USAID
FROM THE AMERICAN PEOPLE

Research Plan (Protocol) Guidelines

INTRODUCTION

The research plan (sometimes called a protocol) is the fundamental basis for ensuring high quality research at USAID. All research funded by USAID must have a research plan and research plans must be evaluated by peer review to ensure their quality.[1] These guidelines outline the minimum standards for USAID-sponsored research.

RESEARCH PLAN COMPONENTS

NOTE: Not every research plan will need to include all of the items described in this guidance. Select those that apply.

IDENTIFYING INFORMATION: Identify the principal investigator, the study team, their respective institutional affiliations, and provide contact information. Provide the agreement name or number. Title the research plan in a way that summarizes the research question. The title should be able to stand alone as a description of the study. Number pages sequentially. As research plans undergo many revisions, it is essential to provide the version date of the plan to be reviewed.

OVERVIEW: Provide a brief overview of the study, its main objectives and rationale, countries and settings where the work will take place, population(s) of interest, and the expected applicability of the study findings. Explain the scientific importance of the study.

LITERATURE REVIEW: The literature review should provide a synopsis of the current state of knowledge on the topic proposed for study. Discuss the key issues or gaps that this research would address. Include citations (either numerical or by author and date) in the text with full references listed in the bibliography or references section.

STUDY OBJECTIVES: List the objectives, specific aims, and research questions or hypotheses the study will answer.

DESIGN: Describe the study design. Explain its appropriateness to the project and the objectives/questions previously outlined. Describe how the study design helps address possible sources of bias. Explain how the study will involve relevant stakeholders and address community-identified priorities.

STUDY POPULATION: Define the population from which the sample will be drawn (e.g., if the study involves humans subjects describe the population in terms of age, ethnicity, socioeconomic status, gender, risk status or vulnerability, geographic location or catchment area, etc.). Discuss what population inferences will be made.

- **Case definitions:** When appropriate, provide a description of an illness/condition, sign(s)/symptom(s) or health event that defines whether potential participants are eligible to participate in the study.
- **Participant inclusion criteria:** Describe conditions or characteristics applicable to the identification and selection of participants. Describe the conditions necessary for eligible persons to be enrolled in the study.
- **Participant exclusion criteria:** Describe the characteristics that would disqualify otherwise eligible participants from the study. Provide a justification for excluding a subpopulation.

1 For more information on peer review, please visit the Quality Standards section of the Scientific Research Policy ProgramNet Collection.

SAMPLING PLAN: Provide details about how the sample will be identified and selected and how participants will be assigned to comparison groups.

- Describe the sample, e.g., convenience, population-based, or systematically chosen for a particular purpose.
- Describe procedures for sampling.
- State the unit(s) of analysis.
- Estimate the required sample size. Provide power calculations for significance testing when appropriate.
- Describe how participants will be enrolled (e.g., the manner in which they will be contacted, screened, and registered in the study) and how they will be assigned to comparison groups. In studies where randomization is used, describe these processes in detail, including whether participants and researchers will be blinded and what procedures will be used to ensure that randomization results in comparable groups. If group level or aggregate information will be collected (e.g., from focus groups), explain how the groups will be formed or what procedures will be followed to enroll participants in the groups.

VARIABLES: Define the independent, intervening, and dependent variables. Describe any study instruments or methods that will be used to collect data or construct variables, including evaluations of instrument reliability and validity or sensitivity and specificity of a diagnostic test or other measure. Discuss all sources of data used to construct variables (e.g., medical records, health information management systems, census data, etc.). Provide a description and background information on any drugs, seed/crops, technologies, devices, interventions, tools, or approaches to be tested or used in the research.

Data handling and collection: Provide a detailed data collection and management plan. Describe data collection procedures, methods to maximize response rates, how losses to follow-up will be tracked, and what procedures will be used to minimize losses to follow-up. Discuss how data collection will be monitored in the field to ensure quality and consistency. Describe how those responsible for data collection will be trained and monitored. Discuss data entry, cleaning, and procedures for data management and quality assurance. Describe how data will be stored and what procedures will be used to preserve confidentiality during transmission, use, and storage of data. Provide the names of persons responsible for data stewardship. Describe the plan for disposition of records, data, computer files, specimens, and other materials at the end of the study. Discuss plans for any sub-awards. Identify local and international partners participating in the research and describe their roles and responsibilities.

Handling unexpected or adverse events: Describe the types of adverse events that might be encountered and how study personnel will be trained to react. Describe methods that will be used to track adverse events and their potential impact on the study.

ANALYSIS PLAN: Discuss potential sources of bias and possible analytic approaches to avoid drawing erroneous conclusions (e.g., stratification, statistical adjustment, etc.) Discuss statistical packages to be used for data analysis.

ETHICAL CONSIDERATIONS: Along with many other Federal Agencies, USAID has adopted the Federal Policy for the Protection of Human Subjects in research (often called the "Revised Common Rule") — see **22 CFR 225** (Annex B, part 1). The Revised Common Rule was published in the Federal Register on January 19, 2017 and subsequently modified to change the required compliance date to January 21, 2019. It describes the various functions and processes needed to ensure protection of human subjects, defines relevant terminology and concepts, and specifies how and when the rules apply in different circumstances.

USAID's guidance document on the Protection of Human Subjects in Research Supported by USAID, Mandatory Reference for ADS 200 (**ADS 200mbe**), will be updated to reflect the Revised Common Rule. This document further explains the underlying principles of human subject protection and the application of those principles to various

situations. This guidance is intended to help A/CORs, Mission staff, and implementing partners understand and apply USAID regulations when supporting or conducting research involving human subjects.

BUDGET: Provide a detailed budget for the study. Identify all sources of funding.

TIMELINE: Provide a detailed timeline for all phases of the study. We encourage the use of Gantt charts for project management.

DISSEMINATION AND KNOWLEDGE TRANSFER: Describe plans for disseminating the findings of the study to relevant stakeholders and target audiences. Define effective communications channels and best formats for presenting the information. Describe how the research will be used to influence practice or policy. Discuss plans for publications, reports, and presentations. List any products, including inventions and patents that may be derived from the study. Identify the owner of the data to be collected and state any limitations to access that may exist for data analyses and publications.

Note: The results and findings of federally funded research are required to be made available to the public. Publication and other forms of knowledge dissemination/transfer should be built into the activity from the outset.

Additional considerations:

- **Environment:** Analyze the environmental impact of the study. Provide a plan for mitigating negative environmental impacts. Pay particular attention to disposal of medical waste.
- **Inclusion:** Analyze the implications of the study on minority groups such as: women, youth, ethnic groups, gender and sexual minorities (e.g., LGBTI persons), people with disabilities, indigenous communities, low-income groups, the elderly, and other socially relevant categories. Ask questions like: are these groups of people affected differently by the research question (e.g., how will you know if the answer to the research question is different for a particular group?) or how the research is being conducted (e.g., are members of various groups equally able to participate or do the methods need to differ based on factors such as gender of the interviewer and participant)? Are there any potential harmful and/or unintended consequences or risks of this activity on participants/customers/beneficiaries? Negative consequences can include, but are not limited to, increasing the risk of gender-based violence or increasing women/girl's unpaid work. Are there any potential benefits of participating in the research that would favor one group over another?
- **Potential dual uses of the research.**
- **Potential of the research to generate intellectual property.**
- **Plans for sub-awards:** Discuss how awardees will be identified, the scope and purpose of the sub-award in the context of the study, and the estimated dollar amount and duration of the sub-award.
- **Identify the implementing partner(s):** Care should be taken to differentiate the roles of researchers from implementers, in order to promote objectivity in research and avoid a potential source of bias. Identify who will implement the intervention under study and how they will be trained.

Annexes/Appendices include:

- Study consent forms
- Data collection forms and other study materials
- Institutional review board (IRB) approval letters
- Disclosures of any real or potential conflicts of interest.