



THE NATIONAL RESEARCH ETHICS BOARD (NREB)  
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MONROVIA, LIBERIA



**OPERATIONAL GUIDELINES  
(Amended Version 2019)  
NATIONAL RESEARCH ETHICS BOARD OF  
LIBERIA (NREB)  
REPUBLIC OF LIBERIA**



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## Forward

Research ethics govern the standards of conduct for scientific researchers. It is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants. As such, all research involving human beings should be reviewed by an ethics committee to ensure that the appropriate ethical standards are being upheld. Discussion of the ethical principles of beneficence, justice and autonomy are central to ethical review.

The National Research Ethics Board (NREB) is a 21-member committee established and appointed by the former Minister of Health of the Republic of Liberia. While a majority of the committee members are clinicians, scientists, and national subject matter experts, they possess valuable and extensive experience, and knowledge of research in different fields, and extensively knowledgeable in research ethics before commencing their roles with the NREB. The broad range of research expertise, together with ethics training, ensures that all proposals are thoroughly and fairly reviewed for compliance with research ethics. The NREB mandate is to ensure that Liberia, a developing country with high rate of illiteracy, only supports research of the highest ethical standards. The NREB reviews all research projects involving human participants that are supported either financially or technically by national and international research scientists. The NREB is guided in its work by the World Medical Association Declaration of Helsinki, as well as the International Ethical Guidelines for Biomedical Research Involving Human Subjects. According to these guidelines, all research involving human subjects should be implemented in accordance with the fundamental ethical principles of respect, beneficence, non-maleficence and justice.

This amended document is intended to provide guidance to research ethics committees, as well as to researchers who design and implement research studies. The need to amend this document was driven by challenges in regulating research ethics in Liberia for the protection of human safety.

Fatorma K. Bolay, PhD  
Chair, National Research and Ethics Board of Liberia



## **Acknowledgements**

The National Research Ethics Board retreat held in 2018 was a reflection of the Board's achievements, challenges, and gains in the past years of its operation, as well as the lessons learned and the way forward. This evaluation led to the strengthening of the existing Guidelines to fulfill the obligation to protect research participants according to the relevant ethical guidelines and regulations. Additional aims include upholding the societal interest and the obligation of researchers by applying the principles of research ethics and relevant guidelines, standard operating procedures (SOPs) and regulations that are socially and culturally acceptable. Moreover, this Retreat accrued the potential to identify the gaps regarding the submission of applications and organizing review procedures in Liberia, as well as a medium for the effective operation of the NREB as per its administration and review guidelines.

Against this background, the National Research Ethics Board of Liberia would like to acknowledge and extend its appreciation to the following institutions, partners and individual for the support in making this a success. This includes members of the Board and the hard-working Technical team for their effort in the finalization of this document.

## **Ministry and Agencies**

1. Ministry of Health, RL.
2. National Public Health Institutes of Liberia (NPHIL)

## **Key Partners**

1. World Health Organization(WHO)
2. PREVAIL
3. National Institutes of Health (NIH)
4. University of Liberia
5. A.M Dogliotti College of Medicine
6. John K. Kennedy Medical Center
7. John Hopkins Berman Institute of Bioethics
8. UL-PIRE Africa Center
9. US Department of Defense
10. US. Naval Medical Research Unit-3 (NAMRU-3)

## **Technical Team – Guidelines/SOP Development**



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## Background

The National Research Ethics Board (NREB) was reconstituted in 2014, during the heat of the Ebola Virus Disease (EVD) Epidemics in Liberia, with the primary intent of protecting research participants while accounting for the interests of researcher during the implementation of research studies. The general ethical framework required for the Protection of research participants is based on the three pillars of respect for person (Autonomy), beneficence and justice. The NREB role is to principally analyze and assess the risk-benefit ratios of proposed research studies for the protection of research participants.

As the advisory institution responsible to oversee all research related protocols from within and out of Liberia, the Board was established to review, evaluate and render decisions regarding the ethical merits of the research protocols. The mission of the Board is to ensure and guarantee the rights, dignity, safety and protection of all individuals and communities that participate in research activities. The committee is also committed to ensuring the scientific merits of the research studies while protecting the rights of human subjects.

The objective of this guideline is to contribute to the effective functioning of the NREB to ensure that quality and consistent ethical review mechanisms for health and biomedical research are instituted by the board as prescribed by the Ethical guidelines for biomedical, health sciences, and behavioral research on human subjects in Liberia.

The NREB, as the national ethics committee of Liberia, shall review all submitted research proposals in keeping with the following internationally recognized ethical standards (the Belmont Report of 1979; World Medical Association's Declaration of Helsinki (1964), as amended (currently 2013); ICH Good Clinical Practice (R1, 1997 & R2, 2016); and the CIOMS International Ethical Guidelines for Health-related research involving human subjects (2016) in keep with country specific regulations and guidelines.

## Functions of the NREB



- Conduct ethical reviews for submitted research proposals from individual investigators, nationally and internationally recognized entities.
- Monitor the conduct of research for health to ensure compliance with approved protocol.
- Establish and maintain a repository of all protocols reviewed in the country along with completed research/study reports.
- Support research ethics capacity building.
- Determine generic guidelines for the functioning of health research in Liberia.
- Maintain a registry of health research ethics committees.
- Set norms and standards for conducting research on humans and animals, including clinical trials.
- Mitigate conflicts among IRBs, researchers and research entities.
- Inform professional bodies of breach of ethical standards on the part of relevant professional.
- Recommend disciplinary action(s), where appropriate.
- Advise the Government of Liberia (GoL) on ethical issue.

## **ADMINISTRATIVE PROCEDURES**

### **Frequency of Meetings**

The National Research Ethics Board (NREB) shall meet bi-monthly for its regular meetings, on the third Saturday of the month. These dates shall be made public and posted on the website of the NREB.

The threshold for the review of research protocols during regular meetings shall be a minimal of three completed applications.

Where applicable, there shall be situational, or Ad-Hoc meetings called by the Director of the NREB, such as an emergency meeting, based on appropriate justifications.

### **Attendance at Meetings**

Regular attendance at all meetings for the effective operations of the NREB shall be highly encouraged.





## Quorum

A quorum for the commencement of meetings shall be two-thirds of the membership of the NREB.

### **Submission of Comments**

In situations where a member cannot attend a meeting, he/she shall advise the NREB Director one (1) week before the scheduled meeting regarding their views and/or concerns on specific agenda items under consideration.

### **Members Not in Attendance**

Members, who for some unforeseen reasons cannot attend a meeting, shall inform the NREB Director two (2) weeks before the scheduled meeting.

Members who are absent from 60% of regularly scheduled meetings during a period of six (6) calendar months without appropriate excuses shall be automatically replaced by new members based on the recommendations of the Appointing Authority.

Members shall acknowledge receipt of invitations regarding availability for meetings.

### **Agenda for Regular Meetings**

The Agenda and Research Protocols shall be distributed by the NREB Director to the Membership no later than three (3) weeks before a meeting. The materials shall be distributed by electronic and hard copies such as post, courier, email and/or in-person, where applicable, to ensure timely delivery. Receipt of the materials shall be confirmed by each member prior to the meeting.

The Agenda shall include, where applicable, the following items:

1. Minutes of Previous Meeting
2. New Proposals
3. Re-submission/Revised Proposals/Protocol Changes
4. Progress/Final Reports on Approved Proposals
5. Administrative/Operative issues
6. Any other Business (AOB)



## **Minutes of Meetings**

The minutes of the previous meeting shall be written and distributed to all members at least two (2) weeks prior to the next meeting.

During the meeting, the minutes shall be read and adopted, signed by the Chair, Co-Chair and/or by the presiding, and archived for the NREB Records.

## **Timely Considerations for Review**

All completed proposals submitted by the deadline shall be reviewed at the next regularly scheduled bi-monthly meeting, if the numbers of proposals meet the threshold.

If additional materials are required from the Principal Investigator (PI) to complete the application, he/she shall be contacted by a written communication (letter or email) to provide the materials.

The PIs maybe asked to be available for presentations and/or contacted during the meetings.

## **Methods of Decision Making**

The NREB will promote open communication by all members (through building consensus). Final determinations shall be reached following the NREB SOPs.

The NREB may seek opinions from content experts regarding designated research protocols and/or issues, as long as the experts have no conflict of interest (CoI), including participation in the research, financial interest in the outcome, and/or involvement in competing research, among others.

## **Notification of Decision**

The PIs shall be notified in writing of the NREB decisions up to two (2) weeks after the meetings, where applicable, after the complete review of the protocols. If there are outstanding issues to address for complete review, the appropriate representatives will



be contacted, after the review meeting, to provide those additional materials or address those additional concerns, where applicable.

## Decision Types

After the review of applications by the NREB, the decision types to be communicated by the Secretariat shall be one of the below categories:

1. Approved: The submission satisfies all requirements in accordance with the NREB SoP and Good Clinical Practice (GCP), including country-specific ethical and regulatory principles, and the protections of human subjects.
2. Not Approved: The submission failed to satisfy all requirements in accordance with the NREB's SoPs and GCP.
3. For Consideration
  - a) Provisional Approval: an approval requiring the investigator to commence the study while addressing minor concerns.
  - b) Pending Approval: The submission partially satisfied the requirements in accordance with the NREB's SoPs and GCP. In such a situation, stipulations and/or concerns will be generated and submitted to the PI or approved designate for redress. The stipulations and/or concerns must be addressed to the satisfaction of the NREB prior to the granting of approval for the commencement of the study.

## Determination of Review Types

On receipt of a study protocol, by the NREB Secretariat, that initially appears to be of minimal risk (by checklist), clarification may be sought from the Chair and/or Co-Chair to decide as to whether the protocol requires consideration for Full Review or re-routed to a subcommittee of two or more members for Expedited Review (ER). All decisions made in this manner, with appropriate justifications, shall be confirmed at the next full meeting of the NREB

## Fees (Please see chart below)



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The NREB shall charge minimal fees for the review of each submission. Submissions include Research Protocol, Re-submission, Amendment and Continuing Review.

The structure of the fees will be based on the below application types. They include:

#### Research Protocol

There are several types of research protocols. The fees will be structured based on the type of research protocol and communicated to the PIs. The determination will be based on the review of the application by the NREB Director in conjunction and collaboration with the Chair and/or Co-Chair, respectively.

#### Behavioral Research

The scope of the project, the duration of the project, the sample size of the project, the type of study populations, and the complexity of the project, among others.

#### Investigational Product (Clinical Trials)

The fees structure is based on the scope of the project, the types and quantities of the investigational products, the duration of the project, the sample size of the project, and the complexity of the project, among others.

#### Non-Clinical Trial

The fees structure is as per the scope of the project, investigational product, population, complexity, among others.

Waivers/Exemptions. The following submissions from undergraduate and graduate students that are studying within academic institutions based in Liberia may be exempted from the fees structure based on the review of the protocol by the NREB Director, in conjunction and collaboration with the Chair and/or Co-Chair, respectively.

### Review Fees Chart

No.	Study Description	Amount
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1.	Behavioral Science Research	\$1000.00
2.	Health Science Research(HSR)	\$2,500.00
3.	HSR-Behavioral (Education Intervention)	\$4,000.00
4.	Clinical Trial	\$7,000.00
5.	Non- Clinical Trial (as described)	\$6,000.00
6.	Re-Submission	\$1,500.00
7.	Continuing Review	\$1,500.00
8.	Amendment	\$1,500.00

### **Undergraduate Academic Project /Graduate Academic Project (e.g., Thesis, Dissertation, etc.)**

Submissions by undergraduate and graduate Liberian students based at foreign academic institutions will be reviewed and determination made on a case-by-case basis in consideration of whether the project is funded or not, among others.

Additionally, submissions by Research and Career Track Faculties based at Liberian academic institutions may be exempted from the fees structure based on the review and determination made on a case-by-case basis in consideration of whether the project is funded or not, among others.

### **Monitoring**

The NREB shall, as a condition for the approval of a research protocol, require the PI to provide regular updates to the Secretariat from the date of approval. It is the responsibility of the PI to comply with this requirement. Additionally, the NREB shall conduct site visits at appropriate intervals. Site visits may be unannounced in certain cases to ensure the integrity of the study.

### **Confidentiality of Protocols**



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The NREB documents and protocols, electronic and/or hard copies, shall be maintained in secured and protected environments, and accessed by authorized users.

All research protocols submitted to NREB members for review shall be securely stored. Additionally, NREB members shall be required to sign confidentiality clauses and/or non-disclosure agreements that prohibit non-authorized individuals from accessing the documents.

## **RESEARCHERS**

### **Responsibilities of Researchers**

All research protocols must be submitted by the PIs. The PIs are considered the focal points of contacts for all communications with the NREB regarding all protocol related issues. In the eventuality that a PI is unavailable, based on justifiable reasons, the institution must submit an official communication to the NREB.

The PIs are expected to be knowledgeable of the values and tenets of ethical and regulatory principles, (research merit and integrity, Respect for person, Beneficence and Justice), and the applications of scientific methods that are associated with the conduct of research in human subjects, including non-human primates, where applicable. This should be reflected in the protocols that are submitted to the NREB for scientific, ethical and regulatory considerations, where applicable.

### **Conflict of Interest (CoI)**

The members of the research team shall establish transparent processes to identify and manage actual and/or perceived conflicts of interest (CoIs).

While a conflict may relate to financial interests, it could also relate to other private, professional and/or institutional benefits or advantages that depend significantly on the outcomes of the research projects. Therefore, it is mandatory that members of the research team declare, as part of the application process, actual and/or perceived CoIs to the NREB.

### **Procedures for Complaints**



Whenever a complaint about a researcher raises the possibility of research misconduct, the matter will be handled in accordance with the 'research misconduct' processes specified in the NREB's SoP.

Where a complaint about a researcher is considered as a 'serious misconduct' that falls outside the purview of the definition of 'research misconduct' as described in the NREB's SoP, it will be referred to and further addressed by the appropriate governmental institutions that handle other forms of misconduct.

## Submission Types

There are several types of submissions. These include:

- 1. New (Initial) Submission:** A research protocol that has not been previously submitted to the NREB for scientific, ethical and/or regulatory considerations. Protocols should be submitted to the Director of the NREB no later than one month to the NREB bi-monthly meeting. Any protocol submitted after the stipulated timeline shall be re-routed to the next review.
- 2. Re-Submission:** A submission of an unapproved research protocol that has been previously considered by the NREB. The submission could be a revised protocol, the provision of additional information or response to stipulations from an application that has been conditionally approved. All re-submissions shall be routed for a full Board review.
- 3. Reportable Event:**

Definition: An event that occurs during the course of human subject research that requires notification to the NREB. Reportable Events include:

- a. Unanticipated problems involving risks to subjects or others (also referred to as UPs).
- b. Non-compliance (including major protocol deviations and non-compliance that is not related to a protocol deviation).
- c. Deaths related or possibly related to research activities.
- d. New information that might affect the willingness of subjects to enroll or continue participation in the study.

**All events except deaths need to be reported to the NREB within 7 calendar days.**



Deaths that are possibly, probably or definitely related to the research must be reported to the NREB within 24 hours.

- 4. Continuing Review Submission:** A submission, prior to the expected expiration date of approval by the NREB, that requests an extension of the ethical approval to continue the implementation of the research project. The Principal Investigators shall submit review reports to the NREB Secretariat for continuing review at least eight weeks prior to the expiration of the approved protocol. For this application, amendment to the research protocol may or may not be integrated.

#### **CR review timeline**

- If the NREB has not reviewed and approved a research study by the study's current expiration date, the NREB approval has expired and research activities should stop. The Board will determine if the continuation of research for all previously enrolled subjects is in the best interest of the participants and is permitted.
  - If the Principal Investigator cannot provide any of the required information, the PI shall provide justification for the delay in the report, and a timetable for provision of the information. The PI shall also submit a copy of the consent documents and procedures currently in use
- 5. Protocol Amendment:** This applies to previously approved study protocols by the NREB which have been amended and submitted for approval. Amendments made to protocols shall not be implemented until reviewed and approved by the NREB. The NREB Secretariat, in consultation with the Chair, will make a determination as per the type of review (full board review or Expedited given the risk) and will notify the investigator within 3 weeks upon submission as per the Board's decision.

Requirement for amended submission:

- A memo to the NREB stating reasons for the amendment.
- A List of amended areas in the protocol.
- A clean version of the protocol/consent form(s) with the changes effected.
- The amended protocol/consent form(s) shall be given a new version number and an effective date.





- 6. Research Exempt ( AS DETERMINED BY THE NREB):** Research proposal that pose no or minimal risk to research participant or that has no formal informed consent process or subject to continuing review by the NREB. Research studies that may be considered for exemption are minimal risk research studies that conform to one or more of the following categories of research. Research involving the use of educational tests (survey, Interviews, observation), of public behavior issues.

### **Expedited Review:**

On receipt of a study protocol that initially appears to be of minimal risk, clarification may be sought from the Secretariat in consultation with the chair and shall determine which protocols may require expedited review.

The following categories shall be qualified for an expedited review:

- Research activities that present no more than minimal risks to human subjects.
- Minor changes in previously approved research.
- Protocol involves interviewing of non-confidential nature and not likely to harm the status or interest or not likely to offend the sensibility of study participants.
- Those that involve in the collection of small amounts of blood samples (and not too frequent) for routine medical assessment, e.g., by finger, heel or ear stick.

### **Detailed Instruction:**

- 1.** Expedited review shall be conducted by one or more experienced reviewers designated by the Chairperson from among members of the Board in accordance with the requirements (SOP # 09). If the review involves a revised version, the selected members shall normally be those who reviewed the previous version of the protocol.
- 2.** The expedited review shall be carried out on a complete study protocol with all required attachments as if it was being submitted for the first time. Results of the review process may be communicated to the PI before being discussed at a Board meeting and reported retrospectively to the Board meeting.
- 3.** Expedited review shall take no more than 3 weeks and if any member of the Committee raises a concern about a protocol that was expedited, the protocol shall undergo a full board review. For an expedited review, the reviewers may exercise all of the authorities of the Board to approve or disapprove. A research activity may be disapproved only after review in accordance with the non-



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expedited procedure. The Director shall inform all members about the outcome of an expedited review as soon as practicable.

## Declaration of Funding Sources

A researcher is required to disclose the amounts, sources or potential sources of funding during the submission of research protocols. Furthermore, following the approval of a protocol, if additional funding sources are identified, they must be reported to the NREB.

**False Declaration: Principal Investigator providing falsehood, upon an investigation by the NREB if found guilty, shall be penalized by withdrawal of the permission for research work in Liberia for a period of ten (5) years.**

## Payments to Participants

Any form of payments to enrolled study participants that has the potential for coercion is not acceptable to the NREB. However, reimbursement of direct costs to participants enrolled in a research study, including costs such as travel, accommodation and inconvenience fee, are permitted.

## Point of Contact

Participants shall be advised of the first point of contact for complaints. The consent forms that are signed by participants shall include the name(s) and telephone number(s) of this contact(s).

The first instance of a complaint shall be directed to the NREB:

### Director

**National Research Ethics Board (NREB)**  
**First Floor West, John F. Kennedy Medical Center**  
**Monrovia, Liberia**  
**Email: [nreb.liberia.gov@gmail.com](mailto:nreb.liberia.gov@gmail.com)**



## **Discontinuation of Research**

The PI is required to inform the NREB, with appropriate justification(s), if and why an approved project has been discontinued before the expected completion date.

## **Withdrawal of Approval**

If the NREB becomes aware that a research project is not being conducted in accordance with the approved protocol and the welfare and rights of enrolled participants are not protected, the NREB shall withdraw its approval and inform the researcher, research organization and/or institution of such withdrawal with the stipulated justification(s), where applicable. The NREB shall suspend such a project immediately. However, if the violations are corrected, the entity may re-apply for NREB approval to continue with the implementation of the project.

## **DISSEMINATION OF RESEARCH KNOWLEDGE**

Considerations shall be provided for the dissemination of research data and findings with the NREB, research participants and implementing country.

Research findings, publications and, where applicable, data should be made available in the implementing country where the research may have been conducted. Nevertheless, the researchers shall consider the potential for harm to research participants, collaborators and/or local institutions. Therefore, appropriate guidelines must be followed to avoid any breach of privacy, confidentiality and anonymity.

## **INTELLECTUAL PROPERTY**

Local institutions, collaborators and/or participants have contractual and/or legal, interests and rights in the data, among other, even though it varies according to agreements and/or jurisdictions. Therefore, the study team shall be transparent to all parties regarding intellectual properties and subsequently report to the NREB, if such exists.

### **Study submission requirements: Application for Ethical Review and Approval**

All applications for ethical review of research should be submitted to the NREB Secretariat. To facilitate the process, we advise prospective researchers to bring along one hard-copy of the protocol or email for pre-review prior to final submission for committee review.



Where the PI and researchers are from foreign institutions, a local (resident) Liberian researcher must be included on the team and should include support letters and CV(s).

### **Deadline for Submission of Application**

Researcher must submit the document three weeks prior to the next Board meeting.

### **Student Application**

Applications shall be submitted under the responsibility of a supervisor involved in the oversight of the student's work or in the student's name, co-signed by the supervisor.

### **Protocol Submission**

An application for ethical review of a proposed health related research shall be submitted by a Principal Investigator (PI) qualified to undertake the particular study. The PI is directly responsible for the ethical and scientific conduct of the research.

### **Protocol Presentation format**

Standard Font size – 12, double spacing, and pages printed on one side only. The applicant should submit all documents required for ethical review of the proposed research.

These may include but not limited to:

1. Full Protocol and executive summary with the following attachments
2. Signed agreement between sponsors and PI (where applicable).
3. A statement that the researcher(s) agree to comply with ethical principles set out in relevant guidelines.
4. Investigators Brochure (where applicable).
5. Material Transfer Agreement (MTA) for shipment of specimen/biological materials outside of Liberia (where applicable).
6. Data Sharing Agreement (where applicable).
7. Administrative Information on sponsors of the study.



8. Full Protocol with executive summary with the following attachments: Signed agreement between sponsor and PI (where applicable)
- Signatory page of key persons of the collaborative institutions involved in the study i.e. Sponsor Signatory Approval Page duly signed, with date (where applicable)
  - Written Informed Consent form (with dates and version number) and translations into the local language appropriately into easily understandable 'Liberian English' (where necessary)
  - Written Parental Consent form for children **>17years** (if study involves Minors)
  - Written Parental Consent for & Assent form for children **> 18 years (15-17years)** (if study involves Adolescent).
  - All forms, documents, Community engagement advertisements to be used in the recruitment of potential participants
  - All data collection forms to be used in the research including but not limited to case report forms, questionnaires, interview schedules, etc. clearly indicated and dated.
  - Referral forms for treatment (where applicable)
  - Budget for the study
  - Time line for the study
  - Any other information deemed necessary to facilitate the review process.
  - Current CV(s) of PI & Co-Investigator(s) where same has not being submitted to the NREB in the preceding 12 months.

### **Additional requirements for Clinical Trials, Biomedical/Epidemiological Studies**

- Profile on previous study i.e. Phase 1 & Phase II studies (where applicable)
- Investigator Agreement (PI's responsibility), Page duly signed, with name and date. Current Certificate of Training in Good Clinical Practice (GCP) for PI(s)
- Investigational Product Brochure for the study
- Data Safety Monitoring Board (DSMB) membership and Charter of Work/Current Curriculum Vitae of members.
- Insurance cover for study participants
- Scientific review approval



- Food and Drugs Authority approval letter for use of the Investigational Product/ Devices and clinical trial approval (This should be submitted after the NREB approval).
- Current CV(s) of PI & Co-Investigator(s)

#### Additional Requirements by Undergraduates, Masters and Postgraduate Students:

- Covering letter and CV of supervisor
- Covering letter from school/college
- Students not taking their academic program in Liberia are required to identify a local supervisor and submit his/her covering letter and CV

#### Number of Copies of Protocol for Submission:

##### Institutional Protocol:

Applicant shall submit fifteen (15) comb-bounded copies of the full research protocol with the items indicated and where applicable, and an email version with protocol title and PI's name stated on it

##### Individual Protocol:

Applicant shall submit fifteen (15) comb-bounded copies of the full research protocol with the items indicated and where applicable, and an email version with protocol title and PI's name stated on it.

##### PhD Student Protocol:

Applicant shall submit fifteen (15) comb-bounded copies of the full research protocol with the items indicated and where applicable, and an email version with protocol title and PI's name stated on it

##### Fellowship Students:

Applicant shall submit fifteen (15) comb-bounded copies of the full research protocol with the items indicated and where applicable, and an email version with protocol title and PI's name stated on it



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### **Masters Student protocols:**

- Applicant shall submit five (5) comb-bounded copies of the full research protocol with the items indicated above and where applicable, and an email version with protocol title & PI's name stated on it.

### **Undergraduate Student Protocols:**

- Applicant shall submit five (5) comb-bounded copies of the full research protocol with the items indicated above and where applicable, and an email with protocol title & PI's name stated on it.

### **Protocol Presentation Format:**

Standard Font size – 12, double spacing, and pages printed on one-sided only

### **Protocol Arrangement:**

Arrangements of the protocol shall follow the same sequence as outlined above.

### **Protocol Numbering:**

- All protocols must be numbered appropriately and separately from all other supporting documents such as: letters, NREB administrative form and Checklist, Participant Information Sheets & Consent forms, Questionnaires, CVs etc. Information Sheets, Consent forms, Questionnaires, CVs etc. must all be numbered separately.

### **Mode of Submission:**

#### **Director**

**National Research Ethics Board (NREB)**  
**First Floor West, John F. Kennedy Medical Center**  
**Monrovia, Liberia**  
**Email: [nreb.liberia.gov@gmail.com](mailto:nreb.liberia.gov@gmail.com)**

### **References**



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1. GHSERC SOP
2. Belmont Report
3. ICH GCP
4. CIOMS Guidelines
5. NREB SOP
6. NIH Intramural Research Program(Reporting Research Events SOP)
7. Tanzania National Ethics Committee Guidelines
8. WHO Guidelines for National Ethics Committees
9. British National Review Guidelines
10. LSHTM EC ToR/Procedure
11. Liberia Research for Health Policy and Strategy