| 1. **COVER SHEET**   Contain the following information:   * Revision date and number * Title of the Study * Author (s) * Implementing Agency * Cooperating Agency * Contact numbers of authors and cooperating agency |
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| 1. **TABLE OF CONTENTS**   This section contains a complete table of contents including a listing of all appendices |
| 1. **INTRODUCTION**   This section contains a brief summary of the background information relevant to the research design and protocol methodology. Sufficient information includes description of disease / condition of interest and present knowledge of the subject matter of the research. This information is necessary in order to understand the rationale for the research. |
| 1. **PROGRAM OR PROJECT TITLE**   The title is the distinctive name given to the research proposal (program or project), which describes the work scope in specific, clear, and concise terms.  A program is a group of inter-related research projects requiring an interdisciplinary or mutli-disciplinary approach to meet established goal(s) within a specific time frame. A project on the other hand is a basic unit in the investigation of a specific research problem with predetermined objectives to be accomplished within a specific time frame. |
| 1. **PROGRAM OR PROJECT LEADER**   This indicates the name of the program and or project leader, his or her designation or title in his or her agency, field of specialization and his or her mailing address, telephone and fax numbers. Percentage time to be devoted to his or her research should be indicated  A program leader is one who directly plans, organizes, supervised the over-all activities of a research, and is directly responsible for the conduct of one of the projects of said program.  A project leader is one who directly plans, organizes, and supervises, and conducts the implementation of a basic unit of investigation of a specific research problem. |
| 1. **IMPLENTING AGENCY**   This refers to the agency(ies) implementing the research proposal |
| 1. **COOPERATING AGENCY**   This refers to the agency (ies) which is /are expected to cooperate or contribute to the research work |
| 1. **SIGNIFICANCE OF THE PROPOSAL**   This is the rationale of the research. It answers the question, “what is the research for?” |
| 1. **LITERATURE REVIEW**   This section should discuss literature relevant and specific to the topic of the research proposal. It should be complete enough so the reader can be convinced that the research proposal being presented is built upon sound information base, addresses current country health priorities and will contribute something new to health and / or allied health sciences. |
| 1. **OBJECTIVES**   This section enumerates the goals that the program or project would attempt to achieve. If possible, delineate the general from the specific objectives. Research objective should be: Specific, Measurable, Attainable, Relevant and Time-bound. If the proposal is a program, the  program objectives as well as specific project objectives should be indicated |

| 1. **EXPECTED OUTPUT(S)**   This refers to the end results (e.g. production technology or knowledge) expected upon completion of the research. The output(s) needs to be identified to highlight impact / importance of the research. |
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| 1. **END-USERS OR TARGET BENEFICIARIES**   This refers to the probable end-users or beneficiaries of the research output and the number and locality of beneficiaries, if applicable. |
| 1. **DURATION OF PROGRAM OR PROJECT**   This refers to the planned start date, completion date, and duration in months. |
| 1. **METHODOLOGY**   **Research Design-** this section indicates how the research objectives will be achieved. It includes a description of the type of research design (e.g., cross sectional, case control, cohort, etc.)  **Research Population** – this is required for studies involving animals and humans. This section states the number of research participants required to enter and complete the research. A brief definition of the type of research participant required is also described.  **Inclusion Criteria** – this section describes the criteria each research participant must satisfy to enter the research. These criteria may include, but are not limited to the following: age, sex, race diagnosis or condition, method of diagnosis, and diagnostic test.  **Exclusion Criteria** – this section details the criteria that would eliminate a participant from participation in the research  **Sample Size Computation** – this section describes the type of sampling design and the assumptions used to compute the sample size.  **Research Site** – this section details the location, station, or unit where research will be conducted.  **Research Plan** – this section explains the plan of action, procedures and methods to be used during the research. Detailed methodology is described for laboratory, diagnostic, interviews, and manner of data collection. Special instrumentation may be described in a subsection (instrumentation or data collection tools, special equipment, etc.)  **Case Report Form** – the case report form (CRF) should be attached to the research proposal. If the CRF is in electronic format, a printed copy should be attached as an appendix.  **Variables to be Investigated** – dependent /outcome and independent variables. |
| 1. **ADDITIONAL SECTION FOR INTERNET RESEARCH**   If the protocol involves internet research, details of data collection should be described in the protocol including the following items:   1. Description on how the PI will authenticate the qualification and or identification of the respondents (e.g. use of personal identification number given to participants) 2. Identification and description of the source of online data will be use in the research   Blog, collaborative (e.g. Wikipedia), e-mails, chats, for a, social media platforms (e.g. Facebook, Twitter, Viber), Website, Video blogs (e.g. Youtube), Others   1. Identification and description of the data to be collected   Audio, correspondence (e.g. emails), film / video, photos, presentations (e.g. downloaded powerpoint presentations), metadata (e.g. profile, geographic location), text or content, others   1. Listing all URLs to be used 2. Identification of method/s of obtaining the informed consent   Written consent, email with name, audio-recorded consent, electronic information sheet with “tick box” for consent or non-consent, consent implied through submission of information, others   1. Description of how participants will get a copy of the ICF 2. Description of how participants will withdraw from the study if they wish to withdraw   (Data protection plan should be included in the section on DATA AND PRIVACY MANAGEMENT PLAN) |
| 1. **PLANS FOR DATA PROCESSING AND ANALYSIS**  * Computer facilities to be used, software packages * Statistical tools or tests to be used * Dummy tables |
| 1. **WORK PLAN SCHEDULE**   This is brief description in chronological order of each activity to be undertaken. The plan of work of a project should reflect the schedule of the study components. For the program, individual schedules of each of the projects should be supplied. A Gantt chart of activities should be given. This chart will indicate the relative time frame and schedule of the major activities of the proposal, including plans for research utilization. |
| 1. **ETHICAL AND BIOSAFETY CLEARANCE**   Ethical Clearance from agency’s Research Ethics Committee (REC) is required for research involving the use of human participants. In the absence of the REC, the implementing agency may submit their research proposal for ethical review to the National ethics Committee (NEC). *An ethical clearance is required prior to review of the proposal.*  Likewise, biosafety clearance is needed to ensure that all studies dealing with genetic engineering and pathogenic organism in the Philippines are conducted under reasonably safe conditions. If the implementing agency has no built-in Institutional Biosafety Committee, then the proposal could be submitted for review by the DOST’s National Committee on Biosafety of the Philippines (NCBP). |
| 1. **ETHICAL CONSIDERATIONS**   This section identifies the ethical issues inherent in the study protocol, in particular: (a) process getting the informed consent / assent, (b) issues of vulnerability and provision for protection of vulnerable participants / communities, (c) risk-benefit assessment and offering measures to enhance benefit and mitigate risks. |
| 1. **DATA AND PRIVACY MANAGEMENT PLAN**   This section addresses privacy and confidentiality concerns in research. It should be the governance and accountability issues regarding data management and security. This section should be indicate the medium in which the research data are stored, including security measures appropriate to the medium of storage. It should describe how data collection and storage will be secured (e.g. use of password, encryption, etc.) and limit access to the server.  The researcher / investigator should disclose other parties who may access the data. In addition, the researcher / investigator should indicate measures to address breaches of confidentiality. |

| 1. **RESEARCH DISSEMINATION / UTILIZATION**   This section should indicate the strategies to be used in disseminating and ensuring utilization of the expected research results. For product-based research, proposal should include the prospective technology user, as well as, plans for technology transfer. |
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| 1. **ESTIMATED BUDGETARY REQUIREMENTS**   Indicate the annual budget of the proposal according to source of funds. For the first year, specify the budget for major expense items. For succeeding years, only the total annual budget is required initially. The detailed breakdown of financial assistance requested should be in accordance with the New Government Accounting System (NGAS); the counterpart funding of the implementing agency as well as other agencies cooperating in the project should also be reflected. Details of the financial requirements per expense item and source of funds are illustrated at the end page.  Under the Personnel Services (PS), segregate the number and positions of those who will be receiving salaries from those who will be entitled to honoraria. Salaried personnel will consist of those who will work fully time for the project.  Part-time staff to be hired for the research will be entitled to honoraria. Likewise, the Project Leader and the consultants will be recipients of honoraria. Indicate the recommended salaries / honoraria rates per position and the coverage of their service periods.  For Maintenance and Other Operating Expenses (MOOE), the traveling expenses of transportation of one’s personal and essential baggage, per diems while in route or away from permanent station and items necessarily incidental thereto in connections with the research work. The item on supplies and materials will include expenses on consumable and semi-expendable field/laboratory/ office supplies and materials needed in the course of the research. Budget for sundry will consist of expenses on communications, repairs and maintenance, estimated cost for research utilization (RU) component, computerization, and miscellaneous expenses. Details for each line item should be provided.  The Capital Outlay (CO) details the budgetary requirement of the research for equipment items needed for the project. Indicate the quantity, unit cost and total amount.  An administrative cost equivalent to 7.5% of total costs under PS and MOOE can be included as part of the budget. This item corresponds to the overhead expenses (PS and MOOE) incurred by the implementing agency in managing, evaluating and monitoring the program / project. |
| 1. **CURRICULUM VITAE**   This portion provides relevant information regarding the proponent’s research capability. |

| 1. **ENDORSEMENT FROM THE AGENCY HEAD**   This is indicative of the support of the implementing agency to the research project in terms of use of facilities and equipment, and assistance in undertaking the project. |
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| 1. **BIBLIOGRAPHY**   An alphabetical, numerical listing referencing or source of relevant information or literature as used in referred medical journals or other international journals, should be followed. |
| 1. **LINE ITEM BUDGET**   *Sample:*   | **PARTICULARS** | **Sources of Funds and Amount (PHP)** | | | | --- | --- | --- | --- | | 1. **Personal Services (PS)** 2. **Salaries** 3. **Honorarium** |  |  |  | | **Sub-Total PS** |  |  |  | | 1. **Maintenance and Other Operating Expenses (MOOE)** |  |  |  | | **Sub-Total MOOE** |  |  |  | | 1. **Capital Outlay (CO)** |  |  |  | | **Sub-Total CO** |  |  |  | | **GRAND TOTAL** |  |  |  | |