LIBERIA INSTITUTE OF BIOMEDICAL RESEARCH/ NATIONAL HEALTH SCIENCE RESEARCH (LIBR/NHSR) Ethics Committee Guidelines:

Procedures for Researchers

September 23, 2011

I. Administrative Procedures

1.1 FREQUENCY OF MEETINGS

The Liberia Institute of Biomedical Research/National Health Science Research Ethics Committee (LIBR/NHSREC) shall meet bi-monthly, on the third Friday of the month. These dates shall be made public or can be seen on the LIBR/NHSREC website. However, there shall be called meetings as necessary.

1.2 ATTENDANCE AT MEETINGS

All members of the ethics committee are required to be at each meeting.

1.2.1 QUORUM

A quorum of a meeting is a third of the members of the LIBR/NHSREC.

1.2.2 SUBMISSION OF COMMENTS

Where a member cannot attend a meeting he/she should advise the Committee Secretary one (1) week before the committee meeting on their views/concerns on the items tabled for consideration.

1.2.3 MEMBERS WHO WILL NOT BE IN ATTENDANCE

Members who for some unforeseen reason cannot attend a meeting should inform the Secretary one day before the meeting

1.3 AGENDA

Agenda and research protocols shall be distributed by the LIBR Administration to committee members no later than four weeks before the meeting. The papers shall be distributed by post or by courier, or by email if necessary, to ensure timely delivery. Receipt of agenda papers shall be confirmed by each member prior to the meeting...

Agenda papers shall include:

1. Minutes of Previous Meeting;
2. New Proposals
3. Re-submission/Revised Proposals/Protocol changes;
4. Out of Session Considerations
5. Progress/Final Reports on approved proposals
6. Any other business

1.4 MINUTES

Minutes of the previous meeting shall be written and distributed to all members four weeks to the next meeting. The minutes shall be read and adopted at the subsequent meeting. The Chair signs the approved minutes.

1.5 Timely consideration

All proposals submitted by the deadline shall be reviewed at the next bi-monthly meeting. If additional information is required from the researcher, he/she shall be contacted by written communication(letter, fax, email) to provide more information. Researchers(PI and Co-PI) and occasionally sponsors, may be asked to make themselves available for contact during the meeting if answers to relatively simple questions are sought.

1.6 METHOD OF DECISION MAKING

The LIBR/NHSREC shall endeavor to reach decisions by general agreement. However, all decisions shall be based on the LIBR/NHSREC SOPs.

The Committee may seek advice and assistance from experts to consider a particular research protocol, as long as the experts have no conflict of interest, including any personal involvement or participation in the research, any financial interest in the outcome, or involvement with competing research.

1.7 Notification of Decision

The Principal Investigator(PI) and, where applicable, the Project Sponsor or other relevant contact shall be notified in writing of the Committee's decision at least one month after the meeting at which the protocol is reviewed.

1.8 Decision Types

Approved – the submission satisfies all requirements in accordance with LIBR/NHSREC SOPs and GCP.

Not Approved – the submission has failed to satisfy all requirements accordance with LIBR/NHSREC SOPs and GCP.

Approved Under Condition– "Partially Endorsed" - does not equate to approval. Specified matters must be resolved to the satisfaction of the Committee prior to commencement/continuation of the study.

1.9 Expedited Review for Minimal Risk Research

On receipt of a study protocol that initially appears to be of minimal risk, clarification may be sought from the Chair to decide whether the protocol requires consideration by the whole Committee or a subcommittee of two or more LIBR/NHSREC members. Any decisions made in this manner will be confirmed at the next full meeting of the Committee.

A study is qualified for expedited review according to the following criteria:

- Modification/ amendment of protocol
- Proposals involve interviewing of a non-confidential nature, not likely to harm the status or interests of the individual and not likely to offend the sensibilities of the people involved
- Those that involve collection of small amounts of blood samples(and not too frequent), e.g. by finger, heel or ear stick.

- Those that involve the collection of biological specimens for research purposes by non-invasive means (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner)
- Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have already been approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However, procedures involving the use of X-rays or microwaves are NOT recommended for expedited review.
- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis
- Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and no additional risks have been identified.
- Biomedical programme review/evaluation

1.10. Fees

The LIBR/NHSREC shall charge a minimum fee for the consideration of research proposals as follows:

- A minimum fee of 3% of a research budget shall be levied for review and deliberation on all research proposals other than academic ones;
- A minimum fee of 1% of the budget shall be levied on all research proposals fulfilling academic requirements.

1.11. Monitoring

The LIBR/NHSREC shall, as a condition of approval of each protocol, require researchers to report on a Three –monthly basis from the date of approval. Researchers are to immediately report anything that may warrant a review of the protocol including:

1. serious and unexpected adverse effects on participants;
2. proposed changes to the protocol; and
3. Unforeseen events that might affect continued ethical acceptability of the project.

1.12. Complaints Procedure

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 LIBR/NHSREC STANDARD OPERATING PROCEDURES. Where a complaint about a researcher alleges serious misconduct that falls outside the range of ‘research misconduct’ as described in the LIBR/NHSREC STANDARD OPERATING PROCEDURES, the matter will be dealt with under governmental processes for dealing with other forms of misconduct.

1.13. **Confidentiality of Protocols**

LIBR/NHSREC documents and protocols are to be maintained in a secure environment. All documents distributed to Committee members must be securely stored. Committee files are to be kept in locked cabinets and accessed only by authorized individuals

2. **Researchers**

2.1. **Researchers' Responsibilities**

Researchers are expected to be aware of the values and principles of ethical and responsible conduct of human research, including appropriate consideration of:

1. research merit and integrity;
2. justice;
3. beneficence; and
4. respect.

This should be reflected in any proposal put to the LIBR/NHSREC for consideration.

2.2. **Conflict of Interest**

Researchers should establish transparent processes to identify and manage actual and potential conflicts of interest.

A conflict of interest in the context of research exists where:

• a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or

• an institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

the institution or researcher's influence/association has possible propensity to compromise the objectivity and outcome of the research.

While a conflict may relate to financial interests, it can also relate to other private, professional or institutional benefits or advantages that depend significantly on the research outcomes.
A researcher with a conflict of interest bearing on research should immediately inform the LIBR/NHSREC about the conflict.

2.3. Submission Types

New Submission – a research proposal NOT considered by LIBR/NHSREC previously;

Re-Submission – a submission on an **unapproved** research proposal that has been considered by LIBR/NHSREC previously. The submission could be a revised proposal, provision of further information or a response to specified matters of conditional approval;

Protocol Change – only on previously **approved** research proposals where there is a change in protocol relating to methodology. A change in rationale need not require LIBR/NHSREC approval but should be assessed before reaching that decision.

2.4. **New Submissions**

All submissions must be typed, dated, signed and presented to the LIBR/NHSREC electronically or by hard copies.

New submissions must also include all documents and material used to inform the potential participants including information sheets, consent forms, questionnaires, letters of invitation and internet content. All participant information sheets should include a signature block. Researchers should also include the name of the principal investigator, sponsor or sponsors, and contact information.

All submissions must be received by the LIBR/NHSREC by no later than the close off for submissions, usually 6 weeks prior to each meeting.

The Principal Researcher or his/her representative should be available for comments and clarifications at anytime the Committee request such presence.

2.5. **Declaration of Funding Sources**

A researcher is required to disclose the amounts, sources or potential sources of funding in any research proposal and, following approval of the proposal, any subsequent funding sources.

2.6. **Payments for Participants**

It is generally unacceptable to LIBR/NHSREC to pay participants for their involvement in research. A payment, gift, reward or any other inducement that is likely to encourage participants to take risks is ethically unacceptable.

Reimbursement of direct costs to participants taking part in research, including costs such as travel, accommodation and parking shall be permitted.

2.7. **Complaints/Adverse Occurrences**

Participants shall be advised of the first point of contact for complaints. The consent form signed by participants shall include the name and telephone number of this contact.

The first instance of a complaint shall be directed to the LIBR/NHSREC ethics committee VIA THE ADDRESS BELOW:
LIBR/NHSREC
Charlesville, Margibi County
Email: director.libr@gmail.com

2.8. Student Research

In considering approval of PhD or other student research, the LIBR/NHSREC shall consider the merit and integrity of the proposed study, including whether:

- the potential benefit of the research will outweigh any possible harm to participants;
- the results of the research will create new knowledge or be a slight revision of other research;
- the design and methodology of the research is appropriate to achieving desired aims;
- the research will be closely supervised by a person or team with experience, qualifications and competence appropriate to the research;

• the research will be conducted using facilities and resources appropriate to the research;
• the research will be carried out using the recognized principles of research conduct**.**

All correspondence from the (student) researcher - especially to participants - should be on university stationery, clearly identifying the status of the Researcher within the University. *Information to Participants* shall also identify the Supervisor in such a way that indicates their professional oversight of, and responsibility for, the research activity.
Students must ensure secure storage and, where necessary, destruction of data. Research files are to be kept in locked cabinets at the university responsible for the research, and accessed only by authorized individuals.

2.9. **Presentation of Research Protocols**

The LIBR/NHSREC encourages researchers to make themselves available for contact, including attendance, at the meeting when their project is being considered in order to answer any questions that may arise. It may be reasonable in some instances for the Sponsor to attend on behalf of the Researcher.

When facilities are available during LIBR/NHSREC meetings for conference call, connection with researchers shall normally be sufficient. The LIBR/NHSREC Secretariat will contact researchers prior to the meeting to make appropriate arrangements.

2.10. **Change to Protocol**

Principal researchers are required to advise the LIBR/NHSREC in writing if their research protocol, as approved by LIBR/NHSREC, changes before the study commences or at any time during the study. The LIBR/NHSREC will then reassess the proposal and reach a decision based on the revised protocol. It is preferable that significant protocol changes on studies which have not yet commenced be shown as changes on the original approved proposal

2.11. **Reporting Requirements**

Principal researchers are requested to provide the LIBR/NHREC with progress reports every three months, for studies covering a period of one year or longer. The Committee shall receive a copy of the final report. Shorter-term studies are required to submit a final report within three months after completion of the study.
Progress reports should be designed to assure the Committee that the research protocol as approved has not changed, and that the project is progressing satisfactorily. While there is no specific format for a progress or final report, researchers must in the very least ensure they provide advice as to:

• progress to date, or outcome in the case of completed or discontinued research;
• any events of significance that have occurred during the study, particularly in relation to adverse outcomes;
• maintenance and security of records;
• compliance with the approved proposal and protocol; and
• compliance with any conditions of approval.

2.12. **DISCONTINUED Research**

Researchers are required to advise the LIBR/NHSREC if and why an approved project is discontinued before the expected completion date.

2.13. **Withdrawal of Approval**

If the LIBR/NHSREC becomes aware that a research project is not being conducted in accordance with the approved protocol and the welfare and rights of participants are not protected, the LIBR/NHSREC shall withdraw its approval and advice the researcher/ organization or institution of such withdrawal. The LIBR/NHSREC shall suspend such a project immediately.

Approved: _____
Chairman, LIBR/NHSRC