A Proposal/Protocol Template for Research, Data Collection and Analyses Requiring Ethical Review.[1]

The following template can be used to guide UNICEF staff on what to include when submitting research or data collection and analysis proposals/protocols to a UNICEF established ethics review board.

With respect to evaluations that require ethical review, the Evaluation Guidance on TORs (How to Draft the Terms of Reference) may be used, as it is consistent with this guidance. However, in the Principles and Approaches section of an Evaluation TOR, the section on Ethics noted below, can and should provide guidance as to the detail required.

In the instance where external, national or institutional ethical review boards (or IRB's) are being utilised to review research, they will likely have their own templates for submission of proposals/protocols. Where this is not the case, this template should be utilised.

Project summary

The project summary, should be no more than 300 words and at the most a page long (font size 12, single spacing). Provided preferably on a separate page, it should summarize all the central elements of the proposal, for example the rationale, objectives, methods, populations, time frame, and expected outcomes. It should stand on its own, and not refer the reader to points in the project description.

General information

- Proposal title, and date.
- Name and address of the sponsor/funder.
- Name and position of the UNICEF Project Manager
- Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.
- Name(s) and address(es) of the institutions involved in the evidence generation.

[1] Based on WHO (2015) Recommended format for a Research Protocol, http://www.who.int/rpc/research_ethics/format_rp/en/, accessed 18 Feb., and, Boddy, J., Neumann, T., Jennings, S., Morrow, V., Alderson, P., Rees, R., and W.Gibson (2015) The Research Ethics Guidebook: A Resource for Social Sciences, http://www.ethicsguidebook.ac.uk/, accessed 18, Feb.

Rationale & Background information

The Rationale specifies the reasons for conducting the evidence generation in light of current knowledge. It should include a well documented statement of the need/problem that is the basis of the project, the cause of this problem and its possible solutions. It should justify data collection from human subjects and particularly vulnerable human subjects and why secondary data cannot be used.

This section is the equivalent to the introduction in a report and it puts the evidence generation in context. It should answer the question of why and what: why the evidence generations needs to be done and what will be its relevance. The magnitude, frequency, affected geographical areas, ethnic and gender considerations of the problem should be supported by a brief description of the most relevant studies published on the subject, any relevant situational analyses undertaken, supporting data and other papers. Where these studies (e.g. Situational analyses) are unpublished they should be provided as an attachment.

Study goals and objectives

Goals are broad statements of what the proposal hopes to accomplish. They create a setting for the proposal. Objectives should be simple (not complex), specific (not vague), and stated in advance.

Study Design

The scientific integrity of the evidence generation project and the credibility of the data depend substantially on the design and methodology. The design should include information on the evidence generation activity, the population or the sampling frame, and who can take part (e.g. inclusion and exclusion criteria, withdrawal criteria etc.), and the expected duration).

The same evidence generation program can be described in several ways, and as complete a description as possible should be provided. For example, a project may be described as being a basic science research, epidemiologic or social science research, it may also be described as observational or interventional; if observational, it may be either descriptive or analytic, if analytic it could either be cross-sectional or longitudinal etc. If experimental, it may be described as a controlled or a non controlled study.

Methodology

The methodology section is the most important part of the proposal. It should include detailed information on the interventions to be made, procedures to be used, measurements to be taken, observations to be made, laboratory investigations to be done, information to be collected, etc. If multiple sites are engaged in a specified proposal, the methodology should be standardized and clearly defined.

Where relevant (primarily research and evaluations), interventions should be described in detail, including a description of the drug/device/vaccine that is being tested.

Interventions in the social sciences include providing training, goods and services or information to groups of individuals.

Procedures could be biomedical (collection of blood or sputum samples to develop a diagnostic test), or in the realm of social sciences (doing a questionnaire survey, carrying out a focus group discussion as part of formative research, observation of the participant's environment, etc.).

Standardized and/or documented procedures/techniques should be described and justified. Instruments which are to be used to collect information (questionnaires, FGD guides, observation recording form, case report forms etc.) must also be provided.

In the case of a randomized controlled trial additional information on the process of randomization and blinding, description of stopping rules for individuals, for part of the study or entire study, the procedures and conditions for breaking the codes etc. should also be described.

The statistical methods proposed to be used for the analysis of data should be clearly outlined, including reasons for the sample size selected. For projects involving qualitative approaches, specify in sufficient detail how the data will be analysed.

A graphic outline of the study design and procedures using a flow diagram would be useful.

Expected Outcomes

The proposal should indicate how the evidence generation will contribute to advancement of knowledge, how the results will be utilized, not only in publications but also how they will likely affect systems, programs and policies.

Expected Products

- List products to be delivered, to whom and when. Consider:
  - The report
  - Completed data sets (filled out questionnaires or surveys)
  - Dissemination materials (newsletter articles, two-page summaries, presentation materials)
  - For UNICEF, evaluation and research consultants should be required to provide all of the information for the UNICEF CO update to the UNICEF Evaluation and Research Database in the required format
  - Assessment of the methodology, including a discussion of the limitations.
- Specify the format for deliverables, including software, number of hard copies, translations needed and structure of the report.

Project Management

This section should describe the role and responsibility of each member of the team

Logistics

Specify as necessary logistical issues related to staffing and working conditions

- Availability and provision of services (local translators, interviewers, data processors, drivers)
- Availability and provision of office space, cars, laptops, tape recorders, and procedures for arranging meetings, requirements for debriefings
- Work schedule (hours, days, holidays) and special considerations such as in emergencies (e.g. often a 7-day work week is combined with R&R breaks)
- Special procedures, for example on relations with press, security, evacuation in emergencies
- Benefits and arrangements such as insurance (particularly in emergencies, consider hazard pay, war risk insurance)
- Seasonal constraints, travel constraints/conditions and socio-cultural conditions that may influence data collection

Dissemination of Results and Publication Policy

The proposal should specify the means of dissemination of results not only in publications but also to the community and/ or the participants, and any dissemination to policy makers where relevant.

Duration of the Project

The proposal should specify the time that each phase of the project is likely to take, along with a detailed month by month timeline for each activity to be undertaken.

Problems Anticipated

This section should discuss the difficulties that the investigators anticipate in successfully completing their projects within the time frame stipulated and the funding requested. It should also offer possible solutions to deal with these difficulties.

Ethics

The proposal should have a description of ethical considerations relating to the study. This should not be limited to providing information on how or from whom the ethics approval will be taken, but this section should document the issues that are likely to raise ethical concerns and ways in which your evidence generation program will address or mitigate against these issues.

So you need to be able to explain how:

- you are ensuring the quality and integrity of your research;

Note: In this section you would need to note any relevant quality assurance processes, ensuring your QA processes are consistent with the Evaluation Guidelines or the Procedure for Quality Assurance in Research.

- you will seek informed consent and assent;

Note: The approved version of the proposal must have copies of informed consent forms (ICF), both in English and the local language in which they are going to be administered. However translations may be carried out after the English language ICF(s) have been approved by the ERC. If the research involves more than one group of individuals, for example healthcare users and healthcare providers, a separate specifically tailored informed consent form must be included for each group. This ensures that each group of participants will get the information they need to make an informed decision. For the same reason, each new intervention also requires a separate informed consent form.

- you will respect the privacy and anonymity of your research respondents;

- you will ensure that your participants will participate in your study voluntarily;

- you will avoid harm to your participants;

Note: The safety of research participants is foremost. Safety aspects of the evidence generation process should always be kept in mind and information provided in the proposal on how the safety of research participants and, if relevant, staff, will be ensured.

The research proposal must also give a clear indication of what follow up will be provided to the participants if there is distress consequent to an interview or focus group, adverse effects to a clinical trial, safety concerns or issues etc.. Support services made available consequent to the evidence generation project should be documented.

- you will ensure that data is managed and its confidentiality maintained.

- You have addressed any conflict of interest

Budget

The budget section should contain a detailed item-wise breakdown of the funds requested for, along with a justification for each item.

Other support for the Project

This section should provide information about the funding received or anticipated for this project from other funding organizations.

Partnerships with communities, organisations and research institutions

Any links to other projects

Curriculum Vitae of Investigators (Evaluations and Research)

The CV of the Principal investigator and each co-investigators should be provided. In general each CV should not be more than one page, unless a complete CV is specifically requested for.

Other evidence generation activities of the investigators (Evaluations and Research)

The Principal investigator should list all current research projects that he/she is involved in, the source of funding of those projects, the duration of those projects and the percentage of time spent on each.