

Liberty University Institutional Review Board

LIBERTY UNIVERSITY PROCESS FOR IRB REVIEW AND APPROVAL OF RESEARCH

A.1 Levels of Review

This section describes the three levels of IRB review for studies that involve human research participants. In accordance with Office of Human Research Protection and Food and Drug Administration Guidelines, these levels include “exempt,” “expedited,” and “full review.”

A.1.1 Exemption Certification Review

A.1.1.1 New Application

Research activities in which the involvement of human participants constitutes no more than minimal risk and falls within one or more of the exempt categories described in 45 CFR 46.101 (see below) may be eligible for exemption. Research activities may be deemed exempt from this policy (but not from IRB review) if one of the following is true.

- Research is to be 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.
- Research involves 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 a manner that human participants can be identified, directly or through identifiers linked to the participants; and
 - (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
- Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt if:
 - the human participants 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.
- Research involves 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 participants cannot be identified, directly or through identifiers linked to the participants.
- Research and demonstration projects to be conducted by or subject to the approval of Official 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

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- (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 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.

Only the IRB may certify that the proposed research meets the exemption criteria. The IRB Chair, after initial review from an appropriate IRB committee member, may take one of the following actions:

- Certify the research project as exempt and requiring no further IRB review, unless modifications are proposed which are outside the exemption categories. The PI is sent an exemption approval notification.
- Require additional information or modification(s). The IRB Chair, Coordinator, or designee will contact the PI to request the required additional information or modification(s). If the IRB Chair is satisfied that the protocol meets the exemption criteria, the research project is certified as exempt and an exemption notification is sent to the PI.
- Deny exemption certification. If the protocol does not fall within one or more of the exemption categories, as deemed by the IRB Chair, the application is considered for expedited or full review.

A.1.1.2 Modification Request of an Exempt Study

If a study is certified as exempt, the PI must request approval from the IRB Chair for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB Chair prior to implementation.

A.1.2 Expedited Review

A.1.2.1 New Application

Research activities in which the involvement of human participants involve no more than minimal risk and falls within one or more of the expedited review categories may be eligible for expedited review. Expedited reviews are for projects that do not meet the criteria for exempt status, and fall into one of the following categories:

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

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from the HHS regulations for the protection of human participants. [45 CFR 46.101\(b\)\(2\)](#) and (b)(3). This listing refers only to research that is not exempt.)

- Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - Research on drugs for which an investigational new drug application (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 (i) an investigational device exemption application (21 CFR Part 812) 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.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - from healthy, nonpregnant adults who weigh at least 110 pounds. For these participants, 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 from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.
- 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.
- 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 including studies of cleared medical devices for new indications.) are not generally eligible for expedited review,
 - 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, electroretinography, ultrasound, diagnostic infrared imaging,

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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.

- 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 from the HHS regulations for the protection of human participants. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
- Continuing review of research previously approved by the convened IRB as follows:
 - where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or
 - where no participants have been enrolled and no additional risks have been identified; or
 - where the remaining research activities are limited to data analysis.

Only the IRB may decide whether the proposed research meets the expedited review criteria requirements. Under the expedited review process, the IRB reviewers may take one of the following actions:

- Approve the research application and decide on the length of time the study is approved (one year or less); the PI is then sent a notification of approval.
- Require additional information or modifications. The IRB Chair or designee will contact the PI to request the required additional information or modification(s). The reviewers may decide that one or both of them need to review the additional information or modifications. If the reviewers are satisfied that the protocol meets the IRB review criteria, the research project is approved for one year or less and a notification of approval is sent to the PI.
- Require a full review of the application. If the protocol does not fall within one or more of the expedited review categories, the reviewers have concerns about the rights and welfare of the participants, or the additional information or modifications are extensive, the reviewers will forward the application for a full review. Additionally, the PI may be asked to revise the application prior to distribution of the application to the full IRB committee.

A.1.2.2 Modification Request

When a study is initially approved by the IRB, it sends the PI information regarding research modification procedures, along with the Change in Protocol form (See attached) that is needed in those cases. The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The Change in Protocol form is completed and sent to the IRB in those cases. The modifications must be approved by the IRB Chair prior to implementation. If the Chair determines that (a) proposed revisions modify participant risk significantly and/or (b) change the basic nature of the research project, the Chair will direct the PI to submit an entirely new application for consideration by the Board.

A.1.2.3 Continuation Request

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Research projects which are approved under the expedited review process will require continuation review at a specified interval, which will not exceed one year. A reminder of the timeline for a continuation request is sent with the initial IRB approval of a project. The Annual Review Form (See attached) is also included in the initial approval. If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the approval expiration date. All research activities, including data analysis, must cease, unless the IRB finds it is in the best interest of the individual participants to continue participating in the research interventions or interactions.

A.1.2.4 Informing IRB members of Expedited Reviews

At the end of each semester, the IRB Coordinator will make available to the IRB a list of new research applications, modification requests, and continuation requests that have been submitted or approved through the expedited review process.

A.1.3 Full Review

A.1.3.1 New application

Research activities involving human participants in which there is more than minimal risk (which therefore does not fall within one or more of the exemption categories or expedited review categories), or involves certain vulnerable populations (e.g., prisoners) must undergo a full IRB review.

The PI is invited and encouraged to attend the meeting in which the application will be reviewed. If the PI is a student, the faculty sponsor and student are both invited to attend. The PI is responsible for submitting the required materials to the IRB for a full Board review 10 working days prior to a scheduled meeting. Submission of materials by the deadline does not guarantee the full review will be conducted at the next meeting. Reasons for delaying review until the next meeting may include an already full agenda or the protocol requires revisions prior to review. Therefore, the IRB recommends that the PI submit the materials as early as possible. If a majority of the IRB members deem it appropriate, they may waive this time period.

Under the full review process, the IRB will discuss issues pertinent to the wellbeing of potential research participants, including issues of adequate informed consent, research designs and procedures adequate to provide safety and confidentiality, and risk/benefit ratios. The IRB may take one of the following three actions:

- Approve the research application and decide on the length of time the study is approved (one year or less from the date of the convened meeting at which the IRB reviewed and approved the proposal). The PI is sent a notification of approval.
- Require additional information or modifications. During the IRB meeting, the IRB members may ask the PI for additional information. If the PI does not have the additional information available at the meeting, the PI will forward this information, in writing, to the IRB Chair or designee, as soon as possible. Additionally, the IRB may require that modifications be made. At the conclusion of the review, the IRB will decide whether:
 - The IRB Chair or designee may review the additional information or modifications to ensure that they meet the IRB requirements and approve the application, if appropriate. If the additional information or modifications are not sufficient, the IRB Chair or designee may continue to work individually with the

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PI until the IRB requirements are met. The IRB may require that the additional information or modifications be reviewed at the next IRB meeting. The PI would again need to be present at the meeting.

- Disapprove the research application. The PI is sent a notification describing the reasons the research application was not approved. The PI may revise the research application in accordance with IRB recommendations; discuss the reasons for disapproval with the IRB Chair or a designee; or withdraw the research application.

Projects that require full Board review that are approved shall provide the IRB an annual report (at a minimum) about the progress of the project and about adherence to the approved project protocol. The IRB may request more frequent reports. Additional information may be required by the Board at the time the project is reviewed and approved, and shall be specified at that time.

A.1.3.2 Modification Request

The PI must request approval for any proposed modifications to the research project's protocol or informed consent or assent forms. The modifications must be approved by the IRB prior to implementation.

A.1.3.3 Continuation Request

Research projects are approved for a period of one year, unless a shorter interval is specified by the IRB. All projects that continue beyond one year shall submit an Annual Review Form by the 11th month of the study. This should be submitted directly to the IRB Chair (or designee) for review. The IRB Chair, or designee, may approve the continuation. If modifications have been made since the original approval that either significantly change the project or significantly increase participant risk, then the IRB Chair (or designee) may inform the PI that submission of a completely new application is required. This application will then be reviewed as a new application (see section A1.1.1, A1.2.1, or A1.3.1). If modifications are approved, then the IRB Chair (or designee) will notify the PI of the approval. If the PI fails to request a continuation or submit requested information, IRB approval will be terminated on the expiration date. All research activities, including data analysis, must cease unless the IRB finds it is in the best interest of the individual research participants to continue participating in the research interventions or interactions. A notification will be sent to the PI and, if appropriate, the funding agency.

A.2 Length of IRB Approval

Typically, the IRB approves a research study or continuation request for up to one year. However, approval may be granted for less than one year in some circumstances, which may include, but are not limited to, high-risk protocols, projects involving unusual types of risk to participants, projects involving vulnerable participants (e.g., prisoners), and projects conducted by a PI who has previously failed to comply with IRB requirements.

A.3 Verification of Sources other than the PI

Some projects may require verification from sources other than from the PI that no material changes have occurred since previous IRB review. The criteria for determining which studies may need outside verification include, but are not limited to, complex projects involving unusual levels or types of risk to participants; projects conducted by PIs who previously failed to comply

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with 45 CFR 46 or the requirements of the IRB; and projects where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

A.4 Preparation of Public Use Data Files

Many funding agencies require or recommend that projects produce public use data files. If the PI knows that a public use data file will be created, he or she must indicate this in the initial application form. Once the project is completed, the PI shall submit the proposed public use data file to the IRB for inspection. The funding agency may provide guidance in creation of public use files. The PI should provide this information to the IRB when submitting the protocol to prepare a public use data file. If the PI does not initially plan to develop a public use data file, once the determination to develop a public use data file is made, he or she will need to submit a modification request to the IRB. For the IRB to classify the file as a public use data file, one of the two following situations must apply:

- The data were anonymous when originally collected or data were collected from unknown persons.
- The data were collected from identified persons, but the file has been stripped of individual identifiers and any other information that may risk disclosure of any subject's identity.

When data have been collected from identified persons, the PI must consider the following elements in determining whether he or she has properly addressed the risk of disclosure of participants' identity:

- All individual identifiers of each human research subject or any person named by any human research subject must be removed
- All variables that can be surrogates for individual identifiers (e.g., street address of subject) must be removed.
- To remove the possibility of identification when a human research subject is in a small subgroup within the sample, it may be necessary to collapse or combine categories of a variable. For example, detailed breakdowns of religious denomination in a survey question, or medical procedure codes may need to be collapsed into fewer categories.
- Delete or mask, as described above, any variable that a secondary user may employ to identify any research subject. For example, the PI may need to assign a new subject ID to each individual if the original subject ID contained identifying information, such as letters from the last name or part of the date of birth.
- Use statistical methods to add random variation to variables that cannot otherwise be masked. For example, a data file may contain a combination of public and private information on a relatively small sample, perhaps demographic characteristics and salary of a public official, along with attitudinal information. The income variable may need to be altered so that it cannot be combined with the demographic characteristics to enable identifying the individual and thereby risking disclosure of private information. This option should be used only if other techniques do not work, because it may compromise the integrity of the data.

B.1 ADMINISTRATIVE REVIEW

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Research proposals sometimes raise non-IRB-related ethical concerns or public relations considerations. In these cases if the IRB approves ethical aspects of the application, the application is then forwarded to the Research Officer for appropriate administration examination and approval. See the separate Administrative Approval Policy for those procedures.