

# **PIRE – AFRICA CENTER**

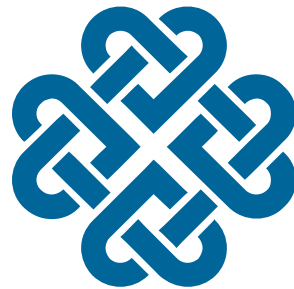
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## **INSTITUTIONAL REVIEW BOARD (IRB)**

### **POLICIES & PROCEDURES HANDBOOK**



University of Liberia (UL)



Pacific Institute for Research  
and Evaluation (PIRE)

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## **Introduction**

The UL-PIRE IRB (University of Liberia-Pacific Institute for Research and Evaluation Institutional Review Board) is available to persons or institutions interested in research work regarding the protection of human subjects in medicine or the social sciences in Liberia. It exposes people to new ideas in a wide range of scientific fields, and the decisions and opinions they bring to bear in the area of research. It has implications for individuals and institutions who conduct research activities as well as those who participate in them in Liberia.

The mission of UL-PIRE IRB is to help researchers conduct important studies in a way that protects the rights and welfare of research participants. People who do not understand how the IRB should function may think that making IRB determinations requires little more than common sense and good intentions. This is often not the case. As you learn more about research ethics and research regulations, you will understand that many research projects present ethical issues that are not simple to recognize or resolve.

This handbook provides information on a structured approach to evaluating the ethics of research protocols and a clear understanding of the fundamental principles that should be used to determine or accept research proposals.

## **Policies**

It is the policy of the University of Liberia Institutional Review Board (IRB) to assure unbiased review of all research proposals submitted and to inform the Principal Investigator(s) of such proposals of the results of the review.

## **Procedures**

1. All research proposals submitted by any investigator affiliated with the University of Liberia and training institutions will be reviewed in a standard manner.

2. All research proposals are to be submitted (either via campus mail or in person) to:  
  
The IRB Coordinator, UL-PIRE Africa Center, A.M. Dogliotti Medical College Bldg., Congo Town, Monrovia, Liberia. Proposals can also be submitted electronically via e-mail to the IRB Coordinator at [jktegli@yahoo.com](mailto:jktegli@yahoo.com). Details concerning the number of copies to submit can be found in the application package.
3. Principal investigators are required to submit materials four (4) weeks in advance of the date that a decision is requested. In the case of Full Review Studies (*see IRB Application Guidelines*), submission is required four (4) weeks prior to the next scheduled IRB meeting: Contact Mr. Jemee K. Tegli, [jktegli@yahoo.com](mailto:jktegli@yahoo.com). The IRB will convene a special meeting if necessary to accommodate the principal investigator's compliance with an external funding deadline; however, submission is required four (4) weeks prior to the special meeting date.
4. On receipt of a proposal for review, the IRB Coordinator will preliminarily assess the completeness of the submission. If the submission is incomplete the IRB Coordinator will so inform the principal investigator and request the additional materials. Once the submission is deemed complete, the IRB Coordinator will so advise the principal investigator and will distribute the materials to the assigned members of the IRB. Exempt studies will be reviewed by all members of the IRB; expedited studies will be reviewed by all members of the IRB; full review studies will be sent to the entire IRB membership for review.
5. The IRB Coordinator logs in all submitted proposals and maintains this log for all proposals. The log entry for each proposal includes: the IRB code number (assigned by the Coordinator); the name of the principal investigator; the title of the proposal; a brief description of the proposal that specifies the intervention or hypothesis to be tested or, in the case of qualitative proposals, the method for data collection and

- analysis; the assignment of the proposal for exempt, expedited, or full review; the dates of IRB review; a summary of action taken by the IRB; the date of enrollment of the first subject; and the date for annual IRB review.
6. The IRB member(s) will perform the initial review of each proposal, including the assessment of the completeness, clarity, scientific merit, risk/benefit, and ethical propriety of the proposal. If the proposal is deemed exempt or expedited, the IRB Chairperson will so notify the principal investigator.
  7. If the proposal is deemed to require a full review, the principal investigator will be required to submit additional copies of the proposal to be forwarded to the entire IRB membership by the IRB Coordinator. The complete proposal will be reviewed by the entire IRB membership. The IRB Chairperson will communicate in writing the results of the IRB review to the principal investigator.
  8. The IRB Coordinator will maintain complete files of all proposals submitted and all correspondence and other documentation pertaining to each proposal.
  9. On a quarterly basis, the IRB Coordinator will report on the full IRB documentation of all logged proposals for that quarter, using the “Log of Proposals Received.”

### **University of Liberia IRB Application Guidelines**

The University of Liberia Institutional Review Board (IRB) is mandated by the President of the University. Its purpose is to review and certify the ethical acceptability of all research involving human participants conducted at the University of Liberia by its employees. All studies, with the exception of certain projects, must be approved by the University of Liberia IRB. This includes all studies conducted by University of Liberia students, faculty, and staff either on or off campus, as well as all research by outside investigators on students, faculty, and staff through the auspices of the University of Liberia. To be granted approval, follow the instructions below.

(*Note:* Before you can submit your proposal and associated materials, you must first determine the level of review through which your project will be processed.) Below are brief descriptions of the four levels of research projects.

### **A. Class Projects/Workshops/Teaching Evaluations**

For these projects, implied consent (to be requested either verbally or via a cover letter) may be acceptable and no IRB packet needs to be submitted. Generally, most master's theses, dissertations, and independent research projects would not fall into this category.

a. Key characteristics of such studies are:

- i. Participants are subjected to no risk.
- ii. Results are not submitted for publication consideration by a refereed journal or conference.
- iii. The investigator is responsible for maintaining all participants' safeguards as outlined in these instructions.

b. Examples of such studies are:

- i. Classroom projects that are not to be submitted to a refereed journal or conference.
- ii. Evaluation of teaching techniques.
- iii. Evaluation of student performance.
- iv. Market research, for which the results would not be submitted to a refereed journal or conference.
- v. Journalistic surveys, for which the results would be published in a newspaper or presented journalistically, but are not expected to be

submitted to a refereed journal or conference for scientific publication and/or dissemination.

### **B. Exempted Studies**

Participants are subjected to no risk. Implied consent (verbally obtained or via a cover letter) may be acceptable. Investigators must submit an application packet. A detailed description can be found below.

### **C. Expedited Studies**

Participants are subjected to very low risk. Signed consent is required and the investigator keeps copies of the signed consent forms. Investigators must submit an application packet. A detailed description can be found below.

### **D. Full Review Studies**

Participants are subjected to some risk or the project involves populations with special consent considerations (e.g., prisoners, minors, or individuals who are not legally competent). All externally funded studies must receive full review. Investigators must submit an application packet.

### **E. How Do I Know What Level of Application to Submit?**

Below are detailed descriptions of the *Exempt* and *Expedited* review categories. If your study does *NOT* fall into either of these categories, it must undergo a *Full Board Review*. After deciding which level of review your study requires, complete the necessary forms in the application packet. The level of review will dictate which forms need to be completed and the number of copies submitted.

## **F. Research Projects That May Qualify for Exemption Status**

Below is a description of research projects that may qualify for the exempted review process. An investigator who believes that his or her project qualifies for exemption should submit one copy of the completed, signed Proposal Form (included in the application packet) and associated materials. A designated member of the IRB must "concur" that the project qualifies for an exemption. An investigator cannot exempt himself or herself. Exemptions and/or expedited approvals may not be requested in person or by telephone. A research project cannot start until after the "concurrence" by members of IRB. Retroactive concurrence or review cannot occur. If personal identifiers that can be linked directly to an individual research subject (names, I.D. card number, hospital admission number, specimen number, etc.) are to be collected, the research project does not qualify for an Exemption and the investigator must submit the project for Expedited or Full Board review (see below).

### **Exemption Categories**

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories will be exempt from review by the IRB:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
  - a. research on regular and special education instructional strategies, or
  - b. research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
- b. any disclosure of the human subjects' responses outside the research project could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

*(Note: When a study uses subjects who are minors, category 2 only applies as follows: Studies using educational tests involving minors as subjects are exempt. Studies using survey or interview procedures with minors as subjects are NOT exempt. Studies using observations of public behavior involving minors are NOT exempt unless the investigator does NOT participate in or contrive the activities being observed.)*

3. Research involving the use of educational tests, as described above in category 2, may not be exempt under the following conditions:
  - a. The human subjects are elected or appointed public officials or candidates for public office, or
  - b. Legal statute(s) require that the confidentiality of the personal identifiable information be maintained throughout the research study and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

*(Note: To qualify for this exemption the data, documents, records, or specimens must exist before the project begins.)*

5. Research and demonstration projects that are conducted by or subject to the approval of Ministries or Agency heads, and which are designed to study, evaluate, or otherwise examine:
  - a. public benefit or service programs, or
  - b. procedures for obtaining benefits or services under those programs, or
  - c. possible changes in or alternatives to those programs or procedures, or
  - d. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies if:
  - a. wholesome foods without additives are consumed, or
  - b. a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an agricultural, chemical, or environmental contaminant at or below the level found to be safe by the Environmental Protection Agency or the Food Safety and Inspection Service of the appropriate regulatory agencies.

#### **I. Categories of Research That Qualify for Expedited Review Process**

An expedited review procedure consists of a review by the IRB Chairperson and one or more experienced IRB members designated by the chairperson. The applicability of this review is as follows:

- A. Research activities that present no more than minimal risk to human subjects and research activities that involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure (Ref: *45 CFR 46.110 and 21 CFR 56.110*). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion

on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

- B. The categories in this list apply regardless of the age of subjects, except as noted.
- C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- D. The expedited review procedure may not be used for classified research involving human subjects.
- E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or full – utilized by the IRB.

## **II. Research Exempt Categories**

The below categories, one (1) through seven (7), pertain to both the initial and the continuing IRB review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a. Research on drugs for which an investigational new drug *application* (Ref: 21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

- b. Research on medical devices for which (i) an investigational device exemption application (*Ref: 21 CFR Part 812*) is not required; or (ii) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared or approved labeling requirements.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week;, or
  - b. From other adults and children<sup>1</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period, and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:
  - a. hair and nail clippings in a non-disfiguring manner;
  - b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

<sup>1</sup>Children are defined "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." (*Ref: 45 CFR 46.402(a)*).

- c. permanent teeth if routine patient care indicates a need for extraction;
  - d. excreta and external secretions (including sweat);
  - e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
  - f. placenta removed at delivery;
  - g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - h. supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and
  - j. sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples include:
- a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

- b. weighing or testing sensory acuity;
  - c. magnetic resonance imaging;
  - d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; and
  - e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the regulations for the protection of human subjects (*Ref: 45 CFR 46.101(b)(4)*). *This listing refers only to research that is not exempt.*
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the regulations for the protection of human subjects (*Ref: 45 CFR 46.101(b)(2) and (b)(3)*). This listing refers only to research that is not exempt.
8. Continuing review of research previously approved by the convened IRB where:
- a. the research is permanently closed to the enrollment of new subjects;

- b. all subjects have completed all research-related interventions; and
  - c. the research remains active only for long-term follow-up of subjects; or
    - (i) where no subjects have been enrolled and no additional risks have been identified; or
    - (ii) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

### **Policy Statement on Confidentiality**

It is necessary that the members of the University of Liberia Institutional Review Board (UL-IRB) function in an atmosphere of mutual trust and respect. We wish to foster honest and direct communication, including concerns. It is important that IRB members feel free to share what they think with one another without having to worry that their statements may be repeated elsewhere to people who do not have the benefit of the full context of what is often a lengthy and ongoing discussion. By definition, any attempt to reproduce the content of an IRB conversation will be partial and incomplete, and there is always a risk that the result will be, or seem, inaccurate. That risk is increased by the fact that IRB members often change their minds during the course of the deliberations, leading them to adopt positions quite different from their starting points. Thus, a later report outside the IRB of what an individual had initially said regarding an issue during deliberation may not be that person final IRB-related consensus or final decision.

Necessary components of the IRB's work are the review of performance of individuals conducting research and assessment of the qualifications of those proposing to conduct research studies. In addition, periodically the IRB considers nominations for new members. Finally, the IRB also must take account of its responsibilities to sponsors and investigators. While the IRB may be legally bound to treat as confidential only trade secrets and other commercially valuable proprietary information, the IRB should dispense information derived from its consideration of proposed protocols with caution and discretion, as a matter of both professionalism and prudence. It is difficult to determine that a particular piece of information clearly falls outside the legally protected category, and every IRB member could be exposed to the risk of litigation and/or liability as a result of a disclosure which was eventually deemed to be improper.

In an effort to clarify these interests and concerns, the University of Liberia IRB has resolved the following:

1. Members of the IRB and staff associated with the IRB and privy to its deliberations agree not to divulge to anyone outside the IRB information learned in the course of their work with the IRB, whether from the review of protocols, adverse reaction or monitoring reports, or during IRB discussions. Copies of IRB minutes and all intra-IRB communications, worksheets, and correspondence with sponsors, investigators, or consultants should be created, transmitted, and maintained in a manner designed to protect their confidentiality. Once the IRB has made a decision with respect to a particular protocol and has communicated that decision to the protocol's sponsor and/or principal investigator, the fact of that decision may be made public.
2. If an IRB member or associated staff believes that a particular item or information ought to be disclosed, either to specific individuals or to the public at large, that member or staff person should raise the issue with the entire IRB. The IRB may decide that the

harm caused by the breach of confidentiality will, in this instance, be outweighed by the important considerations of public interest. In that event the IRB will determine the appropriate timing, audience, and method for disclosure.

3. Under no circumstances will any member of the IRB or its staff purport to attribute particular statements, oral or written, to specific individuals. While it is permissible to describe the various positions expressed, those positions should not be linked to individual proponents or opponents.
4. The IRB may decide, on a case-by-case basis, that it wishes to communicate the fact that it has received certain information about a particular person to the person involved, so as to enable that individual to provide additional or different information. In that event, every effort will be made to avoid revealing the source of the information in question. The fact that disclosure of the information will necessarily reveal the identity of its source, however, will not in and of itself bar disclosure if the IRB believes such disclosure to be appropriate and fair. Again, the IRB will determine the timing, circumstances, and method for disclosure of such information.

### **Institutional Review Board (IRB) Policy on Research Activities Involving Human Subjects**

- A. Resources
- B. Definitions
- C. Scope
- D. Responsibilities
- E. Institutional Review Board (IRB)
- F. Exempt Research
- G. Expedited Review

- H. Full IRB Review
- I. Informed Consent
- J. The Project Application
- K. Actions of the IRB
- L. Continuing Review

## **A. RESOURCES**

1. This policy on “Research Activities Involving Human Subjects” is available online at [www.csusm.edu/research/IRB.htm](http://www.csusm.edu/research/IRB.htm).
2. All relevant application forms and sample documents are available online at [www.csusm.edu/research/IRB.htm](http://www.csusm.edu/research/IRB.htm). In recruiting research subjects, the principal investigator should include the below information in his or her IRB application materials:
  - a. The protocol (procedures) for the project;
  - b. The potential risks to the safety, dignity, rights and welfare of the subjects;
  - c. The proposed safeguards against these risks;
  - d. Potential benefits of the research to the subjects and to society;
  - e. The procedures for obtaining informed consent from the subjects and a copy of any required consent forms;
  - f. Procedures for debriefing research participants;
  - g. Copies of advertisements or flyers used in the recruitment of participants; and

- h. One copy of any relevant grant proposal or research contract.

Project applications should be submitted to the IRB Coordinator. For guidance, concerned parties should consult (1) the Nuremberg Code, (2) the Belmont Report and (3) the Final Regulations for the Protection of Human Research Subjects as published in the Federal Register December 13, 2001, Code of Federal Regulations or the Common Rule (*Ref: 45 CFR Part 46*), and its amendments as they appear in the Federal Register. Many professional organizations have their own policies on the protection of human subjects. Where discrepancies exist, the principal investigator will be responsible to adhere to the appropriate human subject protection policy (*Ref: 45 CFR Part 46*).

## **B. DEFINITIONS**

1. **"Research"** is defined as a systematic investigation designed to develop or contribute to scientific knowledge. Activities that meet this definition constitute "research" for the purposes of federal regulations (see *Code of Federal Regulations, web site: <http://www.hhs.gov/ohrp/>*), whether or not they are supported or funded under a program that is considered research for other purposes. For example, some "education," "demonstration," and "service" programs may include research activity.

2. A **"human subject"** is defined as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information (e.g., name, address, etc.).

3. **"Intervention"** is defined as communication or interpersonal contact between investigator and subject to administer an event, activity, or program.

4. **"Private information"** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. It

also includes information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

5. **"Risk"** refers to physical, psychological, social, and economic risks to research subjects.

6. **"Minimal risk"** means that the risk of harm to human subjects anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life of that subject, or during the performance of routine physical or psychological examinations or tests.

7. **"Children"** and **"minors"** are defined by the Republic of Liberia as those persons under the age of 18.

### **C. SCOPE**

This policy applies to all faculty, staff, and students whenever they are supervising or conducting any activity involving human subjects, regardless of whether the research is funded, and regardless of whether the subjects are members of the University community. This policy applies to research conducted at other institutions by faculty, staff, and students, even if that institution has its own review process. The University accepts the responsibilities of Sections D and E below only if appropriate University policies are followed, including approval by designated administrators and the Institutional Review Board (IRB). The University cannot accept responsibility for research conducted in violation of University policy and without required approval.

### **D. RESPONSIBILITIES**

1. University of Liberia acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this policy statement. The institutional official specifically charged with this responsibility is the Director of

Research. It is the Director's responsibility to disseminate this policy and foster an atmosphere of respect for human subjects across the campus community. The Director is responsible for immediately reporting all research-related problems to the appropriate agencies and must work with the University of Liberia in communicating with government agencies with respect to addressing the necessary assurances and policies. The institution provides administrative support to the IRB and works with the IRB Chair to monitor changes in regulatory guidelines and to revise this policy accordingly.

2. It is the responsibility of the IRB Chair to convene meetings of the IRB, to keep minutes of IRB meetings and document IRB decisions, to provide training for IRB members, to assign protocols to reviewers for expedited review, to oversee the review of protocols, to monitor changes in regulatory guidelines from granting agencies, to communicate IRB decisions to investigators, and to educate the research community on the ethical treatment of human subjects.
3. It is the responsibility of IRB members to attend regularly convened meetings of the IRB, to review protocols as assigned in a timely manner, to know the relevant internationally acceptable guidelines on the protection of human subjects, to obtain training when necessary, and to act as a resource on issues pertaining to the protection of human subjects for members of the research community.
4. It is the responsibility of the heads of departments, programs, units, etc. to bring the existence of this policy to the attention of their faculty, staff, and students.
5. Responsibility for the establishment and maintenance of acceptable ethical practice in research always remains with the individual investigator. The investigator is also

responsible for obtaining training in the protection of human subjects as required by any granting agency.

## **E. INSTITUTIONAL REVIEW BOARD (IRB)**

The responsibility and authority for implementing and administering the policy that will protect the dignity, rights, and welfare of human subjects shall be delegated to the IRB, subject to review by the faculty Senate and University administration. The IRB is the review body for all research involving human subjects.

### **1. IRB Composition**

IRB members shall be appointed by the appropriate University Official based on the recommendation of the appropriate body. The composition of the IRB shall be as follows:

- a. Four members of the faculty who have the professional competence necessary to review research activities and have been recommended by the Faculty Senate Research Publication Committee. Faculty shall be selected so that they represent the disciplines that most commonly engage in research involving human subjects, or they have other expertise appropriate to the committee;
- b. One student member, recommended by the Students' authority;
- c. One non-university community representative recommended by the Chair;
- d. One representative from the Ministry of Planning and Economic Affairs; and
- e. The Director of the Institute of Research, University of Liberia or designate, ex-officio, who shall act as the Institutional Official and the Human Protections Administrator.

One member of the IRB must be a nonscientist. IRB members shall normally serve for two-year terms. The Chair of the IRB shall be a faculty member elected by the voting committee members. To ensure meaningful review, the IRB may consult with nonvoting ad hoc members. Ad hoc members must be selected by the IRB for their relevant knowledge and experience. Composition of the Board will be reviewed every three years to ensure compliance with internationally acceptable standards.

## **2. Convened Meetings of the IRB**

The IRB shall meet at least monthly to review and vote on protocols that require full review. Voting requires a quorum of at least 50 percent of voting members and the presence of at least one nonscientist. Protocols are approved by a majority of voting members. Members may not vote on protocols on which they are the investigator or have other conflicts of interest, although they may provide information to other IRB members regarding the protocol. Investigators may request to attend convened meetings of the IRB to discuss an IRB decision or to provide clarification on a research project.

### **F. EXEMPT RESEARCH**

Investigators may apply for exempt research status. Exempt research is that which involves no risk to subjects. Investigators may not determine whether their research is exempt; they must supply enough information about the proposed research so that the IRB can make the determination. When research is found to be exempt, researchers must still act in a responsible and ethical manner in the treatment of human subjects.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - a. Research on regular and special educational instructional strategies, or

- b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. Such activities must fall under the realm of standard educational practice. Such activities are not exempt if the identities of the participants could become known, for example if they involve the audiotaping or videotaping of participants. The exemption for educational research studies involving children only applies if the activities are conducted in a regular classroom setting, as part of an educational curriculum.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) may be exempt, if the information taken from those sources can be recorded in such a manner that subjects cannot be identified, directly or indirectly, through identifiers linked to the subjects. Thus, all data from individual subjects must be anonymous.
3. Research involving survey or interview procedures may be exempt, except where all of the following conditions exist:
  - a. Responses are recorded in such a manner that human subjects can be identified, directly or indirectly, through identifiers linked to the subjects, through responses that uniquely identify a subject, or through audio or videotaping of the subject;
  - b. The subjects' responses, if they become known outside the research setting or environment, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing; and
  - c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. All research

involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office. Surveys and interviews that put subjects at psychological risk are not exempt. Surveys and interviews with children are not exempt.

4. Research involving the observation (including observation by participants) of public behavior may be exempt, except in situations where any of the below conditions exist:
  - a. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
  - b. The observations recorded about the individual, if they become known outside the research setting, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing; and
  - c. The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or the use of alcohol. The exemption of research involving observation of public behavior applies to children only where the investigator(s) does not participate in the activities being observed.
5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens may be exempt, if those sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or indirectly, through identifiers linked to the subjects. Thus, individual subject data must be anonymous. Archival research in which individual subjects could potentially be identified is not exempt.

6. Unless specifically required by statute, research and demonstration projects that are conducted by or subject to the approval of the Ministry of Health and Social Welfare may be exempt, and that are designed to study, evaluate, or otherwise examine:
  - a. Programs designed for public benefit or service delivery-related programs;
  - b. Procedures for obtaining benefits or services under those programs;
  - c. Possible changes in or alternatives to those programs or procedures; or
  - d. Possible changes in methods or levels of payment for benefits or services under those programs.

#### **G. EXPEDITED REVIEW**

All research projects involving only "minimal" risk may be handled by expedited review. An expedited review shall be conducted by one or more of the IRB members designated by the chair to conduct the review. In all other respects, the expedited review process is identical to the full review process. The IRB member(s) conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. The reviewer(s) shall refer any research proposals that the reviewer(s) would not have approved to the full committee for review.

The expedited review procedure may not be used where the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human subjects.

The reviewer shall determine if:

- a. Risks to subjects are indeed minimal;
- b. Selection of subjects is equitable;
- c. Care has been taken to minimize the likelihood that subjects are vulnerable to coercion or undue influence;
- d. Participants do not include those from vulnerable populations, such as persons with acute or severe physical or mental illness, persons economically or educationally disadvantaged, prisoners and children (except where noted); and
- e. Appropriate methods are in place to obtain informed consent from research subjects and parental permission if necessary, and to document such consent if required.

Expedited review may be used in the following cases, unless other risks are present.

These categories also apply to children as research subjects, except where noted. The list of situations warranting expedited review is regularly updated, (e.g., See *Ref: 45 CFR Part 46.110.*), in:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a. Research on drugs for which an investigational new drug application is not required. (*Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.*)
  - b. Research on medical devices for which:

- i. an investigational device application is not required; or
  - ii. the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared or approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
  - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
  - a. Hair and nail clippings in a non-disfiguring manner;
  - b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - c. Permanent teeth if routine patient care indicates a need for extraction;
  - d. Excreta and external secretions (including sweat);
  - e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum or wax or by applying a dilute citric solution to the tongue;

- f. Placenta removed at delivery;
  - g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - h. Supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - i. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and
  - j. Sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include:
- a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - b. Weighing or testing sensory acuity;
  - c. Magnetic resonance imaging;

- d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; and
  - e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes such as medical treatment or diagnosis. *(Note: Some research in this category may be exempt).*
  6. Collection of data from voice, video, digital, or image recordings made for research purposes.
  7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. *(Note: Some research in this category may be exempt).*

#### **H. FULL IRB REVIEW**

Risks greater than "minimal risk" as defined above will require review by a convened meeting of the full IRB. Determination of whether human subjects are in fact at risk is the responsibility of all levels of review, though the definitive determination will be made by the IRB.

The IRB shall determine if:

- a. Risks to subjects are minimized by using procedures consistent with sound research design and which do not unnecessarily expose subjects to risk;
- b. Risks to subjects are reasonable in relation to the anticipated benefits of the research;
- c. Selection of subjects is equitable;
- d. Care has been taken to minimize the likelihood that some or all of the subjects are vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, persons economically or educationally disadvantaged, prisoners and children. Then additional safeguards are included in the study to protect the rights of those subjects; and
- e. Appropriate methods are in place to obtain informed consent from research subjects and parental permission if necessary, and to document such consent if required.

## **I. INFORMED CONSENT**

Research investigators are responsible for insuring that no human subject will be involved in research involving minimal or greater risk prior to obtaining informed consent in accordance with internationally acceptable standards (*Ref: 45 CFR 46.116.*).

### **1. Legally Effective Informed Consent**

Unless otherwise waived by the IRB, research investigators are responsible for ensuring that legally effective informed consent shall:

- a. Be obtained from the subject or the subject's legally authorized representative;
- b. Be in language understandable to the subject or representative;

- c. Be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
- d. Not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution, or its agents from liability for negligence.

## **2. Minimum Requirements for Written Informed Consent**

Unless authorized by the IRB, research investigators at a minimum shall provide the following information to each subject:

- a. A statement that the study involves research, an explanation of the purpose of the research and the expected duration of a subject's participation, a description of the procedures to be followed, and identification of any procedures that are experiments;
- b. A description of any reasonably foreseeable risks or discomforts to the subject;
- c. A description of any benefits to the subject or to others that may reasonably be expected from the research;
- d. A disclosure of appropriate alternate procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f. A statement explaining how and with whom the results of the study will be shared;

- g. For research involving more than minimal risk, an explanation of any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;
- h. Contact information for the investigator, to whom the subjects can direct research-related questions, and to the IRB, to whom the subjects can direct questions regarding their rights as research participants, and whom to contact in the event of a research-related injury to any subject; and
- i. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Certain research projects may require additional statements of informed consent. For example:

- a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
- b. Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;
- c. Any additional costs to the subject that may result from participation in the research;
- d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

- e. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject; and
- f. The approximate number of subjects involved in the study.

### **3. Obtaining Informed Consent**

Research investigators shall be responsible for making sure that informed consent is documented by using a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB (see below). The consent form shall embody the elements of informed consent as required by internationally acceptable standards (Ref: 45 *CFR* 46.116), and described above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it.

Research investigators shall make sure that each person signing the written consent form is given a copy of that form. In the case of children, the IRB shall determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB such assent is appropriate and the children are capable of providing assent (*Ref: 45 CFR and 46.408*). Permission of one or both parents is also required under appropriate circumstances (*Ref: 45 CFR and 46.408*).

### **4. Waiver of Documentation of Informed Consent**

An IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects if it finds either:

- a. That the only record linking the subject and the research would be the consent document and risk would be any potential harm resulting from a breach of confidentiality. Each subject should be asked whether that subject wants documentation linking him/her to the research, and that person's wishes should be instituted; or
- b. The research presents not more than minimal risk or harm to subjects and involves no procedures for which written consent normally is required outside of a research context. In cases where the documentation requirement is waived, the IRB requires the investigator to provide subjects with a written statement regarding the research. Such statement should include all components of a written consent document.

## **5. Waiver of Informed Consent**

An IRB may waive the requirement for informed consent for research involving minimal or greater risk at the request of the investigator if the scientific value of the research depends on the use of deception. Such waiver may be granted if:

- a) The deception does not adversely affect the rights of the individual;
- b) Subjects are not subjected to procedures to which they would not normally agree, or to a level of risk greater than that to which they have agreed;
- c) The deception is revealed at the earliest possible stage in the research process and the subjects are fully debriefed about the deception and their response to it; and
- d) All alternatives to deception have been considered and eliminated. The potential scientific value of the study must outweigh the considerable risks involved in the use of deception.

## **6. Retention of Consent Forms**

Research investigators are responsible for placing the consent documents signed by human research subjects in a repository approved by the IRB. Completed informed consent forms shall be kept by the investigator for a minimum period of three years. (*See Appendix C for Informed Content Checklist*).

### **J. THE PROJECT APPLICATION**

The basis for expedited or full review of research projects involving human subjects will be a project application (or research proposal) submitted by an investigator. The project application form requires the following information and documentation:

- a. The title of the proposed research project;
- b. The name(s) and title(s) of the supervisor(s) and/or director(s);
- c. The location of the activity and the projected dates for its commencement and completion;
- d. The objective of the project;
- e. The nature of the investigation to be performed on the subjects;
- f. The qualifications of the investigator(s) conducting the project;
- g. The potential subjects and methods for a regularly convened meeting of the IRB. The package will be distributed to IRB members three working days before regularly convened meetings. Applications for expedited review and exemptions will be considered at any time.

### **K. ACTIONS OF THE IRB**

On the basis of full or expedited review, the IRB may take the following actions:

1. The research may be approved for a period of not greater than one year.
2. The research may be approved for a period of less than one year in situations where risks to subjects warrant more frequent review.
3. The IRB may require clarification from the investigator(s).
4. The IRB may require modifications in the research project for the purpose of protecting human subjects.
5. The IRB may disapprove the research project.

Investigators will be informed of all IRB decisions in writing. All correspondence between the IRB and investigators will become part of the IRB research file.

#### **L. CONTINUING REVIEW**

An IRB review is an ongoing process and does not end with the initial project approval. The IRB has the right to audit any research project that has been previously approved, may suspend or terminate any research activity, may require revisions of a protocol if research-related problems occur, or if changes are made in regulatory guidelines. Continuing review occurs in several ways:

1. Continuation of previously approved research. Projects that have been previously approved by the IRB, but whose approval is soon to expire, will undergo continuing review. Continuing review will occur at least annually, or more often, if required by the IRB. Continuing review will ensure that: (a) the selection of subjects is equitable, (b) the risk/benefit ratio of the research remains acceptable, (c) the consent document contains information that is accurate, complete, and up-to-date, and (d) adequate safeguards for the protection of human subjects are in place. Projects

- previously approved by the IRB that have expired will require the submission of a new protocol.
2. Minor revisions in protocol. Minor revisions in protocol that do not substantially change the research methodology and do not introduce new levels of risk may be reported to the IRB as a revision of protocol. Revisions of protocol are reviewed in an expedited manner.
  3. Major revisions in protocol. Major revisions in protocol, such as the inclusion of a different subject population, different research methods, or those that change the level of risk in the research, require the submission of a new project application.
  4. Reports of unforeseen events. All unforeseen negative events that arise in the course of research must be reported immediately to the IRB. Such events may be reported by the investigator, by research subjects, or others. In such cases the IRB shall suspend approval of the research until the events can be reviewed, and a determination made regarding any necessary changes in protocol.

## **The IRB Process**

### Helpful Tips to Ensure a Smooth Approval Process

#### **A. International Research**

##### **1. Introduction**

It is important that all research involving human subjects adequately protect the rights and welfare of research subjects. All research projects in which Liberian investigators are involved, which would be subject to government regulations if it were conducted within Liberia, must comply with national regulations for the protection of human subjects.

## 2. IRB Considerations

Government regulations recognize that "the procedures normally followed in foreign countries [in which the research will take place] may differ from those set forth in this policy." Research may be approved, therefore, if "the procedures prescribed by the [foreign] institution afford protections that are at least equivalent to those provided in this policy." The foreign country's procedures may then be substituted for the procedures required by the government regulations. Approval of relevant modifications to the protocols must be submitted to the local IRB after the review of the foreign procedures.

One difficult issue is determining what constitutes "protections that are at least equivalent" to the government regulations. This determination needs to be made by the Office for Research at the University of Liberia. The broad policy regarding international standards, such as the Declarations of Helsinki or the Nuremberg Code, may serve as a starting place for the development of the research protocol for the protection of human subjects. The written descriptions of the specific procedures for regarding such policies, as adopted by the foreign institution, may be required.

The purpose of the IRB research review procedure is:

- To protect the subjects involved in research against foreseeable injury;
- To protect the University, its faculty, staff, and students who conduct research from foreseeable liability;
- To meet internationally acceptable standard of care for the protection of human subjects; and
- To meet the human subject protection regulations of the Ministry of Health & Social Welfare, including the University, regarding the implementation of research projects.

## **B. Categories of Research**

Following submission, the application is reviewed by the IRB Chair/Expediter based on the IRB guidelines. The Chair/Expediter then determines whether the IRB application is complete and appropriate for review. Proposals must be submitted using the most current forms. (Proposals submitted on outdated forms will be returned unreviewed. Incomplete or poorly prepared proposals will be returned unreviewed.) A reviewed application will be assigned to one of the following categories:

- Level I – No risk to human subjects
- Level II – Minimal risk to human subjects
- Level III – Possible risk to human subjects, a sensitive topic is being researched, or subjects include special populations (including children under 8, mentally handicapped, or legally incompetent)

The following lists of Level I, Level II, and Level III research are provided as examples and are not meant to be inclusive. The activities listed should not be deemed to be Level I, II, or III simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review in that specific category. For additional clarification or guidance, contact the IRB expeditor/chair.

### **I. LEVEL I (No Risk to Human Subjects)**

The following types of research may be classified as Level I and exempt from full board review. Level I status and exemption from full board review must be granted by the IRB Chair/Expediter:

### **A. Educational Settings**

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: Research on regular and special education instructional strategies; or Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

### **B. Educational Tests**

Research involving the use of educational tests if Information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. In addition, any disclosure of the human subjects' responses outside the research environment would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Educational tests include cognitive, diagnostic, aptitude, and achievement tests. Test administration must be appropriate to the test administrator's qualifications and licensing requirements.

### **C. Surveys, Interviews, and Observations**

Research involving survey or interview procedures, or observation of public behavior, provided the responses are recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects. Level I status for survey/interview research is not applicable to children. In observational research involving children, investigators cannot participate in the activities being observed.

### **D. Public Officials**

Research activities involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior are not exempt under Category I, if: Human subjects are elected or appointed public officials or candidates for public office; or Government

statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

#### **E. Existing Data**

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if: The sources are publicly available; or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

#### **F. Service Programs**

Research and demonstration projects that are: conducted by or subject to the approval of department or agency heads; and designed to study, evaluate, or otherwise examine:

Public benefit or service programs; or procedures for obtaining benefits or services under those specific programs; or possible changes in or alternatives to those specific programs or procedures; or

Possible changes in methods or levels of payment for benefits or services under those specific programs.

#### **G. Other**

Research activities involving the use of non-research informants or testimony from identified individuals in a journalistic format.

### **Why Surveys and Interviews Involving Children Are Never Classified Under Level I?**

The Ministry of Health and Social Welfare assumes that adults have the capability to determine whether or not to participate in survey or interview research. However, the Ministry believes that children being surveyed or interviewed by an investigator may not be capable of recognizing that their responses to questions on sensitive issues could be potentially damaging

to themselves or others. Therefore, it is appropriate that the IRB at least review such research to determine whether the rights and welfare of children participating as subjects are adequately protected and whether the requirements for permission or assent could be waived, if possible.

### **Why Observational Research Involving Children with Investigator Participation Is Never Classified Under Level I?**

The Ministry of Health and Social Welfare believes that children involved in observational research, with the investigator(s) also participating in the activities being observed, may not have the capability to determine whether or not to participate and therefore, IRB review of such research is appropriate.

#### **II. LEVEL II (Minimal Risk to Human Subjects)**

The following types of research may be classified as Level II if the research is no more than minimal risk. Level II status must be granted by the IRB Chair/Expediter.

- **Existing Data: Pre-Existing Data**

Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

- **Behavior**

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. In these cases, the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

Exercise: Moderate exercise by healthy volunteers.

- **Drugs**

Clinical studies of drugs and medical devices only when either of the following listed conditions is met.

- Research on drugs for which an investigational new drug application (Ref: 21 CFR Part 312) is not required. *(Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).*
- Research on medical devices for which an investigational device exemption application (Ref: 21 CFR Part 812) is not required. The medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared or approved labeling.

- **Voice Recordings**

Collection of data from voice, video, digital, or image recordings made for research purposes.

- **Blood Samples**

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
- b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the

frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

### **Noninvasive Procedures**

Collection of data from subjects 18 years of age and older through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared or approved for marketing. *(Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)* Examples include:

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- Weighing or testing sensory acuity ;
- Magnetic resonance imaging ;
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

## Biological Specimens

Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

- Hair and nail clippings in a nondisfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- Supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; and
- Sputum collected after saline mist nebulization.

The IRB can approve research with children as Level II (minimal risk) only if adequate provisions are made for soliciting assent of the children and the permission of their parents or guardians.

### **III. LEVEL III (Possible Risk to Human Subjects)**

The following types of research may be classified as Level III if the research involves possible risk to human subjects. *Level III status must be granted by the IRB Chair/Expediter.*

For example:

- **Confidentiality:** Subjects may be identifiable to anyone other than the researcher.
- **Risk of Liability:** Subjects could be at risk for criminal or civil liability, damage to employability or to financial standing, or undue embarrassment, if responses became known outside this research project.
- **Sensitive Aspects of Behavior:** The research deals with sensitive aspects of subjects' behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
- **Private Records:** The research involves the collection or study of existing data from sources not publicly available.
- **Deception:** The research includes deception of subjects.
- **Children:** The research deals with subjects who are children under eighteen years of age.
- **Special Populations:** The research deals with subjects who are not legally competent adults, prisoners, mentally disabled, pregnant women, physically challenged, or other special population.

- **Medical Procedures:** The research involves administering drugs, collecting invasive tissue samples, administering nutritional supplements, giving injections, or other medical procedures.

### **C. Training for IRB Members**

IRB members and their alternates are provided with training that should include copies of the following information:

1. Policies and Procedures Manual for the IRB.
2. The Belmont Report.
3. Web site of the Office for Human Research Protections (OHRP) of the US Department of Health & Human Services (DHHS) regarding internationally acceptable standards for the protection of human subjects, including the codes of federal regulations (e.g., See 45 CFR 46 or 21 CFR 56, etc.). The web site link is: <http://www.hhs.gov/ohrp/policy/index.html> .
4. CD Rom of the PRIM&R 101 Tutorial.
5. A copy of the book *Institutional Review Board: Member Handbook*, by Robert Amdur, 2003..

In addition, IRB members must document that they have completed the online NIH training for IRB members. Continuing review materials are provided at each IRB meeting in the form of relevant periodicals or articles.

### **D. Additional Ethical Training Resources**

Codes of research ethics have been developed, in part to address the historical disregard for human safety and dignity. The Nuremberg Code of 1947 was the first international code of research ethics. Another early code was the Helsinki Declaration, adopted by the World

Medical Assembly at its meeting in Helsinki, Finland, in 1964. The first ethical code covering social and behavioral research was a set of 10 ethical principles adopted by the American Psychological Association in 1972. The American Psychological Association's principles were the first to recognize the principles of confidentiality. Most professional organizations have ethical codes, and most require authors of manuscripts submitted to the journals of these organizations to state that they have followed these ethical principles in their research.

The U. S. Department of Health, Education, and Welfare issued ethical guidelines in 1971 that were codified into Federal Regulations in 1974. However, the primary impetus for current government ethical regulation began with the establishment of a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research under the aegis of the Department of Health, Education, and Welfare in 1974. The Commission was charged with identifying the basic ethical principles that should underlie research with human subjects. The report of the Commission, called The Belmont Report because it was based on deliberations held at the Smithsonian Institution's Belmont Conference Center, was published in 1979. The Belmont Report identified the following three basic ethical principles:

1. Respect for Persons (autonomy): This principle acknowledges the dignity and freedom of every person. It requires obtaining informed consent from all potential research subjects (or their legally authorized representatives).
2. Beneficence: This principle requires that researchers maximize benefits and minimize harms or risks associated with research. Research-related risks must be reasonable in light of expected benefits.
3. Justice: This principle requires the equitable selection and recruitment and fair treatment of research subjects.

These three principles were the underpinnings of both an early (1980) version of a Common Federal Policy for the Protection of Human Research Subjects and the current version of that policy. Sixteen federal departments and agencies, including the Department of Health and Human Services, the National Science Foundation, the Department of Education, and the Central Intelligence Agency, adopted the regulations.

The Food and Drug Administration (FDA) has concurred with the Federal Policy and has made changes in its IRB and informed consent regulations so that they correspond to the Federal Policy. This Federal Policy, sometimes called the Common Rule, is codified as the Common Federal Policy for the Protection of Human Subjects and was published in the Federal Register in 1991. It is referred to as 45 CFR 46 and its regulations underlie the decisions of IRBs.

The regulations further require that each institution at which federally funded research is conducted adhere to the principles of The Belmont Report and set forth in writing its ethical principles, policies, and procedures. For additional online training resources visit:

**<http://cme.cancer.gov/clinicaltrials/learning/humanparticipantprotections.asp>**

## **APPENDIX A**

### **Frequently Asked Questions**

<b>QUESTION</b>	<b>ANSWER</b>
What constitutes research involving human subjects or research participants?	According to <u>Federal guidelines</u> (45 CFR 46, 102(d)), research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”
How do I know if the Institutional Review Board (IRB) should review my research?	Any research involving human participants that is conducted by any University of Liberia faculty member, staff member, or student, and meets the definition of research, must be reviewed by the <u>IRB</u> . Any individual who wishes to use any of the faculty, staff, or students of the University of Liberia as participants in their research must have his/her research proposal reviewed by the IRB.
How do I know if the Institutional Review Board (IRB) should review student research assignments and/or class projects that involve human participants?	Only research that meets the <u>definition</u> of research should be reviewed by the IRB. Normally, course work that is not intended to generate knowledge does not need to be reviewed by the IRB. Individuals who question whether their assignments constitute research may consult with the IRB.
What is considered exempt research?	<u>Exempt research</u> involves no risk to participants. Examples are: (1) research conducted in established educational settings involving normal educational practices; (2) research involving the use of educational tests (if anonymity can be assured); (3) research involving survey or interview

	<p>procedures (if confidentiality can be assured); (4) research involving observation of public behavior; and (5) research involving the collection or study of existing data, documents, records, etc. There are exceptions within some of these examples, so investigators are urged to review the Belmont Report, the web site of the Office for Human Research Protections (OHRP) of the U.S. Department of Health &amp; Human Services (DHHS), as well as other internationally acceptable guidelines for the protection of human subjects in research. Exempt research does not have to be reviewed by the IRB. If you have questions about whether or not your research is exempt, contact the <u><a href="#">IRB Chairperson</a></u>.</p>
<p>What is considered expedited research?</p>	<p>Expedited research involves no more than minimal risk to participants. Examples are: (1) research conducted in established educational settings involving normal educational practices; (2) research involving the use of educational tests (if anonymity can be assured); (3) research involving survey or interview procedures (if confidentiality can be assured); (4) research involving observation of public behavior; and (5) research involving the collection or study of existing data, documents, records, etc. There are exceptions within some of these examples, so investigators are urged to review the Belmont Report, the web site of the Office for Human Research Protections (OHRP) of the U.S. Department of Health &amp; Human Services (DHHS), as well as</p>

	<p>other internationally acceptable guidelines for the protection of human subjects in research. Once research has been deemed exempt by the IRB, no further IRB oversight is necessary.</p>
<p>What does informed consent mean?</p>	<p>The purpose of informed consent is to protect participants from harm and to assure privacy and confidentiality.</p> <p><u>Informed consent</u> is the means by which investigators advise research participants of the nature of the research, as well as procedures, benefits, and risks, and gain written consents for their participation. For some research, for example, certain questionnaires do not require the completion of informed consent forms. Read the Belmont Report, the web site of the Office for Human Research Protections (OHRP) of the U.S. Department of Health &amp; Human Services (DHHS), as well as other internationally acceptable guidelines for the protection of human subjects in research for additional information on the informed consent procedures.</p>
<p>What do I need to prepare for the submission of my research to the IRB?</p>	<p>Guidelines for completing the proposal summary may be obtain from the Coordinator if the UL-IRB, Mr. Jemee K. Tegli via e-mail (<a href="mailto:jktegli@yahoo.com">jktegli@yahoo.com</a>) or phone call (06 583 774).</p>
<p>What will the reviewers be looking for when they read my proposal?</p>	<p>The IRB reviews each proposal to assure that participants are selected fairly and protected from harm. Protection includes freedom from physical and psychological harm and assurance that the research is firmly grounded from the</p>

	<p>review of the literature and has been well thought out (has scientific merit) so that the use of the participant's time is well spent.</p>
<p>How is the IRB structured at the University of Liberia?</p>	<p>The University of Liberia has a centralized IRB that functions within the Institute of Research. <i><u>Ms. Cecelia A. Morris</u> is the Chairperson of the IRB and <u>Mr. Jemee K. Tegli</u> is the IRB Coordinator.</i></p>
<p>Where do I submit the completed forms for IRB submission?</p>	<p>The completed proposal should be submitted to the IRB Coordinator, in the Office of Research (UL-PIRE), either in hard copy or via e-mail attachment.</p>
<p>Who will review my proposal?</p>	<p>The IRB Coordinator assigns each proposal to the IRB Chairperson and one other IRB member to review the proposal. If the proposal is deemed exempt or expedited, the ruling is recorded and the investigator is advised of the ruling. If it is determined that there is more than minimal risk, the proposal is subjected to a full review by the IRB.</p>
<p>How long will the review take?</p>	<p>The review process usually takes 2-3 weeks if a proposal is exempt or expedited. A full review can take up to 2 months, so an investigator who is uncertain as to whether or not there is more than minimal risk should allow sufficient time to have the proposal reviewed.</p>
<p>Under what circumstances would my proposal be revised?</p>	<p>When there are questions about data collection procedures (including participant selection and informed consent) that may have potential risk to human participants (subjects), revisions to the proposal may be needed.</p>

<p>What happens if revisions are needed?</p>	<p>If revisions are needed, the IRB Chairperson will contact the investigator with specific revisions needed to assure protection of human participants. Once the revisions are made, the Chairperson (if expedited review) or full committee (if full review) will rule on the revised proposal. The Chairperson will notify the investigator of the outcome.</p>
<p>How long is the approval for?</p>	<p>The approval is for one calendar year, generally commencing to the date on the approval letter.</p>
<p>What do I do if the research continues beyond a year?</p>	<p>If the research continues, without change, the researcher may request an extension for an additional year. Extensions may be requested on an annual basis. If there is a change of any kind in the research procedures and/or the research methods, the proposal must be re-reviewed by the IRB.</p>
<p>What is the optimum time for submitting a proposal?</p>	<p>Proposals should be submitted as soon as the investigator has all of the completed information to address all sections of the <u>proposal form</u> and before starting data collection.</p>
<p>Should I submit a research proposal before or after seeking external funding?</p>	<p>In some instances, IRB approval must be obtained before a proposal is submitted for external funding. In other instances, IRB approval may be sought while a proposal is being reviewed for external funding. The researcher should determine the funding source's requirements for IRB approval.</p>
<p>Should I submit a research proposal before or after seeking internal funding?</p>	<p>It is highly advisable to obtain IRB approval prior to seeking University of Liberia funding for your research. A researcher who intends to use human participants in his or her research</p>

	may not begin collecting data until IRB approval is obtained.
Where can I get help with any questions I may have?	<p>There are three ways to have your questions answered:</p> <p>(1) by reviewing the IRB Manual;</p> <p>(2) by visiting relevant web sites for the protection of human subjects in research (e.g., <a href="http://www.hhs.gov/ohrp/">http://www.hhs.gov/ohrp/</a>, <a href="http://rock.pire.org/internal/ric.htm">http://rock.pire.org/internal/ric.htm</a>, etc.);</p> <p>(3) by contacting the IRB Coordinator, <a href="mailto:jktegli@yahoo.com">jktegli@yahoo.com</a>; or</p> <p>(4) contacting the IRB Chairperson <a href="mailto:acecemorris@yahoo.com">acecemorris@yahoo.com</a>.</p>

## **APPENDIX B**

### **Definitions of Commonly Used Terminologies**

#### **(From the Code of Federal Regulations)**

**ANONYMOUS:** The participants' names are unknown to the investigator, not requested, and not given.

If the only time the investigator asks for a name is to obtain a signature on a consent form, the investigator should get the verbal or implied consent of participants, to preserve their anonymity.

**ASSENT:** Agreement by participants not competent (e.g., children or cognitively impaired people) to give legally valid informed consent to participate in a research study. A special consent form, called an "assent form," is required and is signed by the parent, guardian, or caretaker, and, if the participant is competent to understand, the participant.

**BENEFIT:** A valued or desired outcome of the study that will be an advantage to the participants of a research study.

**CONFIDENTIAL:** The participants' names are known to the investigator and are usually coded to a master list and/or kept separately from the data and results. For example, each participant may put his or her name on a separate sheet that contains only a unique code number. Code numbers, not names, would then be applied to all survey and test materials. This is used for the investigator to match test results with surveys or follow-up surveys. The investigator has a real need to know the participants' names.

**DECEPTION:** The protocol is designed to withhold complete information when consent is obtained.

**DIRECTLY or INDIRECTLY IDENTIFIABLE:** The identities of individual participants are kept by the investigator. If the participants' identities are inseparable from the data, then the data are directly identifiable. If the participants' identities are kept separate from the data (see "CONFIDENTIAL" above), with the information connecting them maintained by codes and a master list, then the data

are indirectly identifiable. In either case, the investigator must ensure that confidentiality be maintained, and must explain how the participants' identities will be protected.

**HUMAN PARTICIPANTS:** Individuals whose physiologic or behavioral characteristics and responses are the basis of the research study. Participants are defined as living individual(s) about whom an investigator conducting a study obtains: data through intervention or interaction with the individual; or identifiable private information.

**HUMAN SUBJECTS RESEARCH:** Any systematic investigation that is designed to develop or contribute to knowledge and which uses living humans or identifiable information about living humans. Examples: ethnographic interviews, drug/device comparison trials, disease prevention studies, curricular evaluation studies, psychology experiments, or medical chart review studies.

**INFORMED CONSENT:** A participant voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in a study or to undergo a diagnostic, therapeutic, or preventive procedure.

**INTENTIONALLY IDENTIFIED:** The participants' names are used in connection with their data when the project results are presented to the public. This procedure is common for journalistic-type of interview studies, when participants are public figures, or in oral histories. In these cases, the investigator should seek explicit consent from the participants for the use of their names in connection with their data.

**LEGALLY AUTHORIZED REPRESENTATIVE:** An individual or entity authorized under applicable law to provide consent on behalf of a prospective participant regarding the participant's participation in a given procedure associated with a research study or project. The legally authorized hierarchy of individuals to give prospective proxy consent for participants include:

1. A guardian for the participant, if one has been appointed;
2. The participant's spouse;

3. An adult child of the participant;
4. A parent of the participant;
5. An adult sibling of the participant; and/or
6. Possibly, distant blood relatives.

**MINIMAL RISK:** A risk is minimal when the probability and magnitude of harm or discomfort anticipated from the proposed study is not greater, in and of itself, than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.

**POPULATION:** A group of people in society that meets defined criteria for participation in a research study or project.

**PRINCIPAL INVESTIGATOR:** The individual(s) with primary responsibility for the design and conduct of a research study or project.

**PRIVATE INFORMATION:** Includes information about any behavior that occurs within a context for which an individual can reasonably expect that no observation or recording takes place, and information that has been provided for a specific purpose by an individual for which the individual can reasonably expect that the information will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject may readily be ascertained by the investigator or associated with the information).

**PROTOCOL:** The formal design or plan for a study's activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the study design or methodology to be employed, the eligibility requirements for the enrollment of prospective participants, the treatment regimen(s), the data collection strategy and/or the proposed methods for analysis of the collected data.

**RISK:** The probability of harm or injury (e.g., physical, psychological, social, or economic) that occurs as a result of participating in a research study or project. Both the probability and the magnitude of possible harm may vary from minimal to significant.

**SIGNIFICANT RISK:** A study design that presents a potential for serious risk to the health, safety, or welfare of a research subject.

## **APPENDIX C**

### **Informed Consent Checklist**

#### **Basic and Additional Elements**

<b>Check</b>	<b>To be included in the informed consent letter.</b>
<input type="checkbox"/>	A statement that the project is a research study.
<input type="checkbox"/>	An explanation of the purpose of the research.
<input type="checkbox"/>	The expected duration of a subject's participation.
<input type="checkbox"/>	A description of the procedures to be followed.
<input type="checkbox"/>	The identification of all experimental procedures.
<input type="checkbox"/>	A description of any reasonably foreseeable risks or discomforts to the subjects.
<input type="checkbox"/>	A description of any benefits to the subjects or to others which may reasonably be expected from the implementation of the research.
<input type="checkbox"/>	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects.
<input type="checkbox"/>	A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained.
<input type="checkbox"/>	For research involving more than minimal risk, an explanation as to whether any compensation, and/or medical treatments will be available if injury occurs and, if so, what they consist of, or where further information can be obtained.

<input type="checkbox"/>	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects.
<input type="checkbox"/>	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

**Additional Elements (if appropriate)**

<b>Check</b>	<b>To be included in the informed consent letter.</b>
<input type="checkbox"/>	A statement that a particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
<input type="checkbox"/>	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
<input type="checkbox"/>	Any additional costs to the subject that may result from participation in the research study.
<input type="checkbox"/>	The consequence of a subject's decision to withdraw from the research and the procedures for orderly termination regarding participation by a subject.
<input type="checkbox"/>	A statement that significant new findings developed during the course of the research, which may relate to the subjects' willingness to continue their participation, will be provided to the subjects.
<input type="checkbox"/>	The approximate number of subjects expected to participate in the research study.