Institutional Review Board Policy

Effective October 2018

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1.0 BOARD MEMBERSHIP

1.1 The Board will include seven members – six campus members and one external member.

1.2 Members need to be recommended to and will be appointed by the President or designee for a 3 year renewable appointment. The President or designee may consider a variety of factors in determining membership. Composition of the IRB will ideally be diverse, representing different academic disciplines, racial and cultural heritage, and understanding of issues such as community attitudes. The Board will include, at minimum, one member from the social sciences and one from the natural sciences.

1.3 The external member will have no affiliation with the institution and will not be part of the immediate family of a person who is affiliated with the institution.

1.4 All members will be required to complete online certification training course by the National Institutes of Health (NIH) Office of Extramural Research. *http://phrp.nihtraining.com/users/login.php?l=3* All members will be required to be recertified every three years and their recertification numbers kept on file in the office of Institutional Research, Assessment and Planning.

1.5 The Chair will be appointed by the President or designee.

1.6 A researcher may be a member of the IRB. However, the researcher-as-member cannot participate in the review and approval process for any research project in which s/he has a present or potential conflict of interest. Under these circumstances, s/he may be present only to provide information requested by the IRB. S/he must recuse her/himself during the discussion and voting phases of the process.

2.0 APPLICATION PROCESS

2.1 All investigators seeking expedited or full review IRB approval of their research protocols will be required to complete an online NIH Office of Extramural Research training course. *http://phrp.nihtraining.com/users/login.php?l=3*

2.2 Researchers are required to submit an application form and a protocol. No proposal will be reviewed until a completed application form and protocol have been received.

2.3 Research protocols must include the following information:

Abstract: This section should explain the specific nature of the study with clear justification for the participation of human subjects at this stage of the investigation. Researchers should keep in mind that most members of the IRB are not experts in the research being reviewed. Adequate explanations should be provided to allow the members of the IRB to understand the objectives, the methods, and the research implications, especially noting any procedure that may cause harm or injury (*risk*) in any way.

Participants: This section should note who the participants will be and how they are to be recruited. Justification must be provided for the use of subject groups that are members of a population whose capability for providing informed consent is absent or limited. These include children, persons with mental disabilities, and those who are confined to institutions (*whether voluntary or involuntary*). A detailed and specific discussion of potential problems involving the subject groups must be given.

Consent: A detailed description on how informed consent (*Informed consent means the knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.*) will be obtained. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

If the proposed research includes minors (*under 18 years*) then the protocol needs to describe how both Parental/Guardian Informed Consent and Assent (a simpler version of the Consent Form, provided in age appropriate language for the minor) will be obtained. Copies of the Informed Consent and Assent forms need to be included in the proposal.

If a waiver or modification of Consent (or Informed Consent) is requested, the protocol must detail why Consent (or Informed Consent) is not necessary or not practical.

Risks: A discussion of the risks, even if they are anticipated to be minimal, is required. Risks may be physical, psychological or social. Some research involves neither risk nor discomfort, but rather violations of normal expectations. Such violations, if any, should be specified.

Further, discussion of the management of risk is required. Procedures for protecting against or minimizing potential risks should be described. An assessment of their likely effectiveness should be discussed. Management of risk procedures ranges from those applicable to a group to those applicable to an individual subject.

Benefits: This section must present a justification for the proposed study. The discussion should focus on

1) the significance of the new knowledge that is being sought
2) an evaluation of the direct benefits to participant(s) (i.e. course credit, greater awareness, gift) with respect to the risks involved in the study

Confidentiality: Describe how confidentiality will be maintained within the proposed research, with consideration for:

1) the separation of informed consent documents and results of such items as a completed surveys or data gathered
2) the protection of participants' anonymity or a description of why select participants will not remain anonymous
3) the protection of confidentiality in presentations or publications

Debriefing: A debriefing summarizes the research for the participant and provides contact information for any follow up questions or concerns. While a debriefing for a low-risk study may be short and delivered verbally. In higher risk research, a more in-depth statement in writing may be warranted. Regardless of how it is delivered to the research participant it should include:

1) the purpose of the experiment
2) the relation of the purpose to the conditions that they participated in
3) information about publication or presentation of the research study (if known)
4) contact information of the researcher (when the Principal Researcher is a student, contact information for the faculty advisor)

A debriefing statement should be delivered in plain English (*i.e. not laden with jargon*) and provided to participants immediately after their participation.

Materials: Attach copies of all materials (*e.g., survey, etc.)* to be used in the study.

Other: Include any other information that may aid the IRB in the review process.

3.0 CONSENT

3.1 Informed consent (*The knowing consent of an individual or his/her legally authorized representative so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.*) shall be obtained by the use of a process, approved by the IRB. Documentation of consent can take two forms:

3.1.1 Extended Consent Form – A written consent document that details the elements of research study and informed consent. The investigator must provide adequate opportunity for the subject to read the form. It may also be

read to the subject or the subject's legally authorized representative. In any event, the investigator shall give either the subject (or the representative) adequate opportunity to ask questions before it is signed.

3.1.2 Short Consent Form - A short form document stating the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative. In any event, the investigator shall give either the subject (or the representative) adequate opportunity to read it before it is signed.

3.2 The IRB may waive the requirement for the investigator to obtain a signed consent form if

(1) the research presents no more than minimal risk of harm to subjects and
(2) involves no procedures for which written consent is normally required outside of the research context.

However, the researcher must still outline how *consent* will be obtained and provide justification for the waiver of signed consent.

3.3 The IRB may waive the requirements to obtain informed consent (46.116(d)), provided the IRB finds and documents that:

1) The research involves no more than minimal risk to the subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) The research could not practicably be carried out without the waiver or alteration; and
4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation

3.4 If the proposed research includes minors (*under 18 years*), and the IRB has determined that it is not Exempt (see section 4.0) then Assent (a simpler version of the Consent Form, provided in age appropriate language for the minor) may be obtained in addition to Parental Consent, depending upon the age, maturity or psychological state of the child. The judgement may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

3.5 If subjects are to be compensated, the nature of the compensation and its influence on subject participation must be discussed. Experimental subjects may be reasonably reimbursed for their participation in an experiment. Compensation to subjects should never constitute an undue inducement or coercion.

3.6 If participation in research is a course requirement, students must be informed of non-research alternatives involving comparable time and effort to fulfill those

requirements in order for the possibility of undue influence to be minimized. Moreover, students must not be penalized for refusing to participate in research (45 CFR 46.116(a)(8)).

4.0 REVIEW PROCESS

4.1.1 The Board Chair or designee will notify members when a proposal has been submitted for review.

4.1.2 Any member that serves as principal investigator or faculty advisor will be required to recuse him/herself from the review of that proposal.

4.1.3 The IRB may consult with individual(s) who have expertise beyond that available on the IRB. Individual(s) consulted will not vote on matters before the IRB.

4.1.4 Members will submit their evaluation of each proposal in writing on the proposal review checklist.

4.2 Exempt

4.2.1 The IRB reviews proposals that constitute research, as defined by the U.S. Department of Health and Human Services, Code of Federal Regulations. Research is "a systematic investigation designed to develop or contribute to generalizable knowledge." (45 CFR.46.102(d)).

Certain research proposals may be exempt from review. *The determination of whether the research is exempt is made by the IRB.* These proposals may include:

1) Research conducted in established or commonly accepted educational settings involving normal education practices (such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula or classroom management methods)
2) Research involving educational tests, survey procedures, interview procedures or observation of public behavior
3) Research involving the collection or study of existing data, documents, records or pathological or diagnostic specimens
4) Research studying, evaluating or examining public benefit or service programs
5) Research involving taste and food quality evaluation or consumer acceptance studies

It is implicit in these exemptions that there must be little, if any, associated risk. Further, the exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) does not participate in the

activities being observed (45. CFR.46.101 (i)). The exemptions are sequenced so that if it meets criteria 1, then exemption 2 is not relevant.

4.2.2 The Chair or designee will make an initial decision about whether the proposal should be exempt, require expedited review or full review.

4.2.3 If the proposal requires further review, the principal investigator and faculty advisor/staff/librarian (*if not principal investigator*) along with all members of the IRB will be notified.

4.2.4 Changes to exempt research protocols may affect their exempt status. When significant changes are made, investigators should notify the IRB Chair or designee, who will determine whether the research still falls under the "exempt" category.

4.3 Expedited Review

4.3.1 Research proposals that 1) involve no more than minimal risk (*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.*) and 2) involve ONLY procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure.

1) Clinical studies of drugs and medical devices
2) Collection of blood samples
3) Prospective collection of biological specimens for research purposes by noninvasive means.
4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice,
5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
6) Collection of data from voice, video, digital, or image recordings made for research purposes.
7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Source: http://www.hhs.gov/ohrp/policy/expedited98.html)

4.3.2 Board members may be divided into 2 groups of three for reviewing expedited proposals.

4.3.3 Members may determine that the research is:
- Approved, no changes
- Approved, pending changes
- Not approved (see section 5.0)

4.3.4 If Approved, no changes, proposals will be approved for a period of up to 12 months from the date of approval. Written approval will be sent to the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB.

4.3.5 If Approved, pending changes, the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a list of pending changes required for IRB approval and will be notified in writing once the changes are approved.

4.3.6. If Disapproved, see section 5.0. The principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a letter outlining the reasons the proposal was not approved.

4.4 Full Review

4.4.1 Any research proposal involving more than minimal risk will require a full board review.

4.4.2 A full review requires full board review at a face to face meeting. Five voting members must be present at a full review meeting for a vote to be taken.

4.4.3 Proposals requiring full review must be submitted by set due dates. Due dates will be twice per academic year, once in the fall and spring semesters. Research proposals may be submitted in the summer. Proposals submitted in the summer will be evaluated in the same way, but may require additional time for the review.

4.4.4 Decisions are made by majority vote. The following decisions can be made by the board:
- Approved, no changes
- Approved, pending changes
- Disapproved

4.4.5 If Approved, no changes proposal will be approved for a period of 12 months from the date of approval. Written approval will be sent to the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB.

4.4.6 If Approved, pending changes the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a list of pending changes required for IRB approval. If the revisions do not meet the pending changes the principal investigator and in some cases the faculty advisor (*if not principal investigator*) may be asked to meet with the board.

4.4.7 If Disapproved the principal investigator and faculty advisor (*if not principal investigator*) along with all members of the IRB will be sent a letter outlining the reasons the proposal was not approved.

4.5 Disapproval of Research Begun Prior to IRB Approval

4.5.1 Research that is begun prior to receiving IRB approval, regardless of whether registered, expedited or full review will be considered Disapproved.

5.0 APPEAL OF DISAPPROVED RESEARCH

5.1 If the IRB disapproves a protocol, there is no further appeal, as mandated by the regulations (45.CFR.46.112). Researchers can resubmit research protocols after having revised them to meet the IRB's standards of approval.

5.2 Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

6.0 MODIFICATION OF APPROVED RESEARCH

6.1 In general, any change which alters the risk or modifies the informed consent in some way requires additional IRB approval. If research needs to be modified, those modifications need to be submitted to the IRB in the form of an Amendment to the initial application, and receive approval, prior to making the modifications. The expiration date of the research remains the original approval date, not the date of approval of any Amendment.

7.0 RENEWAL OF APPROVED RESEARCH

7.1 Approved protocols are valid for up to12 months from the approval date, as determined by the IRB at the time of approval. Renewal is required for all research that continues beyond the expiration date. A research renewal form is required to be submitted to the IRB. Renewals are valid for up to one year from the renewal date as determined by the IRB.

7.2 Renewal forms need to be received by the IRB at least 30 days prior to the expiration of the research approval/renewal date.

7.3 If a protocol is not renewed by the expiration date, then all activities involving human subjects must cease on the expiration date. Protocols that are not renewed should be terminated by the investigator.

8.0 RECORDS

8.1 All records will be retained in the Office of Institutional Research, Assessment and Planning.

8.2 The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

1) Copies of all research proposals reviewed and any other documents.
2) Minutes of IRB meetings.
3) Copies of all correspondence between the IRB and the investigators.
4) A list of IRB members.
5) Written procedures for the IRB.

8.3 The records required by this policy shall be retained for at least three years, and records relating to research that is conducted shall be retained for at least three years after completion of the research. The records of the IRB pertaining to individual research activities will not be accessible outside the IRB and the individual researcher, except for purposes of audit or inspection to assure compliance.

8.4 The principal investigator or faculty/staff/librarian sponsor shall retain for three years beyond the date of completion of the research or project all protocols, copies of correspondence with the IRB, informed consent forms, and other correspondence related to the project.

9.0 SUSPENSION/TERMINATION OF APPROVED RESEARCH

9.1 The IRB has authority to suspend or terminate 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 suspension or termination of approval shall be sent in writing to the principal investigator and the faculty advisor (*if not principal investigator*) with the reason(s) for the IRB's action.

The suspension or termination will also be reported to the President or designee.

10.0 UNANTICIPATED PROBLEMS

10.1 Any unanticipated problems involving risk to participants must be reported immediately to the IRB chair. Reports should include:

a) Identification of individual(s) involved.
b) Identification of principal investigator and the faculty advisor (*if not principal investigator*), title of project and IRB case number.
c) A description of adverse reactions.
d) Any relevant information on the subject.

11.0 COMPLAINTS

11.1 Participants in research who believe that their rights have been violated should submit in writing to the IRB chair and to the President or designee the following:

1) Name and contact information of the participant.
2) Name of principal investigator and the faculty advisor (*if not principal investigator*), title of project and IRB case number.

3) A description of adverse reactions.
4) Any relevant information on the subject.

12.0 VIOLATIONS

12.1 Any noncompliance with this policy is subject to disciplinary action (See 9.1).

12.2 Violations should be reported to the IRB immediately.

12.3 The IRB will review the violations and will report these violations to the President or designee for disciplinary action.

13.0 POLICY REVIEW

13.1 The policy will be reviewed annually by IRB and the President or designee.

Appendix A

IRB DEFINITIONS

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.

Informed consent means the knowing consent of an individual or his/her legally authorized representative, so situated as to be able to exercise choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

Institution means any public or private entity or agency (including federal, state, and other agencies).

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

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

Legally authorized representative means an individual, judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

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.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.