

Graceland University
Institutional Review Board (IRB)
Guidelines

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Institutional Review Board Guidelines

Background

Graceland University (GU) is committed to the safety and protection of human participants involved in biomedical and social behavioral research. The Institutional Review Board (IRB) meets the highest ethical standards for human research required by local, state, and federal laws and regulations guided by the ethical principles of respect, beneficence and justice set forth in *The Belmont Report*.

To adequately protect the rights of human participants in research, an effective IRB requires an institutional organizational structure in which authority and responsibilities are clearly defined. Responsibility for ethical conduct rests with all parties involved in the review, oversight, or conduct of research involving human subjects. Parties include the Vice President of Academic Affairs (VPAA), Deans, Associate Deans, Division Chairs, faculty, staff, students and the IRB.

Authority

Graceland University has granted the IRB the authority to approve, require modifications in (to secure approval), or disapprove all research activities; to suspend or terminate approval of research not being conducted in accordance with IRB requirements; observe or have a third party observe the consent process and the conduct of the research. The IRB's policies are drafted by the IRB chairs, or designees, and approved by a majority of members present at a convened IRB meeting at which a quorum is present. The policies may be changed or revised as warranted by the majority of the IRB at a convened meeting. When warranted and appropriate in specific situations, the IRB may waive any of its policies and procedures if: (1) the waiver is not inconsistent with federal regulations and (2) the waiver does not increase the risks to participants in research.

Composition of IRB Committee

The IRB is a specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. Membership consists of **at least five members**. At least four should be faculty members, and at least one member must be a non-faculty staff member, or an individual not otherwise affiliated with Graceland University.

There are two leadership positions within the IRB:

IRB Chair: Directs the proceedings of the IRB committees, providing expertise and leadership in a wide range of areas related to IRB functions. The chair is elected by the committee membership.

IRB Vice-Chair. Assists the Chair as needed, performs duties delegated by the Chair, and serves in the absence of the Chair. The Vice-Chair is elected by committee membership.

Responsibilities

Responsibilities of the Vice President for Academic Affairs (VPAA)

On behalf of Graceland University, the Vice President for Academic Affairs (VPAA) serves as the Institutional Official. The VPAA is primarily responsible for setting the level of the institutional culture of compliance, for instilling respect for human subjects, and ensuring effective institution-wide communication and guidance on human participant research.

The VPAA is also responsible for appointment of IRB committee members (see committee composition above). Appointments are for 12 months of service and are for a period of two (2) years. No more than 1/2 of the committee's membership should change each year. In addition, the VPAA is responsible for the creation of the budget and resource allocation necessary to ensure that there are sufficient resources, space, and staff to support the IRB's review and record keeping obligations. The VPAA must ensure respect for the authority of the IRB and its decisions and must ensure that the IRB is free from inappropriate influence. The office of the VPAA will keep electronic records of all IRB files and documents on a restricted private website for a period of not less than six (6) years after the submission of the final report and close-out procedures on the research project for which the research records were prepared, unless a longer period is specified by the sponsor, funding source, or other regulation.

Specific responsibilities of the VPAA include:

- Overseeing the educational instruction and training for IRB committee members, investigators, and research and administrative personnel.
- Overseeing the ongoing evaluation of the performance of committee members.
- Serving as a liaison between the University community and the public at large on issues related to the protection of human subjects.
- Overseeing the development and presentation of the University-wide educational programs and on-line training related to research compliance. These activities include student and faculty awareness of research involving human subjects, ethical obligations and compliance requirements, and training of investigators and key personnel and administrative staff.
- Ensuring compliance with pertinent laws and IRB policies in conjunction with the Compliance Officer.

Responsibilities of the IRB Chair

- Serve at least one year as Vice-Chair of the IRB.
- Understand regulations and guidelines governing the protection of human subjects, work closely with the IRB members to ensure that requirements are consistently applied in the review process, and that work of the member is accomplished in an effective and timely manner.
- Pre-review or assign a designee to review each application to determine if a full board review is necessary (i.e., research involving human subjects).
- Review or assign application review to committee members with topic expertise and no conflict of interest.

- Consolidate and effectively communicate HRSC committee comments and concerns back to the principal investigator (PI) in writing within two weeks of review.
- Serve as a signatory authority for documentation requiring IRB Chair approval.
- Provide leadership to the IRB, participate in training and orienting of new committee members, and provide input on related policies, procedures and educational materials governing the protection of human subjects.
- Set agenda meetings, chair the meetings, ensure that the agenda is completed, and review and edit minutes.
- Answer questions and complaints from PIs, research staff, participants, or community members, and direct issues to the appropriate resource person.
- Ensure that committee members who have potential conflict of interest for a given project are recused during discussions of that project.
- Serve as a resource to researchers who are planning or conducting research involving human subjects.
- Report changes in composition of IRB committee membership and submit annual report by May 1st to the VPAA.

Responsibilities of the IRB Members

- Conduct reviews as assigned by the IRB Chair and return to the Chair within 10-14 working days.
- Attend IRB meetings, review minutes, and provide feedback on applications in a timely manner.
- Notify the IRB chair when absences are necessary to determine whether alternate members must be present on their behalf.
- Maintain integrity of the IRB review process, declare conflict of interest and recuse themselves from Board discussions or deliberations.
- Avoid discussing IRB applications with investigators outside of convened IRB meetings.
- Propose and review new policies and procedures.
- Comply with pertinent laws and IRB policies.

Responsibilities of the PI

Graceland University requires that the PI understands the responsibilities associated with conducting research involving human subjects. PIs must comply with federal regulations, state and local laws, and institutional policies. They are responsible for training staff and for conducting research. Ultimately, they are responsible for the safety of human subjects participating in the study.

Specifically, PI requirements include the following:

- Provide IRB with complete and up-to-date research applications. Ensure that the application submitted to IRB is identical to the proposal when funding for extramural or intramural support is requested.
- Develop a research proposal that is: (a) scientifically valid, (b) consistent with sound

research design, (c) minimal risks to human participants.

- Conduct the study without deviation from the IRB-approved application, except in circumstances of direct threat of harm to any subject.
- Inform IRB of any updates or modifications to the application; secure IRB approval of any application changes prior to implementation except when a delay in implementation would place subjects at risk.
- Engage in recruitment practices that are fair and non-coercive.
- Ensure that no subjects are recruited and no data are collected prior to IRB approval.
- Clarify to the subjects which study activities are standard of care and which are conducted for research purposes.
- Monitor study data to assess subject safety.
- Promptly report any adverse events occurring during the study to the IRB, sponsors, data monitoring entities, or appropriate federal agencies as required.
- Submit progress reports as directed to IRB in a timely fashion for continued review or study closure.
- Maintain documents as required by federal, state and university policies/procedures; make these records available for inspection by appropriate authorities.
- Personally conduct the study or supervise study conduct by sub-investigators.
- Assure that all sub-investigators are adequately trained not only to perform the assigned study procedures but also to protect human subjects. With special emphasis with informed consent and confidentiality.
- Comply with applicable regulations on handling and dispensing investigational drugs or devices.
- Complete Human Subject Protection Training Certification, annually as required by the University, to remain up to date on federal regulations, GU policies and procedures, and compliance expectations. The Human Subject Protection Training Certification can be obtained via National Institute of Health (NIH) or equivalent sources.
- Store and handle research data in accordance with regulations on privacy and confidentiality.
- Research records will be maintained in the department or division in which they were produced or in a network-based electronic file with access limited to authorized personnel.

What is Subject to Review?

Definition of Research

Research is defined by the federal regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” [45 CFR 46.102(d)] This definition may include qualitative and quantitative research studies, surveys, case studies, experiments, interventions, analysis of specimens, demographic and epidemiological research, program evaluations, oral histories, secondary analyses of documents and records, and other methods associated with biomedical, behavioral and social sciences. Research is characterized by the intent to share knowledge with others in professional, scholarly, or scientific publications and/or forums.

Definition of a Human Subject

A human subject is defined in the federal regulations 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.” [45 CFR 46.102(f)] Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. 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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable for the obtaining of the information to constitute research involving human subjects. [45 CFR 46.102(f)]

Guidelines for Submission Process

IRB applications must be approved prior to recruitment of subjects or collection of data. The PI(s) will submit a completed application. IRB Committee meetings are scheduled in January, April, and September unless a full review is needed. All applications will be screened by IRB staff to ensure that appropriate forms and required attachments are complete. Information, forms, policies & procedures, and checklist for complete applications are posted on the GU-IRB website. Completed applications will be sent to the chair/vice-chair or designated primary reviewer for doctoral, master's, undergraduate, or faculty research applications, to determine review status (exempt, expedited or full review) and distribution to selected secondary reviewers if required. Incomplete applications will be returned to the PI for completion and may or may not be reviewed during the review cycle. Applications requiring full IRB review that are complete will be reviewed within 10-14 working days by the IRB reviewers. If the primary reviewer has questions about the proposal, the reviewer should contact the PI in an attempt to resolve the issues. All issues will be addressed through email communication. Other IRB members should express their concerns to the primary reviewer. An approval letter will be electronically sent to the PI from the committee. Electronic copies of all communications will be maintained by the University on the University server. After 90 days, pending proposals requiring revision with no response or communication from the PI will be closed and treated as a new proposal if resubmitted after 90 days.

Types of IRB Review

There are three types of IRB review. Each type usually requires more details to be submitted to the IRB. Investigators should use the descriptions that follow to determine which level of review is appropriate and check with the IRB Chair or a member of the IRB if questions remain. Note that both exemptions and expedited review apply only to research that poses no more than minimal risk to subjects. The regulatory definition of **minimal risk** is that “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of

routine physical or psychological examinations or tests” (45 CFR 46.102). (Foot note: CFR= code of federal regulation)

Exempt" Research Status

Exempt research is low risk and falls into one of six categories delineated by the federal government as defined below. Review of exempt applications is overseen by the IRB chair/co-chair and exempt applications do not require full committee review. Exempt categories include:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving the use of educational tests, surveys, or questionnaires, provided that human subjects cannot be identified and that responses by the subjects will not place them at risk of liability or be damaging to financial standing or reputation.
3. Research involving the use of educational tests or observation of public behavior that is not exempt under the previous category if the human subjects are elected or appointed public officials or candidates for public office or 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 PI 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 Federal Department or Agency heads to review public service programs; procedures for obtaining benefits under those programs; possible changes to those programs or possible changes in methods or levels of payment for benefits under those programs.
6. Taste and food quality evaluation and consumer acceptance studies.

Expedited Review

Expedited review is permitted when the research involves no more than minimal risk and when the study procedures fall into one or more of the seven categories delineated by the federal government. The seven categories of research that may qualify for expedited review are listed below and may be found at

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.110>. The request for Expedited Review must be approved prior to recruitment of subjects or collection of data. Expedited applications may require full committee review. Initial review by the IRB chair/co-chair and a designated committee member will determine the need for full committee review. Expedited categories include:

- 1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to

result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects 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.

For example:

- Collecting hair, nail clippings, sweat, or dental plaque
- Non-invasive physiological recordings of adults
- Minimal physical activities, i.e., running on the treadmill for 30 minutes
- Acquiring voice or video recordings
- Studies involving the use of existing documents, data or specimens
- Non-stressful studies of individual or group behavior, perception, and cognition.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by CFR 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

When some or all of the subjects 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 must be included in the study to protect the rights and welfare of these subjects.

Full Committee Review

Any research involving human subjects that does not fall into an Exempt or Expedited category must be reviewed by the full IRB Committee. Full review is required when the study poses greater than minimal risk or when an external granting agency requires full review.

Research that requires full committee review includes:

- research that involves greater than minimal risk (i.e., ingestion of energy drink, nutrition supplement over the counter);
- non-exempt research that involves children or other vulnerable populations;
- research that involves experimental drugs or devices;

- research that involves invasive procedures; and
- research that involves deception.

Survey research that involves sensitive questions or information about sexual practices or illegal behavior is subject to full review, in keeping with federal guidelines. Additionally, any survey or interview that is likely to be stressful for the subject requires full committee review. The IRB administrator will make this determination. The administrative staff screens all applications before they are assigned to the IRB. *If incomplete, the application is returned to the investigator.* The IRB reviews only complete applications. After review, the IRB will act on the application. Possible committee decisions include:

- approved as submitted;
- approved with minor requests for minor changes;
- approved with contingencies (conditions that must be met before final approval is granted) – most
- common decision;
- deferred pending receipt of additional information or major revisions; or
- disapproved.

Approval of the IRB applications

After a full discussion, the IRB may take one of the following actions by majority vote:

- **Approve:** IRB may approve the project as submitted without any changes for a maximum period of 12 months. Projects that involve risks that require closer on-going monitoring can be approved for any period of less than 12 months at the discretion of the IRB. The decision to require a period of approval of less than 12 months is determined during discussion of the proposal and is part of the motion to approve the project. Any specific findings required by 45 CFR 46 such as those needed for approval of research with prisoners (45 CFR 46.305-306), or for waivers of signed consent (45 CFR 46.117) should be documented in the minutes. Motions to approve a proposal may include a finding that the research involves no more than minimal risk, thus making the project potentially eligible for expedited review.
- **Minor Revisions Required:** The IRB committee may approve a project contingent upon specific, minor modifications that require simple concurrence by the principal investigator. Once the IRB Chair/co-chair receives the revised version of the proposal with changes, it will be routed to the member designated in the minutes (usually the primary reviewer) who will compare the modifications received with the actions requested by the IRB. A memo detailing and locating the changes in the proposal should accompany the submission. If the modifications are in compliance with the IRB directives, the chair will approve the project for the period specified by the IRB. Note: Although the approval is not effective, and the project may not go forward until the modifications are approved, the period of approval is a maximum of 12 months from the date of the convened meeting.
- **Defer Pending Resubmission:** If the IRB deems that the proposal and/or informed consent as submitted require substantive revisions, or if unanswered questions remain,

it will require the investigator to resubmit the application and attachments with all of the changes required and all of the questions resolved, as detailed in an action letter sent to the investigator. In some cases, the IRB Chair may request one or more IRB members (usually the primary reviewer) to assist the investigator in resubmitting the application. If no IRB member has been designated, the investigator is urged to consult with the Chair to receive assistance in the preparation of the revision. A revised version of the proposal with the revisions incorporated will be reconsidered at the next committee meeting following resubmission.

- **Disapprove:** The IRB may disapprove of a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. This action is taken only after all negotiations with the investigator have failed to result in a resolution of the pertinent ethical issues. The IRB will notify the principal investigator, the chair of the investigator's department (or equivalent), and the VPAA. Notification will include a complete rationale for disapproval. Upon disapproval, the principal investigator has the option to revise and resubmit the project to reduce the risks to the subjects. **Please note that Federal regulations specify that the administration of the University cannot approve a project which the IRB has disapproved.**

Letters for projects approved contingently or deferred will include a list of any changes required or suggested by the committee. In addition, after final approval, a letter of approval will be sent to the principal investigator. Electronic copies of these communications will be maintained by the IRB office for review by institutional officials.

The IRB Review Process

For the Full Review, all members are sent applications and other materials for review approximately one week prior to the scheduled meeting called by the Chair. Members are expected to review all materials prior to the meeting. The IRB meets in an executive session. The Chair may permit persons not affiliated with the IRB to attend meetings upon request. Investigators or their collaborators are not permitted to be present at IRB meetings during deliberations on their research. However, the IRB may decide to invite investigators to the meetings to answer questions about their research.

The IRB reviews a proposal first by assessing the risks and benefits of research participation. After determining that the research benefit outweighs the risks involved, the IRB proceeds to the consent process to ensure that potential subjects are fully aware of the risks and benefits and that they participate in the project voluntarily. The consent is a key element in the review. The IRB will also determine whether or not the scientific questions addressed in the protocol have adequate merit to justify the involvement of human subjects. After reviewing all materials, the IRB may opt to approve, table, or reject the application. The IRB may require revisions in the protocol. After the investigator revises a project, the IRB reviews the project again to see whether its concerns have been adequately addressed. To fully protect subjects, the IRB must approve a project before investigators begin work on the project, and before they begin to recruit subjects, since recruitment strategies are part of the review. Although there are different types of review, few projects require "full" committee review. The initial full review

will occur as needed. All IRB actions are communicated in writing to the investigator by the IRB staff. If the investigator is a student, the letter is addressed to the investigator in the care of the faculty sponsor.

No IRB member may participate in the review of or vote on any initial or continuing application, revision, or other matter involving research in which he or she has a conflict of interest. A conflict of interest is assumed to be present when the member is the PI, faculty sponsor, a member of a funded project on any research being reviewed by the IRB, a member of team taught research class, or when the member has a financial interest in the sponsor of research under consideration. Members shall recuse themselves from discussions at IRB meetings of an application or other matter in which they have a conflict of interest. This is recorded in the application. Members may provide information requested by the IRB prior to or after formal deliberations. The Chair recuses him- or herself from reviewing applications for expedited review and revisions or continuations when a conflict of interest is present. The Chair may appoint another IRB member to act as Chair during the review of such applications or research activities. This is noted in forms indicating the IRB's actions. All IRB members are encouraged to avoid the appearance of a conflict of interest that would compromise their ability to make a fair, impartial, and ethical decision on any IRB matter and to excuse themselves from decision making in such instances.

Scope of Review

IRB review and approval is required for any research involving human subjects that:

- is conducted by university faculty, staff, or students;
- is performed on the premises of the university;
- involves university students, faculty, or staff;
- satisfies a requirement imposed by the university for a degree program (if you present at the Scholar showcase orally or poster and the project involved human subjects);
- is performed with, or involves the use of, facilities or equipment belonging to the university.

Research conducted by “adjunct faculty”, faculty members who hold clinical appointments, is subject to the university's guidelines for research on human subjects, and research projects must be submitted for IRB review. Any research project that is conducted by or under the direction of any employee or agent of this institution, in connection with his or her institutional responsibilities, requires IRB approval.

Conflict of Interest

A conflict of interest occurs when an IRB member is the Principal Investigator, faculty mentor/advisor, or member of a funded or non-funded project on any research being reviewed by the IRB or when the member has a financial interest in the sponsor of research under consideration. The IRB member cannot participate in the review of or vote on any initial or continuing application, revision, or other matter involving research in which he or she has a conflict of interest. For example, an IRB member who is on a student's DNP project committee or knows student's work cannot review the application.

The IRB member shall recuse him or herself from reviewing or discussing the application involving research in which he or she has a conflict of interest. This should be recorded in the minutes when it occurs. Members may provide information requested by the IRB prior to or after formal deliberations.

The Chair also must recuse him or herself from reviewing applications for all types of review and revisions or continuations when a conflict of interest is present. The Chair may appoint the Vice-Chair or another IRB member to act as chair during the review of such applications or research activities. This should be noted in the minutes during that period, indicating the IRB's actions.

All IRB members should avoid any form of a conflict of interest that would compromise their ability to make a fair, impartial, and ethical decision on any IRB matter and to excuse themselves from decision-making in such instances.

Research Conducted by Students: The Faculty Sponsor's Responsibility

Theses/dissertation projects, senior honor theses, independent study research projects, and other similar projects must be submitted independently to the IRB by the student-researcher. Faculty sponsors must instruct students on the ethical conduct of research and help them prepare the application for IRB approval. Students should:

- understand the elements of informed consent;
- develop a readable consent form (template & samples are available from our office);
- plan appropriate recruitment strategies for identifying potential subjects;
- establish and maintain strict guidelines for protecting anonymity or confidentiality;
- and
- allow sufficient time for IRB review and completion of the project.

To ensure that the university's guidelines will be followed, the faculty sponsor is required to sign the student's application for IRB approval. After IRB approval, faculty sponsors must take an active role in ensuring that projects are conducted in accordance with the IRB's requirements.

Research Conducted in University Courses

Many research methods courses require students to complete projects as a way of teaching research methods and skills. Institutional review boards at institutions of higher education vary according to whether they require student projects to be reviewed and approved. The IRB does not require student projects conducted in research methods courses to be reviewed if the purpose of these projects is educational in nature and will not be presented to public, published, or used in future research. **Activities not intended to provide generalizable knowledge are not subject to IRB review.** However, *the instructor of the course is ultimately responsible for the protection of human subjects.* Students are not permitted to continue projects conducted for a research methods course after the semester has ended without IRB approval.

Students in graduate methods courses may use projects to refine their research interests and provide a foundation for a thesis or dissertation. A project initially conducted to learn research

methods may yield data that the student subsequently wishes to use to contribute to knowledge. In order to use these data for theses, dissertations, or other research purposes, students must either: (1) demonstrate that individuals provided informed consent for the project at the time, through procedures approved by the instructor; or (2) obtain consent from the individuals to use previously collected information according to procedures approved by the IRB (i.e., an application for exemption, expedited review, or full IRB review). Instructors of methods courses requiring student projects are encouraged to send a memo to the IRB administrator listing the students and their research projects and indicating that the projects were conducted under the instructor's supervision and in accord with procedures approved by the instructor. The administrator will provide a memo verifying that the student projects did not require IRB approval.

Student projects in courses are subject to IRB review if they are designed at least partially to provide data for research and publication purposes. For example, instructors may enlist students to assist in data collection or analysis for their own research or may design seminars in which a goal is for students to collaborate in research that will be submitted for publication. These projects constitute research and must be submitted to the IRB for approval beforehand before the project can begin.

In case of research conducted at another institution: Prior to participation in a research project at another institution, the university researcher must obtain approval of the project by the IRB at Graceland University and all relevant institutions. For example, a university researcher engaged in research with the University of Kentucky must secure approval from the IRBs at both institutions. Changes in protocol or consent forms required by the IRB at the other institution must be brought to the attention of the IRB at Graceland University.

Research Conducted at GU by Researchers from Other Institutions

In case Graceland faculty and/or officials are asked by investigators from other institutions for cooperation in their research, the study does not fall under the purview of the IRB. For example, department chairs/deans are asked to assist in the distribution of surveys to faculty or students. However, the outside PI must submit application for GU IRB approval when the following conditions are met: (1) university facilities and resources will be used; (2) university faculty/officials are actively engaged in or actively cooperate with or encourage participation in the research; or (3) university officials, faculty, staff, or students intend to use the findings or results of these studies for their own purposes. Investigators from other institutions are advised to contact the Research Office for additional information on the required procedures.

Research Conducted Outside the US

Research conducted by GU faculty or students outside the US remains under the purview and guidelines of the university IRB. Documentation of “local approval” from government offices or institutions is a prerequisite to IRB approval at the university. This approval should be from the local equivalent of the university IRB, local experts, or community leaders. Researchers should provide sufficient information regarding the language and culture of the country in question. Researchers proposing international research should allow additional time for this

review process.

Guideline for Application Amendments

When Principal Investigators must change the study procedures including recruitment activities and protocol from that initially approved, letter indicating amendment to the study must be submitted to the IRB for approval prior to initiation of these changes. Exempt studies may not require approval of amendments unless the PI determines that the changes would not fit the study as exempt status. The PI should contact the IRB Chair to consult for the change if in doubt.

“Minor modifications proposed for previously approved studies may be reviewed (during the period for which approval was authorized) via expedited review in accordance with 45 CFR 46.110 and, when applicable, 21 CFR 56.110.” A minor modification is defined as a change that would not materially affect an assessment of the risks and benefits of the study or does not substantially change the specific aims or design of the study. If the proposed change is eligible for expedited review, it will be sent to the IRB Chairperson or designee for review. The IRB Chairperson may not disapprove of a requested modification via an expedited review procedure. Examples of minor modifications that may receive expedited review include:

- changes to advertisements,
- reduction in number of research participants,
- deletion of questions in a survey.

Some minor changes to a study can be acknowledged by the IRB chair. These include:

- personnel changes (other than changes to the principal investigator),
- correction of typos in study documents, or updated contact information.

Modifications of any study document (IRB Application, protocol, consent document, recruitment materials, etc.) require submission of an updated copy of the proposed revised document with changes clearly identified. All minor modifications which have been approved or acknowledged will be immediately available on the IRB agenda for review by all IRB members at any time.

Greater-than-minor modifications proposed for previously approved studies must be reviewed and approved (during the period for which approval was authorized) by the full board of the IRB during a convened meeting before the changes can be implemented. A major modification is defined as any change which materially affects the assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of greater-than-minor changes include but are not limited to:

- newly discovered risks of the study drugs or study procedures,
- previously omitted or changed items that may affect the level of risk;
- an increase in the number of study subjects;
- a change in procedure that changes the level of risk for the study, or changes in the inclusion/exclusion criteria.
- Modifications of any study documents to the protocol require submission of an updated version of the relevant document.

The decisions and requirements for modifications by the IRB will be promptly conveyed to investigations in writing. Written notification of any decision to disapprove of an amendment to a study will be accompanied by the reasons for the disapproval and an opportunity for the PI to reply. Replies are due within 30 calendar days of the date of written notice to the PI unless otherwise specified.

Continuing Review of Approved Studies

Continuing review of all research approved by the IRB, whether funded externally or not, will take place within a year of the initial review. This review must be substantive and meaningful. The IRB meeting minutes and the initial approval letter will indicate the review interval. The frequency of the continuing review will primarily be based upon the degree of risk involved as determined by the IRB. Factors to be considered by the IRB in determining the appropriate interval for review may include, but are not limited to:

- involvement of vulnerable populations;
- location of research site;
- the involvement of recombinant DNA or other types of gene transfer studies;
- the use of waiver or alteration of informed consent procedures,
- classified research;
- research for which subjects would be exposed to additional risks, e.g. breach of confidentiality, Phase 1 studies, disproportionate number or severity of serious adverse events;
- previous suspension of the research due to compliance, record-keeping or other concerns;
- recommendations from other institutional committees;
- accrual information

To provide timely review and approval of each study, the PI shall submit required documentation no less than 10 days prior to the Full Board meeting preceding the study expiration date. The PI is responsible for being aware of upcoming expiration dates (1 year) to submit continuing review materials in a timely manner.

Information required for continuing review includes:

- Number of subjects enrolled, screened, and withdrawn (with reasons for withdrawal);
Note that any participant who signs an informed consent document is considered to be “enrolled” in the project, even if they later withdraw from the project (for not meeting all eligibility requirements, for example). Separate “screening” consent forms might be considered if an investigator anticipates a large number of “screen failures” for a particular project.
- A status report on the progress of the research and interim findings;
- Any information, including that from recent literature relevant to the study which might affect the possible benefits or risks/benefits to the subjects;
- A summary of any incidents of the following: adverse events, unanticipated problems involving the research, and/or complaints about the research since the last IRB review;
- Verification that informed consent was obtained from all subjects, that all subjects received a signed copy of the informed consent document and that all signed consent

- forms are on file (unless requirements were waived by the IRB);
- Summary of any previously unreported amendments or modifications to the research since the last review;
- An updated complete protocol (if changes have been made);
- Any relevant multi-center trial or Data Safety Monitoring Board (DSMB) reports, unless already submitted;
- Any other information which may be relevant to making a determination regarding the potential risks, benefits, or scientific merits of the study.

The primary reviewer will request the currently approved consent document from the IRB staff. Unless changes are being made to the consent document, investigators are not required to submit the currently approved consent document as part of the continuing review of materials. The approved continuing review template is posted on the IRB website. Based on its review, the IRB may require that the research be modified, restricted, suspended, or administratively closed. Alternatively, previously imposed restrictions by the IRB may be lifted.

Continuing review requiring full Board approval

Studies that were originally approved by the Full Board and that are actively enrolling subjects or are continuing to provide study treatment to subjects require a Continuing Review by the Full Board. Documentation received prior to the submission deadline will be reviewed at the next regularly scheduled IRB meeting. The IRB review will include:

- An assessment of risks, benefits, and safeguards for human subjects;
- A determination that the currently approved or proposed informed consent document is accurate and complete; and
- A review of any significant new findings that may relate to the subjects' willingness to continue participation.

Continuing review NOT requiring full Board approval

The following types of studies may receive expedited continuing review in accordance with applicable regulations:

- Studies that received expedited initial review;
- Studies in which enrollment has not yet taken place and no additional risks have been identified;
- Studies closed to accrual of new subjects **and** where subjects are no longer receiving study treatment. These studies must be reviewed at least annually until such time that there is no need to re-contact enrolled subjects.
- Studies in which only data analysis continues to take place.

The criteria for approval of a continuing review by expedited review procedures are the same as noted above for full board review.

Failure to Provide Continuing Review Information

If a PI has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved the research study by the continuing review date specified by the IRB,

all research activity, including enrollment, data collection and analysis, **shall stop** unless the IRB finds that it is in the best interest of individual subjects to continue participating in the research interventions or interactions. **Enrollment of new subjects cannot occur after the expiration of IRB approval.**

Submission of Continuing Review Materials after Expiration Date. **If IRB approval has expired, all research activities, including enrollment and accrual, data collection and analysis, must stop effective at the date of expiration.** However, the IRB will permit the study to remain on the agenda pending continuing review if the PI submits the continuing review materials to the IRB within 30 calendar days after the expiration date. Exceptions to the 30-day deadline will be made by the IRB Chair on a case-by-case basis. Research activity shall resume only after IRB approval of continuing review. If the PI fails to submit the continuing review materials within thirty days after the expiration date, the study will be closed administratively by the IRB. Studies that are administratively closed by the IRB are no longer approved for any research activity. An investigator who wishes to reinstate a research protocol that has been cancelled must submit the project as an initial application.

Continuing review of Exempt Studies

Exempt studies do not require continuing review. However, on an annual basis investigators may receive a notice asking them to inform the IRB if there have been any changes in the study procedures that may remove the study from the Exempt category or affect the risk level of the study or whether the study is ongoing. There is no penalty for failure to reply.

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