Campbell University
Institutional Review Board
(IRB)

Standard Operating Procedures
for the
Protection of Human Subjects in Research
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PRINCIPLES, ROLES AND RESPONSIBILITIES

Ethical and Regulatory Mandates for the Campbell University IRB

The Institutional Review Board (IRB) of Campbell University is concerned with the ethical treatment of humans when they are involved as participants in research. The committee seeks to ensure that the principles of confidentiality, informed consent, benefit and minimal risk are adhered to in the students or personnel of Campbell University as participants.

The regulation of human subjects research by the U.S. Department of Health and Human Services is codified in 45 CFR 46. Because Subpart A of 45 CFR 46 has been adopted for human subjects research by many federal agencies it is known as the —Common Rule. The Common Rule requires that every institution performing federally supported human subjects research file an assurance of protection for human subjects. This research should be guided by the ethical principles espoused in the Nuremberg Code and the Declaration of Helsinki and, additionally, should conform to the guidance documents described below:

The Belmont Report

The Belmont Report elucidates three ethical principles that should guide research:

- **Respect for persons** (applied by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations);
- **Beneficence** (applied by weighing risks and benefits);
- **Justice** (applied by the equitable selection of subjects)

This regulation, published by the Department of Health and Human Services, codifies basic human subject protection measures.

Roles in the protection of human research subjects at Campbell University

Institutional Review Board (IRB)

The IRB falls under the aegis of Campbell University. The IRB is an appropriately constituted group that the University has designated to review, to approve the initiation of, and to conduct periodic review of, research involving human subjects. The primary purpose of such review is to protect the rights and welfare of the human subjects. The University’s IRB has the expertise required for the review of the University’s widely varied human subjects research studies.

The IRB is registered under the US Department of Health and Human Services (HHS) as IORG# IORG0004771. The registration number is IRB00009201. The Federalwide Assurance (FWA)# is FWA00008606.
**Principal Investigator (PI)**
The Principal Investigator is the individual responsible for the implementation of research, and, as such, must personally conduct or supervise the research. The PI is responsible for ensuring the research study is accurately and completely submitted for IRB review, that IRB approval is obtained prior to initiation of research or before making any changes or additions to the research; that the IRB is informed of all changes in information previously presented to the IRB; that progress reports are submitted to the IRB as required; and that all unanticipated problems or serious adverse events involving risk to human subjects are reported to the IRB. The PI is also responsible for ensuring that all members of the research team comply with the findings, determinations, and requirements of the IRB, including adequate performance of the informed consent process. The role of the PI implies ultimate administrative and fiscal responsibility for the project, subject to University review and oversight.

Students may have primary research responsibility and take a leading role in the research, but do not have ultimate administrative and fiscal responsibility for the project. Ultimate responsibility and oversight remains with the faculty advisor for the research project.

**IRB Authority**

**Scope and purpose**
The purpose of the Campbell University IRB is to protect the rights and welfare of human research subjects. To achieve this, the IRB must advise investigators in designing research projects in a manner to minimize potential harm to human subjects, review all planned research involving human subjects prior to the initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ascertain that human subjects are indeed protected.

The IRB also informs and assists Campbell University and its researchers on ethical and procedural issues related to the use of human subjects in research; facilitates compliance with relevant regulations of the United States Government; and provides a framework suitable for continued support by Government agencies, private foundations and industry for research involving human subjects at Campbell University.

**IRB responsibilities and authority**
All human subjects research carried out at Campbell University or under its auspices must be reviewed and approved or determined exempt from further review by the IRB prior to the involvement of human subjects in research.

The Campbell University IRB reviews human subjects research: (1) sponsored by the University; (2) conducted by or under the direction of any employee or agent of the University in connection with his or her institutional responsibilities; (3) conducted by or under the direction of any employee or agent of the University using any property or facility of the University; or, (4) involving the use of Campbell University non-public information to identify or contact human subjects.

The IRB must conduct initial and continuing research and report the findings and actions to the investigator and the institution. These reviews include: the review of all research involving human subjects at a convened meeting of the IRB (except research classified as non-human
subject research (NHSR), exempt or evaluated in expedited review); the approval of research with the concurrence of the majority of IRB members; the evaluation of proposed changes in approved research protocols; and, the determination if any project requires verification from sources other than the investigator that no material changes have occurred since previous IRB review. In addition:

- The IRB has responsibility for oversight of all human subjects research that is not exempt from IRB review;
- The IRB must protect the rights and welfare of subjects according to 45 CFR 46. (Research requiring FDA Compliance is not performed at Campbell University.)
- The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities;
- The IRB shall have 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 include a statement of the reasons for the IRB’s actions and shall be reported promptly to the investigator, Research Ethics Committee, VPAA, and appropriate federal regulatory agency.

**IRB ORGANIZATION AND ADMINISTRATION**

**IRB Membership**

**Membership**

(a) Each IRB shall have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institutions consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Alternate Members
HHS regulations at 45 CFR part 46 do not address the designation of alternate IRB/IEC members. However, for many years, the Office for Human Research Protections (OHRP) has permitted organizations submitting IRB registrations to OHRP to identify alternate members for primary members. When reviewing rosters that include alternate members OHRP assumes that, in general, with respect to the capacity in which the primary IRB member was intended to serve, each alternate IRB member has experience, expertise, background, professional competence, and knowledge comparable to that of the primary IRB member whom the alternate would replace. The minutes of an IRB meeting should document the attendance of all primary and alternate IRB members who attended any part of the IRB meeting. If both a primary IRB member and his or her alternate(s) attend the same IRB meeting, OHRP assumes that the primary member is acting as the official voting member of the IRB for review of research protocols, unless the minutes clearly indicate otherwise. A designated alternate IRB member for a primary IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member. OHRP recommends that the reason for the substitution of the alternate IRB member also be documented in the minutes.

Member Conflict of Interest
No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Examples of such conflicts of interest could include: a member of the IRB who serves as an investigator on research under consideration by that IRB; or a member who holds a significant financial interest in a sponsor or product under study.

IRB Record Requirements

IRB Documentation
The IRB shall prepare and maintain adequate paper documentation of IRB activities listed below. Some of this documentation may be subject to public perusal under the North Carolina
Open Records Act; however, the Institutional Official should be consulted prior to responding to any request for public access to IRB records.

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents, progress reports submitted by investigators, reports of injuries to subjects, and statements of significant new findings provided to human subjects.
- Records of continuing review activities including any activity occurring after initial approval. These may include modifications, renewals, adverse and unanticipated event reports, and descriptions of amendments.
- Paper copies of all correspondence, including substantive email, between the IRB and the investigators.
- A roster of IRB members identified by name, department/school, and academic rank.
- Copies of the minutes of all convened IRB meetings.

**Meeting Minutes**

IRB Meeting Minutes should be in sufficient detail to show the following:

1. Attendance at the meetings:
   - date and time meeting starts and ends
   - names of members' present
   - names of members absent
   - names of investigators present

2. Actions taken by the IRB, including the basis for requiring changes in or disapproving research Approval period

3. A written summary of controverted issues and their resolution IRB Findings and determinations

4. The following are required findings and determinations, and must be noted in the minutes with reference to the appropriate federal regulations:
   - Determination of the level of risk for human subjects in the research study (no citation required).
   - Justification for waiver or alteration of informed consent; [45 CFR 46.116(c) and (d)]
   - Justification for the waiver of the requirement for written documentation of consent; [45 CFR 46.117]
   - Justification for approval of research involving pregnant women, human fetuses and human in vitro fertilization; [45 CFR 46.204]
   - Justification for approval of research involving prisoners; [45 CFR 46.306]
   - Justification for approval of research involving children; [45 CFR 46.404-407] and
   - Special protections warranted in specific research projects for groups of subjects who 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.
INSTRUCTIONS TO INVESTIGATORS

To facilitate appropriate and ethical research practices, the IRB strongly encourages all faculty, staff, and students involved in human subjects research to complete the Collaborative Institutional Training Initiative (CITI) modules located on the IRB portal (under construction – expected finish date December 31, 2018). Please call or email the IRB Office for information regarding CITI training and access.

All proposals must be submitted to the CU IRB using the IRB application form available at https://cphsadmin.wufoo.com/forms/cu-irb-application/. In order to facilitate timely reviews and reduce paper waste, electronic submissions are now used.

 Required Submission Documents:
Proposal Narrative (found on the IRB portal) which includes:

- Introduction
- Subject Population
- Recruitment Procedures
- Procedures to Be Followed/Research Activities
- Potential Risks
- Potential Benefits
- Compensation
- Collaborators
- Conflict of Interest
- Additional Information including but not limited to:
  - Data Security & Handling Privacy/Confidentiality
  - Advertisements
- Tools such as surveys and questionnaires
- Consent(s) Document(s), if applicable
  - Alteration/Waiver of the Consent Process, if applicable
  - Alteration/Waiver of HIPAA Authorization, if applicable
  - Waiver of Consent Documentation, if applicable.

Determination of type of review
Determination of review type – Applicants will submit their suggested type of review.

In order to determine the type of review necessary, the IRB staff screens the entire application and makes determinations as to whether the project constitutes human subjects research and, if so, the type of review required. All applications are assigned to be reviewed at a convened meeting unless (1) they meet the criteria for expedited review or, (2) they meet the criteria for exemption, (3) they meet the criteria for non-human subject research (NHSR) as explained on the next page.
♦ NHSR
Reviewed by IRB Staff
Possible outcomes:
- NHSR determination
- Referred for exempt or expedited review

♦ Exempted
Reviewed by IRB Staff or IRB Chair
Possible outcomes:
- Exempt determination
- Determination contingent upon specific modification/clarification Referred for expedited or full IRB review

♦ Expedited
Reviewed by IRB Chair or a designated reviewer, when possible designated reviewer may be from the department represented by the submission.
Possible outcomes:
- Approved
- Approved contingent upon specific modification/clarification Referred for full IRB review

♦ Full
Reviewed by full IRB Possible Outcomes:
- Approval of Research
- Conditional Approval/Modifications Required
- Deferral
- Tabled
- Rejection/Disapproval

All decisions require a simple majority vote. See “IRB Actions following review by the convened IRB” below for further description.

Review by Convened IRB

Scheduling of Meetings
The IRB sets its own meeting schedule, but generally the IRB should meet at least once a month on a regularly scheduled day with the exact frequency to be determined by workload.

Scheduled meetings may be cancelled by the chair due to a) insufficient number of applications requiring review at a convened meeting, b) inability to secure a quorum for attendance, or c) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate.

The Chair will notify members of meetings.

Recusal of members with a conflict of interest
When an IRB member has a conflict of interest that requires him/her to recuse himself/herself from discussion of and voting on a particular protocol, that member should leave the meeting room for the duration of the discussion and vote, except as requested to address questions
raised by other members. If the member’s recusal causes a loss of quorum, the vote should be postponed to another meeting. For this reason, IRB members should notify the chair prior to the meeting if they have a conflict of interest related to a specific protocol slated for review at the meeting, and every effort should be made to ensure adequate members in attendance.

IRB Actions following review by the convened IRB

Approved
Approval may be granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111 and no changes to the research application are recommended. Research may proceed once the PI receives written documentation of IRB approval.

Unless otherwise specified, the approval period for research approved without changes is one year from the date of the meeting at which approval was granted.

Modifications Required/Conditional Approval
A “modifications required” status is stipulated only when the requested modifications are clear and specific in nature and do not require clarification by the Investigator. Clarifications that are minor and will not change the risk to the subject regardless of the response can also be given a “modifications required” status. Modifications will be reviewed by the IRB Chair or designated IRB member. Those that are not addressed by the Investigator and/or project team may be referred to the Full Board, as determined by the IRB Chair or Board. The recommended modifications must be made to the IRB submission, Sponsor’s protocol, informed consent documents, and/or other required documents before final IRB approval can be granted. The date of approval is the date the conditions were determined to be met. The IRB Board provides a letter to the Investigator stipulating the specific modifications required for approval.

1. Initial submissions receiving a “modifications required” status will be administratively withdrawn if an adequate response to the Board recommendations has not been received by the IRB within 60 days of the date of the “modifications required” letter.

2. Continuing review submissions receiving a “modifications required” status will expire on the date of project expiration if required modifications have not been received and approved by the IRB prior to the project expiration date.

3. Amendments receiving a “modifications required” status may not be implemented until a response by the Investigator has been received and final approval has been granted in writing by the IRB. Some examples of minor changes are: changes in contact information or identity of non-key research personnel, changes in the study title, and changes in the consent form that reflect the minor changes listed earlier.

For minor changes, the IRB Chair or IRB Staff must ensure that the PI makes the appropriate changes to the research protocol. The research may proceed after the required changes are verified and the designated reviewer approves the protocol.

Unless otherwise specified, the approval period for research for which minor changes were stipulated is one year from the date of the last convened meeting at which the protocol was reviewed.
Deferred
A project may be “deferred” when the Board lacks sufficient time, at a full Board meeting, to review a submission. The submission is placed on the next IRB Full Board meeting agenda. A project may also be “deferred” if the primary reviewer and/or consultant or subject matter expert is unable to provide or complete their review of the submission and provide documentation of this review prior to the convened IRB Full Board meeting.

Tabled
A “tabled” status is stipulated when the project does not meet the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111, if the IRB Board requests substantive modifications to the IRB submission that are relevant to the determinations required by the IRB. A project that lacks sufficient information to conduct an adequate review at the Full Board review level is “tabled” pending receipt of the requested information. The revised project must be reviewed by the convened IRB and is placed on the next available agenda pending receipt of the additional information. The Investigator’s response is reviewed by the Full Board.

1. The IRB Board may invite the Investigator to a convened IRB Board meeting to allow the Investigator to personally address the concerns of the Board and to allow the Board to ask questions and seek clarification from the Investigator.

2. Initial submissions receiving a “tabled” status are administratively withdrawn if a response to the Board modifications has not been received by the IRB within 60 days of the date of the tabled letter.

3. Continuing review submissions receiving a “tabled” status expire on the date of project expiration if an adequate response has not been received by the IRB prior to the project expiration date.

4. Amendments receiving a “tabled” status may not be implemented until a satisfactory response by the Investigator has been received and final approval has been granted in writing by the IRB.

Disapproval
A “disapproved” status is stipulated when the project does not meet the criteria for approval as defined in 45 CFR 46.111 or 21 CFR 56.111, and if the IRB Board recognizes the project puts subjects at substantial risk, or presents a significantly unfavorable risk-benefit ratio and cannot recommend substantial revisions to the IRB submission, Sponsor’s Protocol, informed consent document(s), and/or other pertinent documents outside of not conducting the project as presented.

Suspension and termination
A “suspended” status is a temporary halt in IRB approval of some or all research activities until identified concerns can be evaluated and resolved. Suspension may be initiated whenever:

- it is determined that research is not being conducted in accordance with IRB requirements and approval based on outcome from an inquiry or investigation, or
- when significant new risks are identified and need to be evaluated, or
- unexpected serious harm to subjects has occurred.
Though the chair may suspend the study, only the convened IRB can make the decision to terminate a study. A “terminated” status is a permanent halt in IRB approval for all research activities. Termination is initiated when it is determined, through investigation, that research is not being conducted in accordance with IRB requirements in which the reported risks significantly outweigh the benefits, or unexpected serious harm to subjects has occurred.

The IRB may terminate a project without "Suspending" project activities previously.

**Notification of IRB Decision**
The IRB sends written notification of actions taken to the PI. If revisions to new and continuing human subjects’ applications are required, correspondence is sent to the investigator detailing requests for revisions, clarification, or additional information as well as information regarding continuing review.

**Appeal of IRB Decision**
Investigators may appeal IRB requirements for specific changes in the protocol and/or consent document(s). The investigator may make such an appeal in writing to the IRB. At the IRB’s discretion, the PI may be invited to the IRB meeting at which his or her appeal will be considered.

If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person and/or in writing. An appeal of a disapproved research project must be reviewed at a convened meeting.

Other university officials may, in certain cases, decide that a research study may not be conducted despite IRB approval. One example, could be a circumstance in which a certain project or area of research is deemed to be inappropriate or underfunded. In the case of a decision by the IRB to disapprove, suspend, or terminate a project, only the Institutional Official may request that the IRB reevaluate a project because of procedural questions related to the IRB review. However, the IRB decision to disapprove, suspend, or terminate a project may not be reversed by the any officer or agency of Campbell University, state government or federal government.

**Use of Public Data Sets That Do Not Require Campbell IRB Review**
Research projects involving only the analysis of public use data from the following public data sets/repositories requires Campbell IRB approval or determination of NHSR or exemption from Campbell IRB review prior to access to the data:

- Inter-University Consortium for Political and Social Research (ICPSR)
- National Center for Health Statistics
- National Center for Educational Statistics
- National Child Development Study
- National Election Studies
- U.S. Bureau of the Census
- U.S. Bureau of Labor Statistics

If you plan on using public data sets/repositories, please contact the IRB Office prior to submission of an application.
Special Topics: Research Using Existing Data and Materials
Research involving the use of data meeting any one of the conditions below is not considered human subjects research and does not need to be reviewed by the IRB:

- Data on decedents;
- Data that have been stripped of all identifiers that could link that data to living persons.

Under federal regulations, research utilizing only the types of data described above is not considered human subjects research and need not be reviewed by the IRB. Nevertheless, in certain cases, the IRB may be called upon to review projects utilizing such data. Please contact the IRB Office prior to submission of an application.