the results as they will be presented, e.g. Pie charts/ Histograms / Line graphs/ Tables

(Type here)

ix] Dissemination of the Results

- Indicate the person or institution to whom the report is going to be submitted and why.
- How does/do the investigator[s] propose to disseminate their research findings, such as;
 - attendance at local, regional or international conferences/seminars, workshops.
 - holding of a dissemination seminar/workshop.
 - publications in peer-reviewed journals etc.

(Type here)

N.B.

1. A copy of the final report and any published paper(s) or abstracts of papers read at conferences out of the research findings should be submitted to each of the following:-
 - DCRB or The PSG Institutional Human Ethics Committee (IHEC)
 - Library - PSGIMSR
2. Please ensure that the ICMJE Uniform Requirements for Manuscripts Submitted to Biomedical Journals guidelines are read and adhered to before planning any publication.
3. Please pay due consideration to intellectual property rights and data protection laws related to the material being disseminated.

[i] Ethical Considerations

- What ethical issues need to be addressed.
- How are they going to be addressed.

This should include protection of human subjects [client's rights] [Declaration of Helsinki - 1964]. If animals will be used there is need to consider the International Guiding Principles for Biomedical Research Involving Animals [WHO, 1985] and Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA).

- If using human tissues or other biological materials, refer to [Guidelines for the Opportunistic Procurement and Use of Human Tissue and other Biological Materials in Research, WHO 1991] and ICMR guidelines.
- The need for and type of consent must be specified, and how it will be obtained, e.g. - written consent, verbal consent. Please attach **information sheet** and **consent form and translated versions**.

(Type here)

[j] Possible Constraints:

- Gantt chart depicting the activities, person responsible and timescale for all study-related activities.
- Any envisaged problems in undertaking the study.
- How these will be addressed, by whom and when.

(Type here)

[k] Requirements:

Details should be provided on what the research project will require. e.g.

- personnel - and their individual roles
- training (of whom, why, when, where, by who)
- paper - for the questionnaires, reports, etc.
- transport - what form and for what (Field work/sample collection etc).
- reagents - which/how much of each and for what.
- drugs - which, how much of each, for what, their source(s).
- space - how that will be obtained, where, when.

(Type here)

[l] Budgetary Estimates

- Each line item should be quantified in monetary terms.
- The investigator should indicate the amount to be asked for and what the institution(s) under which the research project will be conducted, will contribute.

For example:-



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RESEARCH PROPOSAL FORMAT

(i) Personnel	Institutional Contribution (INR)	Being asked for (INR)
Principal Investigator's salary	X	Y

- Each item should be quantified if possible. If it is not possible (e.g. premises or space), it should just be mentioned as an institutional contribution. However small the institutional contribution is, it should be indicated.

- Sub-totals for each group should be indicated and then the grand total.

[m] Justification of the Budget

- The investigators must indicate how they arrived at the amount of money being asked for, and how it is going to be disbursed. (e.g. 2 principal investigators - for overall supervision of the project, data analysis, report production and dissemination. 10% of their time for 24 months at US dollars 300.00 = 2 x 300 x 24 = US dollars 14,400.00.)

(Type here)

[n] References

The cited literature should be as current as possible and include locally available information. These should be in the internationally accepted format –e.g. Vancouver Style (e.g. Drummond PD. Triggers of motion sickness in migraine sufferers. Headache. 2005;45(6):653-6.).

(Type here)