

Liberty University Institutional Review Board

LIBERTY UNIVERSITY INSTITUTIONAL REVIEW BOARD COMPOSITION, RESPONSIBILITIES, AND ACTIONS

A. 1 Composition of the IRB and Appointment of Members

Federal regulations require that the IRB must be composed of at least five members (45 CFR 46.107). The LU IRB shall be composed of at least nine (9) members. Representation will include members whose primary concerns are in scientific areas, such that social and behavioral sciences, education, and biomedical sciences are represented. The IRB will also have at least one member whose primary concerns are in non-scientific areas, and a community representative who is not otherwise affiliated with the University nor a member of the immediate family of a University employee. At least one member (or alternate) must be able to act as an advocate for “vulnerable populations,” by virtue of experience and/or education. At least one member shall have expertise in both qualitative and quantitative research methods. In addition, the membership shall include men and women, as well as representation of racial and ethnic minority groups reflective of the composition of the University, when at all possible. All IRB members and alternates shall serve their term at the pleasure of the Liberty University Research Officer and other LU administrative officials (Dean of Graduate Studies, Vice Provost, Provost, etc). If a member goes on sabbatical or other leave for a semester, then an alternate will take his or her place from the department they represent. If a member or alternate leaves the University or goes on leave for one year or more, then the Research Officer, in concert with the IRB Chair, will appoint a replacement.

The IRB Chair will be appointed by the Research Officer. If either the IRB Chair takes a sabbatical, other leave of absence, or leaves the University, the Research Officer shall recommend a replacement to the remainder of the IRB. The new Chair will serve during the previous Chair’s absence

A.2 Responsibilities and Actions of the IRB Chair

The Chair of the IRB is ultimately responsible for the conduct of the Board. The Chair:

- Monitors changes in federal regulations and guidelines and consults with the Research Officer in proposing policies and procedures to the IRB;
- Oversees initial training and continuing instruction of IRB members, University administrators, University faculty, and any other personnel for whom federal regulations and University policy requires training regarding policies and procedures;
- Provides that research covered by the regulations will be reviewed, approved, and subjected to continuing review by the IRB;
- Consults with Principal Investigators (PIs), the Research Officer, and other administrative officials as needed about IRB policies and activities.
- Oversees the IRB Coordinator’s activities.

A.3 Responsibilities and Actions of the IRB Coordinator

The IRB Coordinator manages the logistic side of the Institutional Review Board. This person

- Arranges for regular meetings, keeping their minutes,
- Organizes orientations and appropriate training for Board members, staff, and faculty,
- Consults with PIs, the IRB Chair, and Research Officer as needed about current or prospective applications,

Liberty University Institutional Review Board

- Organizes and catalogs IRB submissions and approvals.
- Maintains/updates the IRB website, SharePoint site, and other IRB databases.
- Assists in overseeing continued compliance with federal guidelines regarding IRB policies
- Provides a list of IRB members to OHRP and the FDA, identified by the requirements contained in 45 CFR 46.103(b)(3)

A.4 Meetings and Quorums

A quorum is required to convene a meeting of the IRB. A quorum consists of at least a majority of members (or their alternates) present at the meeting, either in person, via conference call, Skype, or other appropriate technology. When members or alternates are associated with a project being reviewed, they are ineligible to vote on the project due to conflict of interest. However, the IRB may ask them to provide information about the project or they may excuse themselves from the meeting during the review. Potential conflicts of interest should be noted in the IRB meeting minutes. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests), the IRB may not take further actions or votes until the quorum is restored. Alternate members of the Board may be invited to each meeting and may participate in the discussion of agenda items, including reviews, although if they are not serving in a member's place, they are not be eligible to vote.

The Chair will convene meetings of the board for review of new applications, modification requests, continuation requests, suspension or termination of IRB approval, and Board procedural and educational issues. The meeting schedule shall be posted on the IRB website.

A.5 Review of Research

In conducting the review of research, the IRB shall follow the regulations as stated in 45 CFR 46.109 and LU's policy as described herein.

A.6 Approval of Research

In accordance with 45 CFR 46.111, the following criteria are to be met for a research project to be approved by the IRB:

- Risks to participants are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and (ii) whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
- Selection of participants is equitable. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted and is particularly cognizant of the special problems of research involving

Liberty University Institutional Review Board

vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with 45 CFR 46.116.
- Informed consent will be appropriately documented, in accordance with 45 CFR 46.117.
- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

Further, when some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

A.7 Actions and Authority of the IRB

Action on any of the options listed below requires a majority vote of the quorum. Action to require revision of an application may be initiated by any reviewing IRB member upon initial review of an application if the Board member determines that such revisions are (a) needed to determine the level of risk to participants and/or (b) needed to complete an application.

A.7.1 Actions Regarding Approval of Applications

The IRB may reach any of the following determinations with respect to any proposed project, although generally these actions are restricted to those applications receiving full Board review:

- Approve application as submitted.
- Conditional Approval. The IRB determines certain changes that are required for approval and these are communicated via email or in writing to the PI. The PI submits the changes to the IRB Coordinator. The IRB Coordinator, IRB Chair, or designated IRB member(s) may approve the revised application on behalf of the IRB if the changes meet the requirements described in the written communication with the PI.
- Require modifications and an updated submission to the IRB.
- Request consultant review. At any point, the IRB Chair or the IRB may determine that someone not on the IRB with relevant expertise needs to be consulted to address research issues, as they relate to the protection of human research participants. For example, research projects involving multicultural contexts may lead to consultation with cultural experts. The consultant shall not be involved in the proposed project. In some cases, the identity of the consultant may need to remain confidential if there is, in the IRB Chair's or committee's opinion, the possibility that the consultant's activities and objectivity could be altered through interaction with the PI.
- Disapprove the application as submitted: When a project is disapproved, the PI may revise the proposal in accordance with IRB recommendations; discuss the project with the IRB Chair or respond in writing; or withdraw the proposal application.

A.7.2 Additional Actions and Authority of the IRB

The IRB

Liberty University Institutional Review Board

- Consults with the Research Officer concerning matters of development and implementation of policies and procedures regarding the protection of human participants and the training of LU faculty, employees, and students regarding the conduct of research involving human participants.
- Monitors projects having received a full Board review for adherence to an approved protocol.
- Suspends or terminates approval of research that is not being conducted in accordance with Federal Regulations and University policy or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a written statement of the reasons for the IRB's action and shall be reported promptly to the Research Officer, the PI's Department Head, and the funding agency (if applicable).