National Research Ethics Board (NREB) - Liberia

Research Protocol Template

Instructions: Complete this template to provide IRB members and designated reviewers with sufficient information to conduct a substantive review of human research. If applicable, submit a Sponsor's Protocol in addition to this document. Detailed instructions for preparing this template can be found in the NREB- Liberia Operational Guidelines.

GENERAL INFORMATION
Protocol/ESTR Record Number (if assigned):
Version Number/Date:
Principal Investigator:
Protocol Title:

1. **Specific Aims**

2. **Background and Significance**
   - **2.1 Provide the scientific background and rationale for the research.**
   - **2.2 Describe the significance of the research, and how it will contribute to general knowledge.**

3. **Research Locations and Collaborating Sites**

   Research Locations refer to the geographic location that the research will take place, not to the institutions or researchers you may be collaborating with. All Research Locations should be listed in ESTR on the Research Locations page.

   Collaborating Sites refer to institutions or researchers that are also taking part in the research study. All Collaborating Sites should be listed in ESTR on the Sites page.

   - **3.1. Where will the research activities take place?** *[Fill in study-specific details.]*
   - **3.2. Describe the sites or locations where the research will be conducted.**
   - **3.3. Describe plans for communication among sites regarding adverse events, interim results, protocol modifications, monitoring of data, etc.** ☐ **N/A.**
   - **3.4. Describe any local laws, regulations, and/or customs affecting the research (e.g., age of majority, mandatory reporting requirements, etc).** ☐ **N/A.**
   - **3.5. Identify any approvals or permissions required of collaborating institutions, community leaders, or government officials, including approval from another IRB or local research ethics committee.** ☐ **N/A**

3.6. Will your collaborators interact with human subjects, have access to identifiable data/specimens,and/or be responsible for the design, conduct, oversight, or reporting of the research?
☐ **No** ☐ **Yes:** *If yes, indicate if the collaborators will obtain their own IRB review.*

3.7. Will any institution conducting research activities as part of this study, including collaborators, rely on the NREB?
☐ **No** ☐ **Yes:** *If yes, list each relying institutions, their site responsible Investigator, and describe what research activities will be conducted there.*

4. Study Team

4.1. Describe the Principal Investigator's experience conducting research at the study site(s) and familiarity with the local research context.

4.2. Describe how the Principal Investigator will ensure that sufficient time is devoted to conducting and completing the research.

4.3. Describe how all research staff members are trained to ensure that they are adequately informed about the protocol and study-related duties.

4.4. Describe the minimum qualifications for each research role (e.g., RN, social worker, phlebotomist, statistician), their experience in conducting research, and their knowledge of the local research context.

5. Study Design

5.1. Describe the study design type.

5.2. Does the study involve more than one participant group?
☐ **No** ☐ **Yes:** *If yes, identify each group here and throughout all applicable sections.*

5.3. Indicate the duration of a participant's involvement.

5.4. Indicate the total number of participants to be screened (if applicable) and/or enrolled (i.e., signed consent form). If the proposed research involves secondary data analyses only, indicate the number of data, documents, records, and/or specimens that will be obtained.

5.5. List inclusion and exclusion criteria, including age ranges of all participants, and describe the screening process.

5.6. Describe study procedures.

5.7. When all research-related study procedures are complete, are there plans for long-term follow up?

☐ **No** ☐ **Yes:** *If yes, indicate what data will be collected during this period.*

5.8. Does the study involve the collection of specimens (e.g. blood, cells, tissues, fluids, secretions, recombinant or synthetic nucleic acids, biological toxins, bacteria, virus, fungi, etc.)
☐ **No** ☐ **Yes:** *If yes, indicate the COMS Registration Number or plans to obtain COMS approval.*

5.9. Does the study involve the use of existing data, documents, records, and/or specimens for secondary analysis?
☐ **No** ☐ **Yes:** *If yes, indicate how, when, where, and from whom data, documents, records, and/or specimens will be obtained.*

5.10. Are there provisions for medical and/or psychological support resources available to participants (e.g., in the event of incidental findings, research-related stress)?
☐ **No** ☐ **Yes:** *If yes, describe the provisions and their availability.*

5.11. Describe the data and safety monitoring plan for the study. This plan should outline how study progress will be monitored throughout the lifecycle of the research to ensure the safety of subjects, as well as the integrity and confidentiality of data.

5.12. Are there any anticipated circumstances under which participants will be withdrawn from the research without their consent?
☐ **No** ☐ **Yes:** *If yes, describe the circumstances for withdrawal as well any associated procedures to ensure orderly termination, appropriate referrals, and/or follow-up care.*

6. Recruitment Methods ☐ N/A. *Skip to next section.*

6.1. Indicate how, when, where, and by whom participants will be recruited. Provide a list of materials used to recruit participants, e.g., emails, posters, and/or scripts here.

7. Consent Process

7.1. Describe how the research team will invite participants to take part in the research and obtain consent to participate. If the research team will not obtain informed consent, provide justification.

7.2. Describe how the research team will document the consent process (e.g., participant/researcher will both sign and date the consent document; participants will thumbprint the consent document). If the research team will not obtain signature and date, provide justification.

7.3. Will participants be offered a copy of the consent information?
☐ **Yes** ☐ **No:** *If no, explain why not.*

7.4. If consent will be obtained in a language other than English, identify the language(s) that consent information will be provided, who will be responsible for translation, and the provisions for communicating this information to participants. ☐ **N/A**

8. HIPAA Privacy Protections ☐ **N/A.** *Skip to next section.*

8.1. Describe plans for obtaining authorization to access protected health information or provide the rationale for a waiver of authorization.

9. Vulnerable Populations ☐ **N/A.** *Skip to next section.*

9.1. Identify all vulnerable populations (e.g., children; pregnant women, human fetuses, neonates; prisoners; elderly; economically disadvantaged; employees or students of the investigator or sponsor; undocumented individuals; refugees; racial and/or ethnic minorities; illiterate or low-literacy; military personnel; terminally ill; cognitively impaired or mentally ill; persons with a stigmatizing disease or condition, e.g. AIDS/HIV, etc.) and describe safeguards to protect their rights and welfare.

10. Risks

Risks may be physical, psychological, social, legal, reputational, and/or financial.

10.1. Describe the reasonably foreseeable risks, discomforts, and/or inconveniences to participants and/or the group/community to which they may belong. Indicate the probability, magnitude, and duration of each risk.

10.2. Identify whether any of the information collected, if disclosed outside of the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, or reputation.

10.3. Outline provisions in place to minimize each risk identified above.

11. Benefits

11.1. Describe the potential benefits to individual participants, if any, and/or society. If there are no direct benefits, state that here. Note: payment/compensation is not a benefit.

12. Participant Privacy

12.1. Describe provisions to protect participants' privacy (their ability to control and limit the extent, timing, and circumstances of sharing information about themselves with

others, e.g., the use of a private interview room) and to minimize any sense of intrusiveness that may be caused by study questions or procedures.

13. Data Confidentiality

13.1. Indicate the identifiability of the data/specimens:

☐ **Data/specimens will not contain any direct or indirect identifiers (anonymous data).**
☐ **Data/specimens will contain direct or indirect identifiers, but the research team will remove them upon receipt (de-identified data).**
☐ **Data/specimens will contain indirect identifiers (i.e., number, letter, symbol, or combination thereof) and the research team will maintain a key that links identifiers to individual participants (coded data).**
☐ **Data/specimens will contain direct identifiers (identifiable data).**
☐ **None of the above; describe:**

13.2. Have any identifiable data/specimens been de-identified for use in this research study?

☐ **No** ☐ **Yes:** *If yes, describe how you will prevent any re-identification.*

13.3. Identify where data/specimens will be stored (e.g., At the LIBR/NPHIL or remotely, in a specimen laboratory) and describe the provisions to maintain confidentiality (e.g., password protection, encryption, locked filing cabinets, etc.).

13.4. Describe whether any data/specimens will be transmitted and, if so, how, when, and to whom.

13.5. Indicate who is responsible for data/specimen management and how the research team and/or other collaborators are permitted access to information.

13.6. Indicate how long data/specimens will be stored and describe the plans at the end of the storage period (e.g., are data/specimens destroyed, returned to data/specimen provider, etc.).

13.7. Provide proof of Material Transfer Agreement.

14. Data/Statistical Analyses Plan

14.1. Describe plans for analysis (including the statistical method, if applicable).

14.2. Is there a sample size/power calculation?

☐ **No** ☐ **Yes:** *If yes, describe the calculation and the scientific rationale, and, if applicable, by site and key characteristics such as participant demographics.*

15. Costs and Compensation ☐ **N/A.** *Skip to next section.*

15.1. Identify any costs that participants may incur during the study, including transportation costs, childcare, or other out-of-pocket expenses.

15.2. Identify remuneration that participants may receive during the study. Specify the amount, timing of disbursement, and method (e.g. money, and transportation). Describe how compensation will be calculated and paid if a participant withdraws. If any participant will receive a single payment more than $100, or $600 or more in one calendar year.

16. Sharing Study Results ☐ **N/A.** *Skip to next section.*

16.1. Describe the plan to share study results with individual participants, the participant group/community, and/or others.

17. Research Related Injuries ☐ **N/A.** *Skip to next section.*

17.1. Describe plans for medical care and compensation for research-related injuries.

18. Reportable Events

18.1. Outline plans for communicating reportable events to the IRB, Sponsor, or others as applicable (e.g., adverse events, unanticipated problems involving risks to participants or others, breach of confidentiality).

19. Regulatory Compliance

19.1. Describe plans for monitoring regulatory compliance. The monitoring plan should include how you will ensure proper record keeping, retention of required regulatory documents and participant files, and adherence to the IRB-approved protocol and/or IRB policies and procedures. Monitoring plans should describe 1) who is responsible for file maintenance, 2) what will be maintained, 3) how often files will be reviewed and using what method, and 4) where documentation will be retained (for both Regulatory Documents and Participant files).

20. Data or Specimen Banking (Repositories) ☐ **N/A.** *Skip to next section.*

20.1. Identify what data/specimens will be collected for the repository and what information will be associated with the data/specimens.

20.2. Describe where and how long the data/specimens will be stored, who will have/may request access, and how data/specimens will be accessed.

20.3. Indicate whether participants' permission will be obtained to use the data/specimens in other future research projects.

20.4. Describe the procedures to release data/specimens.

20.5. Describe the plan to send data/specimens <u>to</u> research collaborators outside of the country. ☐ **N/A**

20.6. Describe the plan to receive data/specimens <u>from</u> collaborators outside the country.
☐ **N/A**

21. Clinical Trials ☐ **N/A.** *Skip to next section.*
Complete this section for NIH funded clinical trials or applicable clinical trials (ACT) under the FDA Amendments Act.

21.1. Describe plans for registering this project in a clinical trials registry, e.g., clinicaltrials.gov. If available, provide the registry record number.

22. Device ☐ **N/A.** *Skip to next section.*

22.1. Describe the device, including the generic or common name, brand name (if applicable), purpose, function/operation, and whether it is an implant. Indicate who is providing this device for research use.

22.2. Indicate the FDA/LMHRA status of the device as it is being used for the proposed research:
☐ FDA/LMHRA-approved device being used "on-label" (i.e., FDA/LMHRA-approved purpose, population, and manner).
☐ FDA/LMHRA- approved device that is being used "off-label" (i.e., for a different purpose, population, or in a different manner than approved).
☐ Not approved by the FDA/LMHRA.

22.3. Indicate the IDE Status of this device:
☐ The use of this device has an IDE.
☐ The use of the device qualifies for an Abbreviated IDE.
☐ The use of the device is exempt from the IDE requirements.

22.4. Has the FDA/LMHRA made a determination as to whether the device is Significant Risk or Non-Significant Risk? ☐ **No** ☐ **Yes:** *If yes, indicate the LMHRA/FDA's determination.*

22.5. Describe plans for storage control, and dispending of the product so that (1) only authorized investigators will use the product; (2) the product will only be used in participants who have provided consent, and (3) there will be documented tracking of each product, including unique identifiers and any return/disposal.

23. Drug/Biologic ☐ **N/A.** *Skip this section.*
23.1. Describe the drug or biologic, including the generic or common name, brand name (if applicable), dosing, route of administration, number of doses, timing of administration. Indicate who is providing the drug, biologic, supplement for research use.

23.2. Indicate the IND Status of this drug or biologic and who holds the IND:

☐ There is an IND approval from the FDA for the use of this item.
The IND is held by: _____

☐ An IND application has been, or will be, submitted to the FDA.
The IND will be held by:_____

☐ An IND approval is not required.

23.3. Describe how dispensing, delivery and administration will be performed, and by whom. Include information about control (e.g., locked storage), tracking (e.g., lot number, returned pills), documentation, storage, and return/disposal.