

**Instituional Research Committee
Government Medical College, Kozhikode**

Guidelines for submission of Research Protocols

The faculty and residents submitting their protocols are requested to submit their protocols well in advance so that IRC gets at least 45 days time for processing it.

Usually IRC meets once a month. The actual date can be obtained from the IRC Office. Only protocols that have been received at least 7 working days before a scheduled meeting shall be included in each meeting. The reserachers can know about the result of IRC evaluation of their protocols 2 working days after the meeting.

General instructions:

1. Language used should be in future tense
2. Avoid copy pasting long passages from other published sources.
3. Uniform font size to be maintained
4. KUHS format to be adhered too.

A few suggestions on submission of protocols are given below.

Names of Investigators

Name of the Principal investigator and full contact details including mobile number and email id to be given in the protocol. In case of PG dissertations the same details of guide / supervisor also has to be given. PG dissertations have to be forwarded by the concerned Head of department. The concerned resident shall be the Principal Invesitagtor in the project done by them. In case of interdepartmental work, the proposal has to be signed by the other concerned department head, where the data collection is to be done. It is desirable to have a co-guide from that department, but this is not compulsory. The PI can choose any number of co investigators or co guides for his / her project. Disputes related to authorship etc have to be settled by the researsh team with help of concerned faculties or heads. IRC need not be apporached for this purpose. Name of the Principal investigator, Guide & Co-guide, Designation, Department, Phone number, e-mail id, etc. to be added at the beginning of the protocol.

1) Title

The title has to be brief and precise. Do not use abbreviations in the title. The aim of the research is to produce findings that are generalizable to a wider set of points and not to

those attending our hospital only. Hence it is better to avoid terms like “in a tertiary care center”, prospective study, a study of, name of the college or hospital etc.

2) Introduction

This has to be a concise summary of already available knowledge on key aspects of the research question. Only references directly pertinent to the research question need to be cited. In addition to what is known, what is unknown in that specific area has to be briefly stated. Then how this proposed study is expected to contribute to any aspect of the knowledge gap can be described. The research question or major hypothesis can be stated in conclusion of this section. Any abbreviation used in the proposal has to be given in full form the first time first is used. Thereafter the standard short forms can be used.

3) Objectives

The objectives have to be stated using terms like “To study, measure, compare, assess, etc”. It is better to list a maximum of 2 or 3 objectives. The primary objective should be stated first. This is the objective based on which sample size is calculated and will form the major finding of the study. All variables in this have to be defined in operational terms in the Materials and Methods section.

4) Materials and Methods

This section is the most important one and should contain the following details.

Operational Definitions

Operational definitions of all important variables that will be studied in this particular work have to be provided. Both exposure and outcome variables that are being studied or manipulated in the research work has to be clearly defined.

The specific variables that are studied have to be defined operationally in a manner understandable to one with basic knowledge of that subject.

Sample size and recruitment

Sample size has to be calculated using appropriate formula applicable to the variable under study. Selection of sample from the community / hospital - How this is proposed to be done – continuous, non random, random etc. If random sampling is attempted please give further details of this in consultation with statistician or guide.

Any measurement tools or rating scales to be used in the study should be briefly described along with references. Copies of the tool have to be attached along with the proposal. It can be in English, if the researcher states that it will be translated and used. Otherwise it has to be provided in languages like Malayalam, Hindi etc.

Procedure of the study

The actual steps in conducting the research work has to be described in some detail so as the committee can look in to its feasibility and chance of errors creeping in during data collection. This should include how each point will be handled after recruitment, the kind of interventions to be done, points of assessment of outcomes if any etc.

Ethical aspects

A brief note on how ethical aspects will be dealt with has to be there. Procedure of taking informed consent, mention of points right to withdraw consent, assurance that this will not affect their treatment etc. have to be made. **A copy of the informed consent form has to be attached.**

A copy of the data sheet to be used for data collection has to be attached. Plan of analysis has to be briefly described, especially with regard to the primary outcome of the study.

5) **Results and discussion**

How the results will be analyzed and the statistical tests that would be applied, how the results will be interpreted and discussed also has to be briefly stated at this stage itself.

6) **References**

References are to be given in any standard format. Vancouver format is preferred as this is used by most medical journals. Preferably include only recent references.

7) **Attachments** –

Please attach a numbered list of all documents provided with the proposal

A soft copy (in PDF or Word format) of the proposal has to be mailed to IRC's mail id **irccalicutmedcialcollege@gmail.com**. Two hard copies are to be submitted with the needed signatures of concerned persons.