ICMR School of Public Health, National Institute of Epidemiology, Chennai, India

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Study protocol template

Title

Primary investigator: Name, First Name, Institution

Co-investigator(s): Name, First Name, Institution

Version # - date

Background - justification

The introduction must contain key background information that sets the stage for the study question. It highlights specifics about the problem that may not be known or that may simply not be available (i.e. not yet published or not clear). It progressively zooms in towards a third paragraph that introduces the need of the study and spells out the research question. It makes use of linked references to document statements made.

First paragraph of the introduction: Provide a review of the background from a global perspective: the global consequences of the health problem in terms of death, disability, as well as effectiveness and cost-effectiveness of interventions. Avoid general undocumented statements and provide quantified data when available (e.g., rather than saying "Disease X is a major health problem", quantify burden in terms of prevalence, incidence or Disability Adjusted Life Years [DALYs]).

Second paragraph of the introduction: Explain how the problem affects the place where the study is being considered: zoom into the regional / national perspective.

Third paragraph of the introduction: Describe how the problem presents itself in the national / local context. Provide information on completed, ongoing or planned prevention and control efforts (or treatment options) targeting this problem in South Asia, India and / or the State/place where the study will be conducted. Specify (1) the information needs of different stakeholders (health professionals/public/health programme/policy makers & implementers/community…) to improve this health problem (2) why currently available information is insufficient. End the paragraph with the research question that the study will address.

Last paragraph of the introduction:

- Spell out first objective. Make sure that you make it clear whether you propose to *estimate a quantity* (e.g., prevalence, incidence) or whether you propose to *test a* hypothesis (e.g., Determine whether an exposure is a risk factors for a disease).
- Spell out other objectives (e.g., second, third) if applicable using the same approach.

Proposed methods

{This template lists general items required for conducting research studies; Please include specific items required for the type of study design planned; Refer to www.equator-network.org for such specific items as may be required for diagnostic or intervention studies; Use SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013 Statement [www.spirit-statement.org]; CONSORT (CONsolidated Standards of Reporting Trials) [www.consort-statement.org]; for Herbal medicinal or Non-pharmacological treatment}

Study population

Describe the population in which the study will be undertaken (State, District, population size or study setting) Specify inclusion and exclusion criteria.

Study design

Describe the type of study (e.g., survey, case-control or cohort) that will be conducted. Mention if study participants will be recruited prospectively or retrospectively. Specify the referent period that

will be used to ascertain the exposure(s) (e.g., exposures two to six weeks prior to onset for a study on hepatitis A).

Operational definitions

Provide information regarding the criteria that will be used for key exposures and outcomes (e.g., case definition criteria, control recruitment strategy). Refer to standardized criteria (e.g., Ministry of Health (National programme guidelines, Integrated Disease Surveillance Programme), WHO or internationally used guidelines issued by professional bodies) through the use of linked references if applicable.

Sampling procedure

Describe the type of sample that will be used (e.g., simple random sample, systematic sample, cluster sample) and the practical procedures that will be used to select that sample, step-by-step. Refer to methodological guidelines (e.g., article on cluster samples, book chapter) through the use of linked references wherever possible.

Sample size

Mention the main assumptions that will be used to calculate the sample size. Provide sample size calculation results, adjusted for non-response and design effect (if applicable). If the study will be analytical in nature, make sure that the sample size will be sufficient to make comparisons (e.g., a common mistake is to power a study according to a descriptive objective to then use the data for analytical comparisons while the sample size is not adapted and insufficient). Make explicit reference to the software (e.g., through a reference) or the formula used (e.g., through a linked reference) for the calculation.

Data collection

Information collected

Describe the information that will be collected. Do not enter in the details of each questionnaire item but provide and overall summary of the broad categories of items [e.g., socio-demographic-economic characteristics, clinical features, categories of risk factors (e.g., hygienic practices, travel or medication history and consumption of food items and beverages)].

Data collection procedure

Mention who will be collecting the data. Describe all the methods that will be used to collect the information (e.g., interviews, medical record reviews, observations). Refer to the instruments that will be used to collect information and provide these instruments as part of the appendices.

Laboratory specimen collection, transport and analysis

Mention the methods to be used for biological specimen collection, transport and analysis.

Other methods used to collect data

Mention possible other methods to be used to collect data (e.g., entomology, environmental assessment).

Data analysis

Describe the steps that will be followed for the data analysis, including recoding of key exposure / outcome variables, indicators to be calculated for the descriptive analysis [e.g., measures of disease frequency (prevalence, incidence), measures of central tendency (mean, median)], indicators to be calculated for the analytical purpose [e.g., measures of association (relative risk, odds ratio, prevalence ratio), measures of impact]. Anticipate key main stratifications (e.g., key effect modifiers and confounding factors). Specify if a multivariate analysis model will be constructed. Mention the statistical software that will be used. Make reference to key dummy tables and provide them as part of the appendices.

Quality assurance

Describe the quality assurance procedures that will be used for:

- Protocol development (e.g., peer review);
- Field procedures (e.g., sampling methods);
- Data collection (e.g., pilot testing, training of field workers, translations, supervision, cross-checking);
- Laboratory methods;
- Data analysis

Bias and limitations

Enumerate the possible sources of bias / limitations of the proposed study. For each of these biases/ limitations, describe:

- The nature of the bias or of the limitation;
- The possible consequences of the limitation on the data (e.g., would over-estimate or underestimate a parameter, a measure of association);
- The steps that will be taken to minimize the impact of the bias / limitation on the quality of the study.

Human participants protection

Vulnerable populations

Mention if a vulnerable population will be studied (e.g., pregnant women, children, prisoners), with adequate justification if applicable.

Risks

List the key possible risks to which the participants could be exposed through participation in the study. Do not downplay risks.

Benefits

List the key possible benefit that the participants and / or the community could receive through participation in the study. Do not exaggerate benefits. Mention if a reasonable compensation will be given for participation (avoiding undue / inappropriate incentive).

Confidentiality

Describe the practical steps that will be taken to protect the confidentiality of study participant (e.g., use of codes, collection of identifiers on a separate support, protection of identifiers).

Biological specimen

List the biological specimens that may be collected and the use to which they will be made. Specify the duration of storage and the plans for destruction of leftovers.

Informed consent

Describe the procedures that will be used to obtain consent (or assent) from study participants and the key elements that will ensure that the consent will be fully informed.

Ethics committee clearance

Determine whether the protocol requires full ethics committee review, expedited ethics committee review or whether the protocol is exempt (e.g., programme evaluation). If ethics committee is planned, specify the committee from which approval will be sought.

Practical considerations

Logistics for data collection

Describe practical arrangement for the data collection.

Timeline

Provide a timeline with the key milestone for completion of the study.

Expected benefits

Output (s)

Describe the expected output (e.g., presentation, reports, and manuscripts) that this study will generate and the timeline for production of these outputs.

Outcome (s)

Describe the expected outcome: How this study will influence prevention and control activities or management of this problem in question in the area where the research will be conducted.

Appendices [1]

Data collection instruments [2]

Questionnaires

Attach the questionnaire(s) to be used for the study. Those should contain only codes and no identifiers (e.g., names, addresses) / surrogate identifiers (e.g., date of birth).

Other data collection instruments

Attach non-questionnaire data collection instruments to be used for the study (e.g., medical record or chart abstraction forms, observation records). Those should contain only codes and no identifiers (e.g., names, addresses) / surrogate identifiers (e.g., date of birth).

Identifier collection sheet

Attach the identifier collection sheet for the study. This should contain the identifiers and the codes (to be kept under lock and key).

Dummy tables

Attach the dummy tables that will outline the approach that will be used for the analysis of the data

Informed consent form

Attach a consent form developed on the basis of a standard template. Check that it contains all items needed through the use of the standard checklist (http://icmr.nic.in/human_ethics.htm). Ensure that it does not contain any jargon (e.g., avoid words of more three syllables).

Participant recruitment material

Attach material you may use to recruit study participants.

Others

Attach any other forms/ documents required for the completion of the study (e.g., adverse event monitoring form).

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[1] A protocol cannot be considered complete and cannot be submitted to an ethics committee in the absence of the appendices (i.e., dummy tables, instruments, consent forms, others).

[2] All data collection instruments and consent forms to be used with study participants must be available in local language with an English back-translation

References *(Please follow ICMJE guidelines available at www.icmje.org)*

Insert a list of references needed to document key points made in the introduction or to provide explanation / documentation about specific methods to be used (e.g., sampling methods guidelines, list of case definitions). All these references must be linked to a caption in the protocol (linked references).

Budget[3]

Describe in few lines of text the key points of the table outlining the budget of the study

Table 1: Proposed budget for the study (add columns and rows as needed)

		Description	Unit cost	Number of units	Total
Staff	Salary	…	XXX	XX	XXXX
	Per diem	…	XXX	XX	XXXX
	Subtotal, staff				*XXXX*
Transport	Air	…	XXX	XX	XXXX
	Rail	…	XXX	XX	XXXX
	Road	…	XXX	XX	XXXX
	Subtotal, staff				*XXXX*
Equipment and supplies	Stationery	…	XXX	XX	XXXX
	Reagents	…	XXX	XX	XXXX
	Others	…	XXX	XX	XXXX
	Subtotal, equipment and supplies				*XXXX*
Miscellaneous		…	XXX	XX	XXXX
Total			XXX	XX	XXXX

[3] *The budget requirements may be tailor-made based on the study type and the requirements of the funding agency.*