Policies and Procedures of the Institutional Review Board of Belmont University

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I. Introduction

The Belmont University Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of people who participate in research at our university consistent with ethical principles and federal, state and local regulations. The Provost serves as the Institutional Official for the IRB.

The IRB functions independently and makes independent determinations whether to approve or disapprove research protocols based upon whether or not human subjects are adequately protected.

In order to protect the rights, well-being, and personal privacy of individuals, to assure a favorable climate for the conduct of scientific inquiry, and to protect the interests of Belmont University, the policies and procedures described below have been established for the conduct of investigations involving human subjects at Belmont University ("University"). The policies and procedures shall be in compliance with regulations promulgated by the Department of Health and Human Services (HHS) in 45 CFR 46[1] and when applicable shall be in compliance with the Food and Drug Administration (FDA) regulations in 21 CFR 50 and 56.

These policies and procedures, taken together with additional special guidance to the University community and related application forms (see www.belmont.edu/irb/ for forms), define the procedures and responsibilities for the Institutional Review Board (IRB) and principal investigators for the protection of the rights and welfare of human research subjects.

The current U.S. system of the protection of human subjects is heavily influenced by the *Belmont Repor*t.[2] The full report and additional information can be found at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

The primary purpose of the *Belmont Report* is to protect subjects and participants in clinical trials or research studies, and it identifies three principles essential to the ethical conduct of research with humans:

Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Justice requires that the benefits and burdens of research be distributed fairly.

These three basic principles serve as the foundation of the current HHS regulations and guidelines for the ethical conduct of human subjects research supported by HHS.

For more information on the history and background of the U.S. system of protection for human research subjects see:

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

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[1] Subpart A of 45 CFR 46 is known as the "Common Rule."

[2] The Report was named after the Belmont Conference Center at the Smithsonian Institution where the discussions began which resulted in this report. As such, the title of this report is not connected to Belmont University.

Definitions of key terms as provided by 45 CFR 46.102 are also provided at the end of this document.

II. General Principles and Policies

The following general principles apply equally to all investigations involving human subjects at the University and to activities carried out at other sites under the aegis of faculty and professional staff of the University, whether supported solely by institutional resources or with the assistance of outside funds:

- The University and the individual members of its faculty, staff, and student body engaged in research recognize their responsibility for safeguarding the rights and welfare of human subjects.
- It is the obligation of the investigator (faculty, staff or student) to bring any proposal involving the use of human subjects that meets the definition of human subject research per 45 CFR 46.102 to the IRB prior to initiation of the study. No investigation involving the use of human subjects shall be initiated until the IRB has reviewed and approved the study or provided exempt verification.
- It is the responsibility of faculty advisors who are supervising student investigators to ensure that the research application is accurate and complete prior to its submission to the IRB. It is also the advisor's responsibility to ensure that the study is carried out as outlined in the protocol and approved by the IRB and that informed consent is appropriately obtained from all research subjects.
- All investigators (include principal investigators, co-investigators, faculty, staff, and students) who engage in human subject research are required to complete the National Institutes of Health (NIH) Human Subjects Protection Training prior to the submission of research protocols. This training certificate must be renewed every five (5) years. See this link for the online training: https://phrp.nihtraining.com/users/login.php.
- In order to approve research, the IRB must determine that all of the following requirements are satisfied in accordance with HHS regulations at 45 CFR 46.111:

  (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.

(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. Additionally, the IRB should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, persons with mental disabilities, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 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.

(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, persons with mental disabilities or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

- As indicated above, part of the IRB review is to determine that participants are not coerced to participate in research studies. Therefore, compensation to volunteer subjects should never be such as to constitute an undue inducement to participate in investigative work and should be limited to nominal amounts, including reimbursement for out-of-pocket expenses.
    - Additionally, faculty are discouraged from giving extra credit to students for participating in research studies. The IRB may approve projects that give extra credit to students who participate in a research project only when alternative means of obtaining equivalent extra credit with equivalent effort is made available to students who do not wish to volunteer as research subjects. The IRB carefully reviews the alternatives to ensure that students are not being coerced into participating.
- A key part of gaining IRB approval is submitting an informed consent document. The basic elements of informed consent as required in 45 CFR 46.116-117 must be included in every informed consent document. Approved University consent form templates can be found at www.belmont.edu/irb/.
    - The research procedure(s), its purpose and any anticipated risk or substantial stress or discomfort shall be described in lay language (6^{th} to 8^{th} grade reading level) in the consent document.
    - The explanation of the procedures to be followed should identify those that are experimental.
    - The benefits reasonably to be expected should be described, and appropriate alternative procedures that might be advantageous for the subject should be disclosed.
    - The investigator shall offer to answer any questions, and further, he/she shall be

satisfied that the individual, or his/her legally authorized representative, understands all aspects of the procedure(s) or treatment(s) he/she is to undergo. In giving consent, the subject must be able to exercise free power of choice without the intervention of any elements of constraint or coercion.

- When appropriate, time will be allowed to elapse between the explanation of the study and disclosure of risks and the signing of the consent form to permit due consideration by the subject.
- The consent form shall contain no exculpatory language (i.e., language meant to excuse Belmont University of its liability or legal responsibility) through which the subject is made to waive, or appear to waive, any of his/her legal rights, or to release the institution from liability for negligence.
- If the subject is under 18 years of age or otherwise legally incompetent, the subject's parent(s) or legally authorized representative is required to consent.
- Signed written consent is mandatory unless the IRB specifically determines that oral consent or other procedure is acceptable or waives the requirement for consent.

- As part of the review process, 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 University officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB as required in 45 CFR 46.112.
- After a study has been approved and begun, a request by any subject to withdraw his consent and to discontinue participation in the investigation shall be honored promptly and unconditionally.
- As all of the above requirements are considered, each chairperson or head of an academic or clinical department or division shall be responsible to the IRB for the supervision and proper conduct of research involving human subjects in his/her department or division in accordance with procedures prescribed by the IRB and as certified by the Chair's signature on the application forms for expedited and full review studies. Although applications submitted for exempt verification or quality improvement do not require a chair's signature, faculty should communicate with their chairs regarding their current exempt projects.

III. The Belmont University Institutional Review Board (IRB)

A. Responsibilities

The IRB has as its primary concern the protection of the rights and welfare of human subjects involved in research and is responsible for the review and approval, in accordance with the procedures set forth below, of all investigations involving human subjects. No study involving human subjects may be undertaken at the University *or by faculty, staff, or students of the University at other sites* without prior approval of the IRB. In addition, the IRB will be responsible for:

- conducting initial review and approval of all research involving human subjects to be conducted at the University or by the faculty, staff, or students of the University at other sites;
- conducting continuing review of all research approved by the IRB committee;
- providing advice and guidance to investigators regarding the rights and welfare of subjects and the IRB review procedures; and
- reporting any serious or continuing non-compliance by an investigator with the requirements and determinations of the IRB to the Institutional Official. Additionally, if the research is federally funded, the IRB will report to the Office of Human Research Protections (OHRP) and to the Food and Drug Administration (FDA) when the investigation is an FDA regulated study.

The chair and vice chair are voting members of the IRB and assume the aforementioned responsibilities of IRB members and

- complete exempt, quality improvement, and continuing reviews;
- sign all documents relevant to the review and approval of human subject research, documents for post approval monitoring;
- plan IRB professional development for the University community, individual schools and departments;
- provide guidance to IRB committee members as questions or issues arise during reviews;
- review the University's policies and procedures with respect to the utilization of human subjects in research on a continuing basis; and
- work with Departmental Review Committees to ensure comply with regulatory requirements, the Belmont Report, state laws, and University policy.

Additionally, the IRB chair

- works with the Provost in the appointment and renewal of appropriate IRB committee members;
- consults with the Provost regarding IRB member performance and needs;
- may designate signature and additional review authority to qualified IRB members (e.g., continuing reviews);
- oversees IRB meetings to ensure reviews and approvals comply with regulatory requirements, the Belmont Report, state laws, and University policy; and
- writes annual service letters for IRB committee members.

B. Membership

The IRB members shall be sufficiently qualified through maturity and diversity to ensure respect for their advice and counsel for safeguarding the rights and welfare of human subjects, and be able, in addition to professional competence, to ascertain acceptability of

proposals in terms of organizational commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. Members will therefore be appointed from among individuals in various fields (e.g., social sciences, health sciences, biological and physical sciences, business, religion, education) as well as individuals representative of the larger community served by the University.

- The IRB shall have a minimum of 5 members.
- The IRB shall have at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person affiliated with the University and at least one member whose primary area of expertise is in a non-scientific area. This could be the same committee member.
- The IRB members shall include both males and females and shall have diverse backgrounds and varied areas of professional expertise so as to assure competence necessary to review the range of research activities conducted at the University and to assure sensitivity to racial and cultural issues as well as community attitudes. When deemed necessary by the IRB, it may seek advice from experts within or outside the University.
- When research is reviewed involving a category of vulnerable subjects (e.g., prisoners, children, individuals with mentally disabilities), the IRB shall include in its reviewing body one or more individuals who have as a primary concern for the welfare of these subjects.
- The Provost shall appoint all IRB committee members. Members shall serve for terms of three years. An IRB member may resign his or her appointment, be removed upon expiration of the appointed term identified in his or her IRB member appointment letter, or may be reappointed for successive terms. Terms shall be staggered so as to assure continuity.
- The Associate Provost (or his/her representative) may serve as an ex-officio member without a vote.
- New members will be assigned an experienced IRB member to work with on the first several reviews. Initial and ongoing training for all IRB members will be provided.

C. Meetings

The IRB shall meet regularly. Additional meetings may be called at the discretion of the IRB chairperson. The IRB meeting schedule can be found on the IRB website (www.belmont.edu/irb). All members of the IRB committee are expected to complete reviews in the designated time periods and to attend these meetings.

D. Quorum

A majority of the voting members of the IRB, including the one member who is not otherwise affiliated with the University, shall constitute a quorum during the process of review. Meetings for the purpose of reviewing a study shall be canceled if a quorum is not present. A vote on an application requiring full committee review may not be

executed without a majority of the members present.

E. Conflict of Interest

If an IRB member believes that he/she might have, or be perceived as having, a conflict of interest in reviewing a given application, or if one member of the IRB suggests that another member might have such a conflict then, the member who might have a conflict of interest will excuse himself/herself from acting as a designated reviewer of an expedited application or absent himself/herself from the meeting during the discussion and voting of that application. If a disagreement arises as to whether the potential for a conflict of interest exists, it shall be resolved by vote of the IRB after discussion of the issues involved.

F. Minutes and Other Records

1. Minutes

- Written minutes shall be prepared for all IRB meetings.
- The minutes shall include: (1) attendance at the meeting; (2) actions taken by the IRB; (3) the IRB vote on the actions taken, including indication of any dissenting votes or abstentions; (4) a summary of discussion of controverted issues and their resolution; and (5) the basis for requested changes in research proposals or consent documents or for disapproval of research proposals.

2. Other Records

- The following additional records shall be maintained to document IRB activities: (a) copies of research proposals reviewed and members' evaluations of them; (b) copies of approved consent documents; (c) progress reports by investigators, including final reports; (d) reports of adverse events; (e) records of continuing review of research; (f) copies of all correspondence between IRB and investigators; (g) a list of IRB members; and (h) statements of significant new findings provided to subjects.
- All of these records shall be maintained for a period of at least three (3) years after completion of the research. Minutes and other records shall be available for inspection by authorized representatives of the U.S. Department of Health and Human Services (*applicable to federally funded projects per University Federalwide Assurance*). The Institutional Official will be notified of IRB actions by receipt of a monthly report from the IRB chair.

G. Determination of the Need for IRB Review

The IRB has authority to oversee research involving human subjects and has assured federal regulatory agencies that the institution will review and approve all research that meets the federal definition of human subjects. Studies which qualify as "research" and which involve "human subjects," as defined in the federal regulations (45 CFR 46.102) require IRB review. *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *Human subject* means 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.

Human Subject Regulations Decision Charts are provided by the U.S Department of Health and Human Services at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html. University researchers are strongly encouraged to make this determination jointly with the IRB chair or designee.

Freedom from IRB review does not negate the legal, ethical and institutional policy requirements to which the researcher may need to adhere.

H. IRB Protocol Application Submission

Investigators who wish to conduct a research project involving human subjects shall submit an online protocol application describing the research using forms provided by the university for that purpose. Approved University forms can be found at http://www.belmont.edu/irb/forms-instructions.html.

The link for the online protocol management system (i.e., Axiom Mentor) is https://www.axiommentor.com/login/axlogin.cfm. The institution ID is **belmont** and faculty, staff, and students should use their MyBelmont credentials to access the system. Please see the IRB webpage (www.belmont.edu/irb/) for more information on how to submit an online IRB application.

Expedited and full board applications shall include:

- a complete description of the research procedures and methods to be employed;
- the background to the proposed research;
- the current state of knowledge in the field;
- the significance of the research proposed;
- all risks to the subjects which can be anticipated as a consequence of their participating in the research;
- procedures to be employed to minimize risks to subjects;
- any benefits to the subjects which might reasonably be expected from their participation in the study;
- procedure for obtaining informed consent and informed consent document;
- nature of the research subject population, including sex, age, racial and ethnic characteristics;
- procedures for recruiting subjects;
- number of subjects to be studied;
- alternative procedures for diagnosis and/or treatment and their benefits and risks;
- procedures to be employed to maintain anonymity or confidentiality of subjects and subject-related data;
- source of funding to support the research;

- financial compensation, if any, for the research subjects; and
- University contact information for questions or arising issues/concerns.

I. Grants and Contracts

If the research is to be supported by a grant from an external agency, a copy of the complete grant application, as submitted to the granting agency, must accompany the application and consent document. If the research is to be supported by an industrial sponsor, a draft of the proposed contract between the industrial sponsor and the University, as well as any sponsor developed research protocol must be submitted to the IRB together with the application and consent document. The consent document shall normally contain all of the basic elements of informed consent as per 45 CFR 46.116-117.

J. Levels of IRB Review

Depending on level of risk and subject demographics, a study proposal will fall into one of three review categories; exempt, expedited or full board review. The pre-protocol survey will guide investigators towards the appropriate level of review, and level of review will be confirmed by the IRB chair or reviewer designee. Outcomes of all reviews will be communicated electronically to the primary investigator.

1. Exempt Verification

- To qualify for exempt level review, the research study must fall into any of six (6) categories delineated in the federal regulations (45 CFR 46.101(b) – see https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.101).
- Exempt **DOES NOT** mean the study is exempt from IRB review. The categories represent studies that present minimal risk to subjects. Risk is minimized through anonymity of responses or through the use of non-invasive procedures that will not harm subjects.
- The University does not allow faculty, staff or students to make their own exemption verifications
- The online pre-protocol survey will help investigators determine whether their research may quality as exempt. However, investigators may not make an exemption verification independently.
- To qualify for exempt verification, the study must be reviewed by the IRB chairperson (or designee) or an appropriate Departmental Review Committee (e.g., Psychology Department). Divisions without a DRC will rely on the University IRB for review.
- When submitting a protocol that may be exempt verified, investigators will use forms provided by the university for this purpose.
- Projects involving interaction with prisoners, persons incompetent to provide valid consent, pregnant women where pregnancy is the focus of the research, and fetuses in utero cannot be exempt. Experiments, interviews, and surveys

with children are not exempt. For children, exemption may only apply for research involving educational tests or the observation of public behavior when the investigator does not participate in the activities being observed.

- An exempt verification does not lessen the researcher's ethical obligations to subjects. All exempt research involving human subjects should maintain an adequate standard of informed consent and confidentiality of data. Maintaining an "adequate standard of informed consent" for exempt studies *very seldom* would mean using a consent form similar to regulated research. Although subject consent is always needed, signed consent forms are typically not recommended for exempt projects if these forms are the only identifying variable in an otherwise anonymous project. See guidance on IRB website for consent guidelines for exempt verified projects.
- Projects receiving an exempt determination are not subject to the continuing review process (See Section L). However, the exempt status of research may be affected if changes are made to the original application protocol. If investigators are considering changes in any of their research that has been verified as exempt, they are required to contact the IRB chairperson to discuss whether the changes impact the exempt status.
- Exempt applications do not have deadlines and will be reviewed on an ongoing basis during fall, spring, and summer.

2. Expedited Review

- An expedited review procedure may be used for certain kinds of research involving no more than minimal risk and for minor changes/amendments in approved research (45 CFR 46.110 or 21 CFR 56.110). The specific categories of research for which this procedure is applicable are listed in HHS Office of Human Research Protection guidance. http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/. Additionally, the HHS has provided decision charts regarding whether a review may be performed by expedited procedures. See https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html.
- Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated for the participant if the research procedures 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 (i)).
  - If the responsible investigator believes that the research that he/she is proposing to conduct involving human subjects is appropriate for expedited review, the investigator will submit a completed application and related documents (e.g., informed consent) through the IRB online protocol management system.
  - The department chair's signature must be on an expedited application form. This chair's signature on the application form confirms that the chair has read

the protocol, is in support of the proposed project, and will be responsible to the IRB for the supervision and proper conduct of research involving human subjects in his/her department or division in accordance with procedures prescribed by the IRB.

- The IRB chairperson or designee will confirm that the research is in a category appropriate for expedited review, officially noting the category, and that the research involves no more than minimal risk for the research subjects.
- Expedited review of research involving children can be conducted by the IRB in accordance with 45 CFR 46.110 and 21 CFR 56.110.

a) Expedited Review Process

- Expedited applications are reviewed each semester, including summer, excluding holidays and breaks. There are no deadlines for expedited review submissions; however, investigators should plan sufficient amount of time for review and possible revisions. If applications are incomplete or completed without sufficient detail to University and federal IRB requirements, the length of review could be extended, delaying the start of a project.
- Expedited reviews are typically assigned to one member of the IRB committee. Expedited applications are typically reviewed within 15 business days. The length of the review process depends on the need for and amount of revisions; therefore, investigators should ensure that a thorough and professional application is submitted to reduce the length of time for completion of the review. Investigators will be notified via email by the assigned reviewer of any areas for clarification or needs for revision. Reviewers will notify the IRB chair once the review is complete.

b) Expedited Approval Process

- *IRB approval* means the IRB has determined that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements
- Expedited reviewers may exercise all of the authorities of the IRB except that they may not deny a protocol. If the expedited reviewer does not support approval, the protocol goes to "full" review and is placed on the agenda for the next IRB meeting.
- The IRB chair or vice chair will send a certificate (i.e., notification) of approval to the responsible investigator via email. Approval shall be effective as of the date on the notification, and the certificate of approval will include notification to the investigator of reporting and continuing review responsibilities.
- Immediately following approval, consent forms will be generated within the online protocol management system with the stamped approval date. Investigators should use the approved stamped form to obtain written consent prior to data collection. Participants should be provided with a copy of

stamped approved consent form, and the PI should file the signed consent in a secure location.

- The IRB chairperson shall report actions taken in regard to research proposed for expedited review to the IRB at its next convened meeting. A copy of the research proposal and consent document shall be accessible to the committee so that members may review it if so requested.

3. <u>Full Committee Review</u>

- Should an application protocol be submitted that does not meet the requirements to be expedited, a full committee review will be scheduled.
- Research that requires a full committee review is judged to involve more than minimal risk, or involves prisoners or individuals with impaired decision-making capacity.
- All of the application guidelines for expedited review outlined above apply to full board applications with the exception of the application deadline. Applications for full board review must be submitted one month prior to the next scheduled IRB committee meeting. Full board applications will not be reviewed during the months of May, June, or July. Investigators should check the IRB calendar at www.belmont.edu/irb/calendar.html for specific submission deadlines.

a) Full Review Process

- A primary reviewer system will be employed. Two members of the IRB committee will be assigned to each application as primary reviewers, and the *initial* review will be completed within 15 working days.
    - Prior to the convened IRB meeting, the primary reviewers will be responsible for an initial in-depth review of all pertinent materials.
    - The reviewers will provide the primary investigator with a written review and request clarification and changes as needed.
    - The PI will provide those revisions electronically. The reviewers will then read these revisions and prepare a critique of the application that will be presented to the convened IRB.
- Each committee member shall receive a copy of all application materials including and informed consent documents at least one week in advance of the scheduled meeting.
- Each application that requires a full board review will be discussed by the convened IRB. Before approving a full review research proposal, the IRB shall determine that the following requirements are satisfied:
    - risks to subjects are minimized;
    - 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;

- selection of subjects is equitable, taking into account the purposes of the research and the setting in which it will be conducted;
- that informed consent will be sought from each prospective subject or 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 appropriately monitors the data collected to ensure the safety of subjects;
- subjects' privacy is appropriately protected and confidentiality of subject related data maintained; and
- that appropriate additional safeguards are included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion.

b) Full Approval Process

- Given the authority that IRBs have under HHS regulations at 45 CFR 46.109(a), the University IRB can take any of the following actions:

  (1) Approve the research study as submitted without any conditions;

  (2) Approve the research study or proposed changes with conditions (non-substantial revisions);

  (3) Defer or table the research study or proposed changes for further review at a future date; or

  (4) Disapprove the research study or proposed changes.

- A quorum of the voting IRB membership must be present and include at least one member whose primary concerns are in non-scientific areas. The convened IRB will approve or disapprove an application by majority vote of those members present. Except in the case of non-substantive revisions, if the IRB requests additional information, clarifications or revisions in the protocol or consent documents, approval or disapproval will be deferred.
- The IRB cannot approve a proposed research project undergoing initial review when the IRB (a) is unable to make the required determinations about research risks and benefits, the adequacy of privacy and confidentiality protections, or the adequacy of the informed consent process because the research protocol provides insufficient information related to these aspects of the research, and (b) is unable to specify changes to the research protocol that if made would allow the IRB to make these required determinations.
- When the IRB is reviewing a research project at a convened meeting and is unable to approve research because it cannot make the determinations required for approval, the IRB can either disapprove the project, or defer or table the project for further review at a future date. When deferring or tabling the project, the IRB, under its authority to require modifications in order for

an investigator to secure approval, may require that the investigator (a) make changes to the protocol or informed consent documents, or (b) submit clarifications or additional documents prior to the next review. If the IRB defers or tables a research project and requires that the investigator make changes to the protocol prior to the next review, the research may not proceed until the IRB reviews the revised research project and approves it at a subsequent convened meeting.

- For any full review research protocol that is approved, the IRB will state the duration of approval, which shall not exceed one year.
- Investigators will receive electronic notification of the results of the IRB review.
- When the IRB requests modifications or defers action, the investigator is informed electronically of the reasons for the IRB's actions and the substance of such correspondence is included in the meeting minutes.
- Upon approval of the research proposal, the investigator is sent a certification of approval notifying the investigator of responsibilities related to reporting and continuing review.
- If the full IRB votes to disapprove a research proposal it shall notify the responsible investigator in writing of the disapproval and the reasons for it. The responsible investigator or his/her representative may respond to the IRB in writing or in person at a convened meeting of the IRB.

K. Review of Requests by the Investigator for Changes in an Approved Application (Amendments)

- A principal investigator may not implement any changes to an approved study (including the protocol or informed consent document) without **prior** IRB review and approval, unless the change is necessary to eliminate apparent immediate hazards to the subjects.
- For projects that were approved via expedited or full committee review, investigators are required to submit an amendment for IRB approval for any proposed change to the:
    - research/project team members
    - research/project procedures
    - research documentation (e.g., informed consent, recruitment materials, survey instruments)
- As indicated previously under the "Exempt" section above, investigators must contact the IRB chair if they considering changes in any of their exempt verified research to discuss whether the changes impact the exempt status. If the proposed change does impact exempt status, the investigator will need to submit a new application. For example, a request to change a survey project's protocol from the collection of anonymous data (which qualifies for an exempt #2 determination) to

the collection of sensitive data linked to personal identifiers would require the submission of a new application for IRB review.

1. Minor Amendments

- The expedited review procedure (See Section J) will be used to review minor changes in previously approved research during the period for which approval is authorized.
- A minor change is defined as one that does not change the risk/benefit ratio of the study, does not increase the risk presented by the study above minimal risk, or, in and of itself, does not present more than minimal risk. Examples of minor changes include:
    - addition or deletion of research/project team members
    - addition of procedures that do not increase risk
    - removal of procedures which would result in reduced risk to subjects
    - addition of non-sensitive survey or interview questions
    - document changes that do not modify the intent of the content (e.g., typographical error corrections, improvements for clarity)
    - addition of, or changes to, recruitment materials or recruitment strategies
- The IRB chairperson will determine if the proposed change is minor and can therefore be approved by this procedure.
- If the IRB chairperson approves the requested minor change he/she will notify the investigator electronically.
- The IRB chairperson shall also inform the IRB during its next convened meeting of the approval of the requested minor change.
- Once the IRB approves an amendment, the information, protocol, and documentation in the amendment becomes the record of the approved study.

2. Substantive Amendments

All requests for amendments that represent substantive changes to research previously approved (other than minor changes discussed above) shall be reviewed by a IRB chair or designee, who shall prepare a written critique of the proposed amendment(s) and present this critique to the convened IRB for its discussion. After discussion, the IRB shall vote to approve or disapprove the proposed amendment or shall request additional information, clarification, or revisions in which case approval of the proposed amendment shall be deferred. The decision of the IRB shall be communicated to the responsible investigator in writing electronically.

L. Continuing Review of Research

- The IRB shall conduct continuing review of approved research at intervals determined by the IRB as being appropriate to the degree of risk but not less than

once a year. In determining the frequency of review, the IRB considers the nature of the study, the degree of risk and the vulnerability of the study participants.

- The electronic certificate of approval issued to the investigator and the minutes specify the required frequency for review and the deadline for re-approval of the study at the interval determined by the IRB.
- The IRB shall have the authority to observe or to designate a third party to observe the conduct of the research and the consent process.
- The IRB may also determine that a study needs verification from sources other than the investigator that no material changes have occurred since the previous IRB approval or that an independent committee is required to monitor the research.
- Primary investigators will receive electronic notification that deadline for re-approval is approaching. At this time, the responsible investigator shall submit a:
    - summary of the aims and objectives of the research;
    - summary of the protocol and the status of the research, including the number of subjects accrued;
    - description of any adverse events or unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints by subjects;
    - summary of recent literature related to the study;
    - summary of findings obtained to date;
    - description of modifications to research since the last review;
    - summary of any new information regarding risks to the subjects since the last review; and
    - copy of the current informed consent document.
    - If the aims, objectives or research procedures employed have changed since the last review by the IRB, such changes should be clearly indicated.
    - Continuing review will be conducted at a convened meeting of the IRB unless eligible for expedited review.
    - Failure of the responsible investigator to submit an application for continuing review by the date stipulated by the IRB will result in automatic termination of IRB approval.

M. Duration of IRB Approval and Termination of Research

1. <u>Duration of IRB Approval</u>

- IRB approval of research is always for a limited period of time not to exceed one year from the date at which the research was approved. The duration of approval will be stated in the certificate of approval from the IRB to the responsible investigator. If the study is to continue beyond the period of approval stated by the IRB, then continuing review and approval of the project

is required. If continuing review information is not received in time for IRB review prior to the end of the period of approval then a new application must be submitted and approved by the IRB if the study is to be continued.

2. Termination of Approved Research by Investigator

- Research typically terminates at the time when the period of IRB approval expires. If, for unusual circumstances such as new information about adverse events or efficacy or a decision by the sponsor of the research, the research is to be terminated before the end of the approval period, the responsible investigator should notify the IRB and provide information regarding the reasons for the termination.
- Many times, student research is approved and completed in less than a year's time. Student investigators who complete their research studies in less than a year and who plan to graduate before an annual termination date should work with their advisors to terminate the study when completed and prior to graduation.
- With the exception of student research that is approved and completed in less than a year's time, primary investigators will receive electronic notification of pending expiration of IRB approval approximately one month before approval ends. This notification requires the investigator to submit a study termination report. The IRB chairperson reviews that report and sends electronic notification that the report has been accepted and the study has been closed for IRB purposes, specifying the date of closure.

3. Suspension of Approved Research by the IRB

- Studies that have not received re-approval before the expiration date will be automatically suspended until re-approval is given or the study is terminated.
- The IRB has the authority to suspend approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any such suspension of approval shall be reported promptly to the investigator and shall include a written statement of the reasons for the IRB's action. The IRB chair will notify appropriate University officials, and appropriate funding and/or federal officials. Such suspension will normally be made at a convened meeting of the IRB unless immediate suspension is indicated. In this case, the IRB chairperson may suspend approval. Subjects may not be enrolled or research interventions conducted during the period of suspension.

IV. Definitions of Key Term from 45 CFR 46.102

IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

Research means a systematic investigation, including research development, testing and evaluation,

Human subject means 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.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) 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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk means 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.

Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.