Livingstone College

Institutional Review Board

Policies and Procedures
Livingstone College is committed to safeguarding the welfare, rights, and privacy of all persons who participate as subjects in research projects conducted under its auspices, and to ensuring that the subjects of such research are aware of the rights and the protections available to them. Moreover, the College is required to assure the federal government that such safeguards are being provided and enforced for all federally funded grants. These safeguards derive from the following ethical principles, which were first articulated in the Belmont Report¹.

**Respect for persons:** Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.

**Beneficence:** The obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits to the subjects, as well as against the possible improvement of knowledge.

**Justice:** Fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of participants is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

**Jurisdiction of the Institutional Review Board**

The Institutional Review Board (IRB) is the body charged with reviewing and approving all proposed research involving human subjects, whether funded or not, conducted under the auspices of Livingstone College by its faculty, students or staff, or by outside investigators using Livingstone College students, personnel, facilities, or data collected at the College. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of Livingstone College. However, those officials may not approve research if it has been disapproved by the Livingstone College IRB².

Research subject to review includes, but is not limited to: pilot studies; class projects aimed for publication; master's theses; Ph.D. dissertations; co-supervised work; independent research; and senior theses, whether such research takes place on or off the Livingstone College campus, including work done outside of the United States.

¹ Ohsr.od.nih.gov/guidelines/Belmont.html
² www.hhs.gov/ohrp/irb/irb_chapter1.htm
Composition of the Institutional Review Board

The IRB must have at least five members, with varying backgrounds, to promote complete and adequate review of research activities commonly conducted by the institution. An IRB can have as many members as necessary for it to perform its duties effectively; however, it should not become so large that its management becomes cumbersome.

The three categories specified by the 45CFR 46\(^3\) are:

- At least one member whose primary concerns are in scientific areas
- At least one member whose primary concerns are in nonscientific areas
- At least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas. No IRB, however, may consist entirely of members of one profession or entirely of all men or all women.

In addition, the IRB requires the oversight of its activities and of research projects by an Authorized Institutional Official, usually an official of the institution who has the legal authority to act and speak for the institution, and should be someone who can ensure that the institution will effectively fulfill its research oversight function. At Livingstone College, this will be either the President of the college or the Vice President of Academic Affairs.

In accordance with the above categories, the IRB at Livingstone College will consist of at least five members nominated by the Vice President of Academic Affairs (VPAA) on the basis of their education, training and experience with human subjects in research. All appointed members will be voting members of the IRB.

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\(^3\) www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
Each member will serve a two-year term. The Authorized Institutional Official will designate one of the members from the Livingstone College faculty as chair of the IRB. The membership of the IRB will appoint a Secretary who will be responsible for the minutes of the IRB meetings.

The IRB, once established, needs to be registered with the Office for Human Research Protections (OHRP) located within the US Department of Health and Human Services. Before any human subjects research can be conducted, the IRB at Livingstone College must apply for Federal wide Assurance (FWA) at http://www.hhs.gov/ohrp/assurances/assurances_index.html once the Livingstone College IRB has been established and ready to review protocols. Every three years, the IRB registration should be renewed ⁴.

Internal audits need to be conducted to ensure that IRB policies and procedures are being adhered to by researchers and that they are proper in scope and content. The IRB must ensure that reporting of noncompliance is accomplished and that appropriate follow-up measures are taken ⁵.

The IRB can meet in accordance with the volume of research proposals that require its review, such as once a month or twice a semester. The IRB’s meeting schedule must be made available to the members of Livingstone College so that members interested in conducting research involving human subjects can plan the submission of their proposals for an IRB review accordingly. The IRB, once established, can determine rules for quorum and voting for the conduct of business at regular meetings. The Secretary of the IRB will record in the minutes all meeting proceedings, which must be kept for a minimum of three years.

If someone from another institution wants to use Livingstone College’s employees or students in a research project, that individual’s home institution must first provide documentation of its IRB approval. Similarly, if Livingstone College’s employees or students want to use another institution’s or agency’s employees or students in a research project, they must provide evidence of IRB approval to the other institution.

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⁴ [www.hhs.gov/ohrp/irbfaq.html](http://www.hhs.gov/ohrp/irbfaq.html)

⁵ [www.hhs.gov/ohrp/irb/irb_chapter1.htm](http://www.hhs.gov/ohrp/irb/irb_chapter1.htm)
Criteria for Exemption

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 are exempt:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the 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: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research 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.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
Criteria for Expedited Review

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. The IRB shall adopt a method for keeping all IRB members advised of research proposals that have been approved under the expedited review procedure. The IRB reviewers may exercise all the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB.

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. 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 (security-sensitive) 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 convened—utilized by the IRB.

(F) Research categories one (1) through seven (7) pertain to both initial and continuing IRB review.
Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) above is met.

(a) Research on drugs for which an investigational new drug application\(^6\) 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\(^7\) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/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\(^2\), 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 nondisfiguring 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 gumbase 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 subgingival 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; (j) sputum collected after saline mist nebulization.

\(^6\) [www.accessdata.fda.gov](http://www.accessdata.fda.gov) (21 cfr 312)

\(^7\) [www.accessdata.fda.gov](http://www.accessdata.fda.gov) (21 cfr 812)
(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/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: (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, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (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).

(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.

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) 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.
Additional references

http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm