Template for Study Proposal

(For scientific review committee)

How to use this template:

The template (the table on page 3) provides ALL the sections, headings and subheadings that you will require in your proposal, as well as the line and paragraph spacing, page breaks, page numbering, referencing system and referencing styles. You should simply type (mostly in column 2) and insert your own text as per your proposal, i.e. simply type into the document (Delete the content of the cells in column 3 as those are the instruction about the particular row and afterwards the space will be used for the review and comments by the review committee.).

Do not attempt to change the styles for the headings or subheadings, and do not use more than three level headings (i.e. A main heading, a sub-heading and a sub-sub-heading). Do not type anything in column 3 as the same is made for scientific review committee.

WHEN YOU ARE DONE, DELETE THIS FRONT INSTRUCTION PAGE AND THE ANNEXURES (WHICH ARE THERE ONLY FOR THE GUIDANCE) FROM YOUR PROPOSAL

Proposal must reach researchcaho@gmail.com on or before June 25, 2023 5.00 pm

List of documents to be sent by email only:

1. **Study Proposal in MS Word format (In the prescribed attached format)**
2. **Power-point presentation in MS power-point format (Max 10 slides - Title, Aims/Objectives, Methods in detail, Dummy Tables - Only 1 slide of Introduction can be kept in the presentation)**

3. **Case Record Form in MS Word format**
4. **Patient Information Sheet & Informed Consent Form in MS Word format (English & Gujarati)**
5. **Scanned/downloaded copies of relevant/cited articles in .pdf format**
6. **Dummy tables in MS Word format (with title of the table and also of each row and column)**
7. **Your proposal must be forwarded by head of institute with his remark of institutional support during this project**

PROPOSAL FOR THE SCIENTIFIC REVIEW

Title of the Project/Thesis/Dissertation:

Name of the Student/ Principal Investigator:

Department(s):

Mobile No.: **E-mail ID:**

Name(s) of the PG Guide/Co-investigator(s) :

No.	Name with Designation	Mobile	Email
1			
2			
3			

1 Heading	2 Details	3 Instructions / Comments
Title		Neither too short nor too long. (Who + Study Design + Where + What) Indicate the study's design with a commonly used term.

		Should be concise yet descriptive, informative and catchy. The title may need to be revised after completion of writing of the protocol to reflect more closely the sense of the study.
Introduction & review of Literature (Justification) Max 750 words		Why do you want to conduct this study? Why are these questions important? What is the existing knowledge in the area? What are the gaps in the existing knowledge? Were the previous studies methodologically robust? This section cites previous research that is relevant & indicates the problems and what questions

		remain Imagine you are writing for a general science reader rather than an expert audience. Never leave your reader in doubt as to the source of your information! Cite thoroughly and cite properly (For Details – Annexure II)
Research Question		You should be very clear about it as your whole study design will depend on this. What question(s) will the study address? The research question should be clear and answerable by yes/no or a number.

		The research question should be relevant and address a **hypothesis**. Examples of research questions: Among children of Bhavnagar district, what is the difference in the level of protection by a new vaccine between vaccinated and non-vaccinated children? (For Details – Annexure III)
Aim	1.	What do you want to find at the end of study? It is a statement of the hypothesis,usually derived from the research question. Generally, it is broader than the objectives. For example, to determine whether or not a new vaccine should be incorporated in a public health

		program.
Objectives: Primary Secondary		Research objectives are the goals to be achieved by conducting the research. The specific objectives relate to the specific research questions the investigator wants to answer through the proposed study and may be presented as primary and secondary objectives, For example - primary: To determine the degree of protection that is attributable to the new vaccine in a study population by comparing the vaccinated and unvaccinated groups. - Secondary:

		To study the cost-effectiveness of this program. Don't put too many objectives or over-ambitious objectives that cannot be adequately achieved by the implementation of the protocol. (For Details – Annexure III)
Methodology:		
Study design/type		Only name of the design - Cross-sectional, cohort, case control, randomized (or non-randomized) controlled trial, etc. **As per CTRI**

Study population		Target population to whom your result will be applied
Sample size		Number of study participants How the sample size has been fixed/decided? Ideally, a calculated sample size using statistical software Since feasibility is the primary pre-requisite, a convenient sample size can be decided by the investigators
Study duration		Time required in months (after IRB approval till submission of the thesis/report) There is no such thing as a single “correct” design... hypotheses can

		be studied by different methods using different designs.
Study site / Settings		Place of study e.g. Community, hospital, area, village, district, etc..
Study procedures: Details of procedures including study groups, randomization, blinding, Inclusion & exclusion criteria, intervention, follow-up, etc.		It is a brief description of the broad research approach (qualitative or quantitative or mixed method) to justify the appropriateness of the proposed research.

		Research approach and data collection methods must align well with the problem, the research aim and research hypothesis/question. Proposed research approach and methods of data collection must be appropriate to the research aim. Brief outline of the research setting, methods of data collection (example survey, qualitative interviews etc.), who the participants would be and a brief explanation of how participants will be selected (sampling technique) and accessed. What processes are you going to use? What kind of equipment and supplies will be necessary for the

		project? What will you use for a control, and what will be your replicate? Be thorough, but avoid unnecessary and non-relevant description. If this research is a part of a bigger research project, provide a brief description of the overall research project and a brief explanation of how this proposed research fits into the bigger research project. (For Details – Annexure IV)
Outcome, exposure and confounding variables		Identify the key variables of the study and their method of measurement and unit of

		measurement must be clearly indicated. Four types of variables are important in research. a. Independent variables: variables that are manipulated or treated in a study in order to see what effect differences in them will have on those variables proposed as being dependent on them. The different Synonyms for the term 'independent variable' which are used in literature are: cause, input, predisposing factor, risk factor, determinant, antecedent, characteristic and attribute. b. Dependent variables: variables in which changes will be measured.

		Synonyms: effect, outcome, consequence, result, condition, disease, sensitivity/specificity of a test c. Confounding or intervening variables: variables that should be studied because they may influence or 'mix' the effect of the independent variables. For instance, in a study of the effect of measles (independent variable) on child mortality (dependent variable), the nutritional status of the child may play an intervening (confounding) role. d. Background variables: variables that are so often of relevance in investigations of groups or populations that they should be considered for possible inclusion in

		the study. For example, sex, age, ethnic origin, education, marital status, social status etc. The objective of research is usually to determine the effect of changes in one or more independent variables on one or more dependent variables. For example, a study may ask "Will alcohol intake (independent variable) have an effect on development of gastric ulcer (dependent variable)?"
Dummy table		Not here Include this in power point presentation.
List of References		As per Vancouver style:

		You can use mendeley, zotero, endnote,software for reference management.
Amount of Grant Requested:		Disbursement of Grant 40% after sanction 40% after completion of project 20% after publication of project (you must mention funding support from CAHO during publication)
Justification of Grant along with detail breakup		

Annexure – I

RESEARCH PROTOCOL

TITLE: PICO –Population + **I**ntervention + **C**omparison + **O**utcome

BACKGROUND AND JUSTIFICATION: existing knowledge – gaps in knowledge – present study is going to fill these gaps

RESEARCH QUESTION: FINER – Feasible **I**nnovative **N**ovel **E**thical **R**elevant

OBJECTIVES: SMART – Specific **M**easurable **A**chievable **R**elevant **T**ime-bound

RESULTS FROM PILOT STUDY (if conducted):

STUDY DESIGN:cross-sectional / case-control / cohort / Randomized Control Trial / qualitative designs (focused group discussion / in-depth interview / participatory methods)

STUDY SETTING: community / hospital (ward or OPD) / urban slum / village / district

STUDY PERIOD: mention duration with month and year

SAMPLE SIZE:calculated with the help of Epi Info software

SAMPLING / SELECTION OF SUBJECTS / RECRUITMENT PLAN: random sampling / non-random sampling / method of selection of cases or subjects

DATA COLLECTION METHOD: house-to-house / camp approach / clinic based / classroom / conference gathering / group approach

CLINICAL PROCEDURES / INVESTIGATIONS (if any): explain in detail

VARIABLES: outcome variables / exposure variables / confounders

DATA COLLECTION TOOL: any specific tool / questionnaire / scales / indices / case definitions / field definitions

FLOW CHART OF METHODOLOGY:

QUALITY ASSURANCE: standardized instruments, validated tools, training, software

INCLUSION CRITERIA: age, gender, specific diseases, specific exposures, etc.

EXCLUSION CRITERIA (if any): e.g. advanced stages of cancer, known cases, etc.

STATISTICAL ANALYSIS: software, dummy tables, statistical tests

ETHICAL CONSIDERATIONS: Confidentiality / IRB approval / written or verbal informed consent

TIMELINE: Gantt chart

REFERENCES: Vancouver Style

BUDGET: reasonable, well-searched, **justified**; avoid honorarium for PI / co-PI

BIOGRAPHIES OF PIS / CO-PIS: brief, list of relevant projects / publications

Annexure II (Introduction-Justification-Background)

Provide background information for the research (i.e. the problem being addressed) and is typically structured from general information to narrow or focused ideas; whereupon your research question/s or hypotheses are presented.

The Introduction includes a brief review of relevant literature or knowledge in the field, so that you are able to present the gap in the existing knowledge and, therefore, the significance and originality – the purpose and aims – of your research (how your study will fill the gap in the existing knowledge).

Use a plethora of sources especially primary sources such as journal articles. Textbooks, web sites (with great caution) and personal communications with professors can also be useful sources. Make sure to cite appropriately in the text.

For Citations, your sentence structure should look something like this: (Vancouver style)

- *P. Oyibo et al (2011) in their cross-sectional study among 208 pregnant women in South Eastern Nigeria found that about 26% women had a high risk pregnancy while about 9.1% had very high risk pregnancy.*
- *According to J. Chaubey et al (2017) prevalence of high risk pregnancy was 30.7% in Karnataka.*
- *Globally, the IMR has decreased from an estimated rate of 64.8 deaths per 1000 live births in 1990 to 30.5 deaths per 1000 live births in 2016 (WHO, 2017).*

Annexure III

The research question should pass the FINER test! FINER means feasible, interesting, novel, ethical and relevant.

Feasibility is the most important criteria (that is, you should be able to include sufficient number of patients in the given time span of data collection). Ethical means follows the principles of ethics in research (like doing no harm to patients, etc.). Relevant means which is useful to the scientific community and helps in advancement of existing scientific knowledge.

No.	Research question	Type of R.Q	Hypothesis	Objectives
1.	Among patients with cervical cancer, what is the *prevalence* of HPV positivity (defined as HPV-DNA test being positive)?	Descriptive	Descriptive R.Q do not require a hypothesis	To *estimate* the prevalence of HPV positivity among patients with cervical cancer
2.	Among patients with liver disease, what is the *prevalence* of severe alcoholism (defined by a WHO-AUDIT score ≥20)? **Note:** AUDIT - Alcohol Use Disorders Identification Test	Descriptive	Descriptive R.Q do not require a hypothesis	To *estimate* the prevalence of severe alcoholism among patients with liver disease
3.	Among patients coming to the casualty, are high cholesterol levels (defined as >200 mg/dl) *associated* with acute myocardial infarction as compared with those not presenting with acute MI?	Analytical	High cholesterol levels are associated with development of acute myocardial infarction among patients coming to the casualty	To *determine* the effect of high cholesterol levels on the development of acute myocardial infarction
4.	Does a new drug for treating fever cause	Analytical	Liver toxicity by a new drug	To *determine* the effect of a new

	less liver toxicity as *compared with Paracetamol* among patients with fever?		for treating fever is less as compared with Paracetamol among patients with fever	drug for treating fever on causing liver toxicity as compared with Paracetamol

Annexure IV

Sampling / selection of subjects/recruitment plan

- Try for a random sampling procedure (Simple Random Sampling or Stratified Random Sampling)
- Mention how will you get your sampling frame
- How are you going to select subjects such that each participant has an equal chance of getting included?
- For small surveys/studies
  - Convenient sampling (ease of access)
  - Purposive sampling (based on judgment, investigator decides whom to include in the study)

Describe Recruitment Plan

- Descriptions should be very explicit
- So as to achieve high response rates

Data collection method& Clinical Procedures

- House-to-house, Camp approach, Clinic / hospital based,Others: classroom based, etc
- Explain the clinical procedures in detail (even if a gold standard procedure is used)
  - Should be replicable by readers.

Data collection tool

- any specific tool, Questionnaire, Scales, Indices, case definitions, field definitions, Socio-demographic information

Inclusion and Exclusion Criteria

- Inclusion criteria - Geographic location, Time period, Demographics: age, sex, other
- Exclusion criteria (if any) – Exclusions from among the inclusions

Ethical considerations

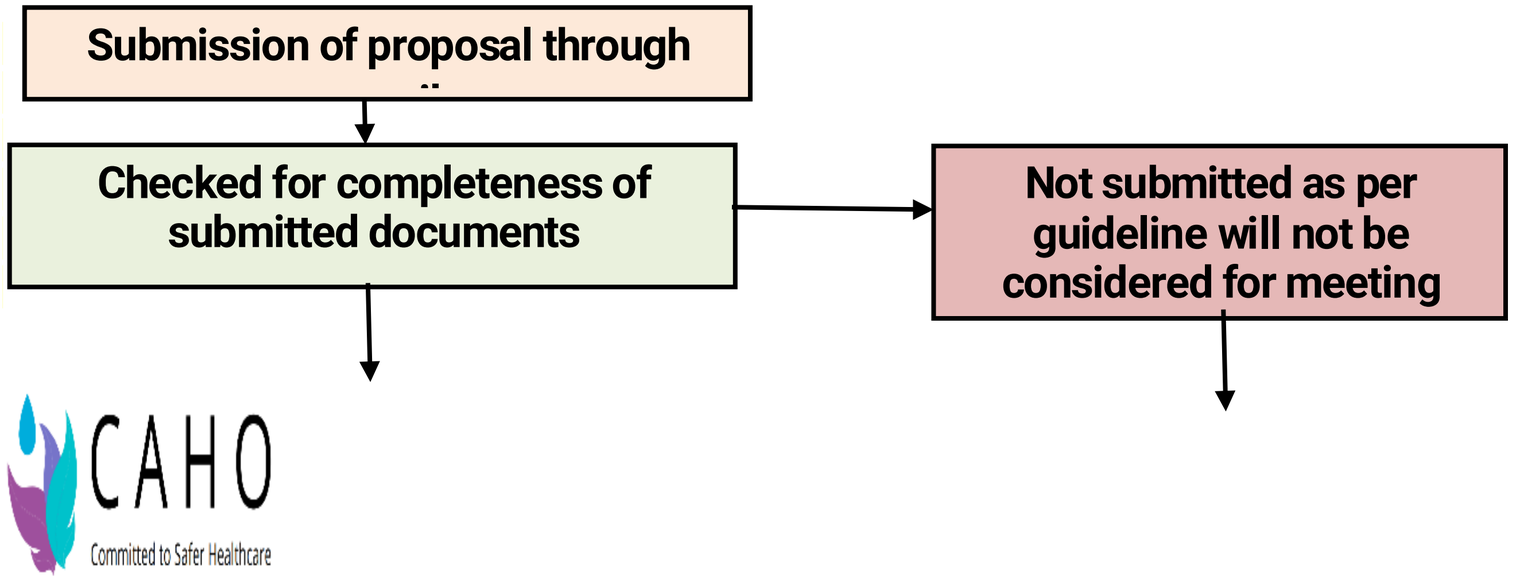
- Confidentiality of participants would be maintained
- Say that the research protocol will be reviewed by your Institutional Review (Ethics) Board

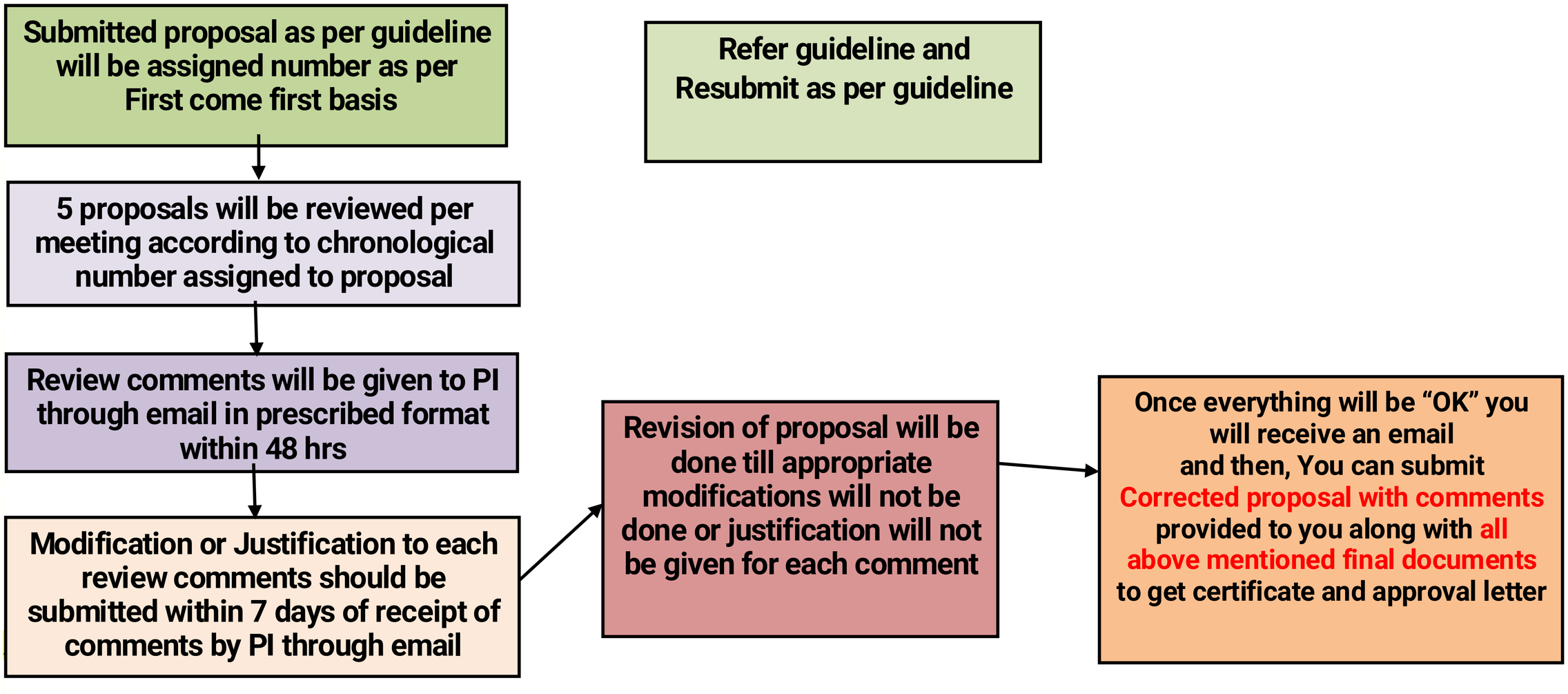
Consent Procedures

- Advise participants of procedures and purposes (what is expected of them and what will be done)
- Explain how the information will be used and its value to the participant and society
- Discomforts and risks
- Availability of medical treatment and compensation for injury
- Safeguards for maintaining confidentiality
- Right to withdraw without affecting future care
- Name and telephone number of contact person for questions

Timeline

Gantt Chart


Submission of proposal through
Checked for completeness of submitted documents
Not submitted as per guideline will not be considered for meeting


Submitted proposal as per guideline will be assigned number as per First come first basis
5 proposals will be reviewed per meeting according to chronological number assigned to proposal
Review comments will be given to PI through email in prescribed format within 48 hrs
Modification or Justification to each review comments should be submitted within 7 days of receipt of comments by PI through email
Revision of proposal will be done till appropriate modifications will not be done or justification will not be given for each comment
Refer guideline and Resubmit as per guideline
Once everything will be “OK” you will receive an email and then, You can submit Corrected proposal with comments provided to you along with all above mentioned final documents to get certificate and approval letter