# ANNEX 4

**Form AF/04-008/01**

**Protocol Summary Sheet (**Checklist of items)

**Guidelines for filling up the protocol summary sheet or checklist of items:**

1. Indicate the page number(s) of the main protocol in the right hand column.
2. If any of the section is not applicable then write ‘NA’ instead of the page number(s).

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| --- | --- | --- |
| **Sl.No** | **Protocol Sections or Items** | **Specify the page numbers of the main protocol** |
|  | **Study Title:** (Please **WRITE** the study title): |  |
|  | **Names and institutional affiliations** of the principal investigator and other investigators |  |
|  | **Project summary:** (Like the abstract of a research paper, 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 protocol, 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.) |  |
|  | **Background and rationale:** (A clear statement of the justification for the study, its significance in development and in meeting the needs of the country /population in which the research is carried out, including summary of relevant literatures ) |  |
|  | **Objectives:** (State specific objectives, including any pre-specified hypotheses) |  |
|  | **Study Design:** (A detailed description of the design of the trial or study. In the case of controlled clinical trials the description should include, but not be limited to, whether assignment to treatment groups will be randomized (including the method of randomization), and whether the study will be blinded (single blind, double blind), or open) |  |
|  | **Study setting:** (A brief description of the site(s) where the research is to be conducted, including information about the adequacy of facilities for the safe and appropriate conduct of the research, and relevant demographic and epidemiological information about the country or region or site; and relevant dates, including periods of recruitment, exposure, follow-up, and data collection) |  |
|  | **Study Participants /Eligibility criteria:** (The criteria for inclusion or exclusion of potential participants, and justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons. The justification for involving as research participants children or adolescents, persons who are unable to give informed consent or vulnerable persons or groups, and a description of special measures to minimize risks to such persons) |  |
|  | **Sample size:** (Estimated number of participants needed to achieve study objectives. Mention how the sample size was determined, including clinical and statistical assumptions supporting any sample size calculations) |  |
|  | **Recruitment:** (Strategies for achieving adequate participant enrolment to reach target sample size. Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. The process of recruitment, e.g. advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment) |  |
|  | **Interventions and outcomes, if applicable:** (Interventions for each group with sufficient detail to allow replication, including how and when they will be administered; Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease); Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests); Relevant concomitant care and interventions that are permitted or prohibited during the trial; Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended; Assignment of interventions (for controlled trials) |  |
|  | **Data collection:** (Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors) and a description of study instruments (e.g., questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol;  Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols. Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications. |  |
|  | **Variables:** (Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable) |  |
|  | **Data sources/** **measurement:** (For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group) |  |
|  | **Data management:** (Plans for data entry, coding, security, and storage, including any related processes to promote data quality (e.g., double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol) |  |
|  | **Data Analysis:** Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol;  Methods for any additional analyses (e.g., subgroup and adjusted analyses); Definition of analysis population relating to protocol non-adherence (e.g., as randomised analysis), and any statistical methods to handle missing data (e.g., multiple imputation) |  |
|  | **Research ethics:** (Plans for seeking IRB or other research ethics committee/institutional review board approval. The known or foreseen risks of adverse reactions, including the risks attached to each proposed intervention and to any drug, vaccine or procedure to be tested. The potential individual benefits of the research to participants and to others. The expected benefits of the research to the population, including new knowledge that the study might generate. For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide treatment for such injury, including the funding of treatment, and to provide compensation for research-related disability or death. Provision for continued access to study interventions that have demonstrated significant benefit, indicating its modalities, the parties involved in continued care and the organization responsible for paying for it, and for how long it will continue. For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child) |  |
|  | **Protocol amendments:** (Plans for communicating important protocol modifications to relevant parties (e.g., investigators, IRB or other REC/IRBs, trial participants, trial registries, journals, regulators) |  |
|  | **Informed Consent/Informed Assent Process:** (State who will obtain informed consent or assent from potential participants or legal guardians, and how. Additional consent provisions for collection and use of participant data and biological specimens in future studies, if applicable. An account of any economic or other inducements or incentives to prospective participants to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the participants, such as payment for medical services. Plans and procedures, and the persons responsible, for communicating to participants information arising from the study (on harm or benefit, for example), or from other research on the same topic, that could affect participants’ willingness to continue in the study. Plans to inform participants about the results of the study) |  |
|  | **Confidentiality:** (How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the study) |  |
|  | **Declaration of interests:** (State any financial and other competing interests for principal investigators for the overall study and each study site. Even if there is no COIs state that there is no COIs) |  |
|  | **Access to data:** (Statement of who will have access to the final study dataset, and disclosure of contractual agreements that limit such access for investigators) |  |
|  | **Ancillary and post-trial care:** (Provisions, if any, for ancillary and post-study care, and for compensation to those who suffer harm from study participation) |  |
|  | **Sponsor(s)/ Funding:** (Sources and types of financial, material, and other support. Provide the itemized budget details as well) |  |
|  | **Trial registration, if applicable:** Trial identifier and registry name. If not yet registered, then name of intended registry. |  |
|  | **Appendixes:** (Provided the list of all appendixes, if applicable) |  |
|  | **Facilities:** (Provide the important facilities required/available for the study namely computers, laboratories, special equipment, etc.) |  |
|  | **Study Timeline:** (Gantt Chart showing major activities from proposal development to report dissemination phases of a research project) |  |
|  | **References:** List bibliographic references included in the proposal. |  |

**Note:** *Please don’t forget to write* ***dated version number*** *in the protocol and all relevant documents to ensure that everyone refers to the same version of a given document as well as to ensure that what is approved is what is eventually put to use.*