Abilene Christian University

Institutional Review Board

Policies and Handbook

Version 06/01/2018

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STATEMENT OF PRINCIPLES

Abilene Christian University is comprised of a community of scholars who are committed to the highest level of integrity and ethical conduct in their work. This commitment grows out of the distinctive Christian character of the institution and its members. Respectful of the biblical doctrine of the creation, members of the ACU community are expected to engage in their scholarly activities with due regard for all the created order, both human and non-human. As a teaching institution, the research activities of the faculty and staff serve as exemplars for the students who observe and learn from these activities.

In order to ensure ethical behavior in the conduct of scholarship and research, the University has established this Institutional Review Board policy. This document is meant to ensure that research practices minimize risk to subjects and that potential benefits from research activities are maximized. This document articulates procedures that assure the human subject participation is based on equitable selection of subjects, and that participation in human subject research is non-coercive and based on the principle of informed consent.

The procedures described in this document are designed to conform to state and federal requirements for the protection of human subjects. While such conformity is necessary for receiving external funding, the rationale for developing and implementing this document is primarily an expression of the Christian commitment of the institution and its faculty, staff and students.

IRB: 1.1 IRB ORGANIZATION AND COMPOSITION

STATEMENT/PURPOSE

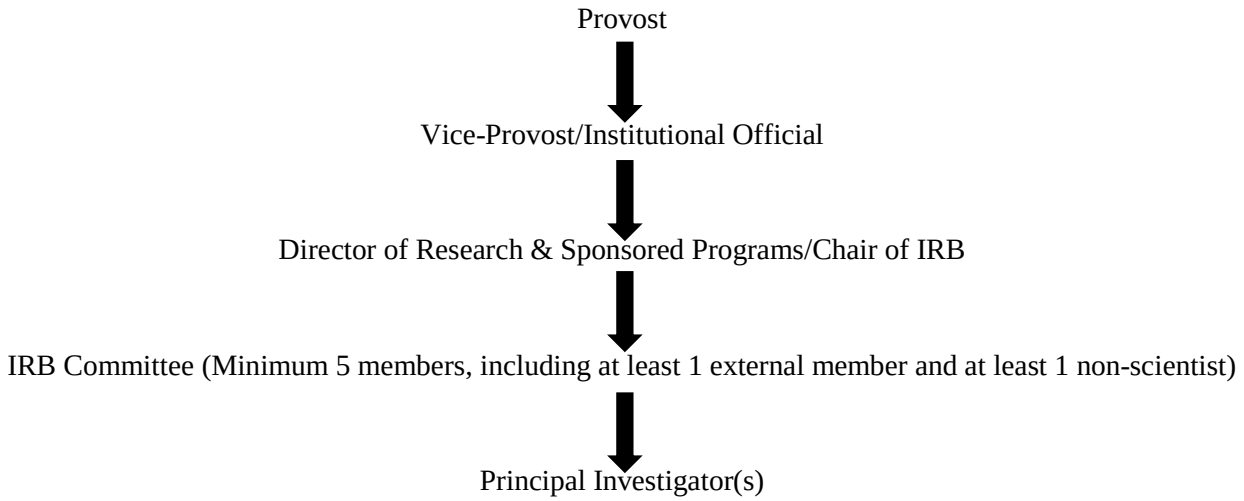
This policy outlines the composition of the Abilene Christian University Institutional Review Board (IRB), including but not limited to the number of members, their qualifications, how they are selected, and their tenure. Procedures are developed in order to maintain compliance with federal and institutional regulations.

APPLICABILITY

This policy applies to all current and prospective members of ACU's IRB, as well as any administrative units involved in the nomination, selection, and/or oversight of IRB members and activities.

POLICIES & PROCEDURES

The lines of authority and responsibility for administering the research program involving human subjects and ensuring compliance with the policies outlined in this handbook are:



Abilene Christian University Institutional Review Board members will be appointed by the Provost. The Provost may appoint up to 14 faculty members, as the institutional need arises.

The Chair shall be the director of the Office of Research and Sponsored Programs. The Chair will be notified of all decisions made by the IRB and will report those to the Institutional Official, as appropriate. The Chair may also serve as an alternate member of the committee.

Criteria for Membership

The Provost, considering advice from the Deans, will appoint IRB members using the following criteria, which were adapted in accordance with federal regulations 45 CFR 46 and 21 CFR 56 to safeguard the rights and welfare of human subjects in research:

1. Each IRB will consist of at least five and not more than fourteen voting members, with varying backgrounds to promote complete and adequate review of human research activities commonly conducted by the institution.
2. Each IRB will be sufficiently qualified through the experience, expertise, and diversity of the members, including consideration of race, gender, 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.
3. No IRB will consist entirely of men or entirely of women. Qualified persons of both sexes will be considered so long as no selection is made to the IRB only on the basis of gender.
4. Each IRB will consist of members of various professions including at least one scientist, at least one nonscientist, and 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 currently affiliated with the institution (community member). Members will be full-time tenured or tenure-track faculty members, with the exception of the individual representative who is not otherwise affiliated with ACU.
5. Alternate members may be appointed, in keeping within 14 total faculty members plus the Chair. Alternates may replace any member in a full board meeting, when alternates are needed to meet quorum. Alternates may also be assigned exempt and expedited reviews as needed.

Replacing members

When a vacancy occurs on an IRB, the chair of the IRB shall contact the Dean of the appropriate university college/school/division and request a nomination to fill the vacancy. The nominee's name and current curriculum vitae should be returned to the chair. Once the nomination has been returned, the Provost will review the credentials.

The Office of Research and Sponsored Programs (ORSP) staff will review the functions and responsibilities with the nominee to ensure that the nominee fully understand the time commitment needed for service on this committee.

Once the nominee has agreed to participate as a member of the IRB, a recommendation for appointment may be sent to the Provost, indicating whether to appoint the nominee as a full committee member or an alternate and the term of service with the IRB.

Once appointed, the IRB member will complete the following forms and submit them to the ORSP:

1. Disclosure of Significant Financial Interest (annually)
2. Non-disclosure agreement (annually).

Length of Term/Service and Description of Staggered Rotation

The standard length of service for an appointed IRB member is five years. Usually, no more than one fifth of membership may be considered for replacement each year. If a member resigns prior to the end of his/her term, a nominee may be appointed to complete the original term or may be appointed to a full term.

During the first year of the IRB member's initial term, the IRB chair may assign a senior committee member to serve as a mentor for the new appointee. This mentor will assist the new member, when requested, in preparing for committee meetings, contacting investigators for additional information, and working through any problems noted with the IRB submission, before the scheduled IRB meeting.

Near the end of the five-year term, the ORSP staff will inquire as to whether or not the appointee wishes to continue to serve. If the IRB member wishes to continue to serve on the IRB, the ORSP staff will submit a request to the Provost for the member to remain on the committee. The ORSP staff, in consultation with the Provost, may extend an invitation for a committee member to remain for an additional five years for a total of no more than 10 years. Once the extended term (10 consecutive years) is complete, the member may not be nominated to be a voting member of the IRB for a period of three years.

IRB Member Training and Continuing Education Requirement

All new members should complete training as directed by the chair of the IRB prior to beginning their work with the board. Continuing Education must be done annually through online modules, local training, and/or external training.

Functions and Responsibilities

Each IRB member shall:

1. Protect the rights and welfare of human research subjects.
2. Determine that subject risks are minimized. IRB members will ensure that the investigators:
    a. use procedures which are consistent with sound research design and which do not expose subjects to risk, and
    b. whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes.
3. Determine that risks to the subjects are reasonable in relation to the anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB member 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 member should not consider possible long-range effects of applying knowledge gained in the research.
4. Determine that selection of subjects is equitable. In making this assessment, the following should be taken into account:
    a. the purpose(s) of the research and the setting in which it is conducted; and
    b. special problems of research involving vulnerable populations (such as children, prisoners, pregnant women, cognitively or mentally impaired persons, or economically or educationally disadvantaged persons). The IRB member should be particularly cognizant of these circumstances.

5. Determine whether the informed consent is adequate, and if not, request clarifications and changes in the consent form to adequately explain the purpose of the research, the risks and benefits entailed therein, and to contain all other federally or locally mandated elements.
6. Determine that the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
7. Determine that the research plan makes adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
8. Ensure additional safeguards are in place to protect the rights and welfare of vulnerable populations.

Members and Alternates may be asked to serve as Exempt and/or Expedited Reviewers, if the IRB determines that a research request qualifies for an expedited review as defined by HHS.

Removal

When a committee member consistently fails to attend IRB meetings or fails to meet expectations, the ORSP staff and the Provost will meet with the committee member to determine the cause. If the IRB member indicates an inability to continue to function effectively as an IRB member, the ORSP staff or the Provost will request assistance from the Dean and/or department chair in obtaining a replacement member to serve on the IRB.

IRB: 1.2 MEETINGS

STATEMENT/PURPOSE

This policy outlines the procedures for scheduling and conducting Abilene Christian University Institutional Review Board meetings and notifying members of the scheduled meetings and itinerary.

APPLICABILITY

This policy applies to all current members of ACU's IRB, as well as any administrative units involved in the scheduling, planning, and/or conducting of IRB meetings.

POLICIES & PROCEDURES

1.2.1 Scheduling & Notification

IRB meetings are generally scheduled once per month during the academic year, on an as-needed basis. Full Board meetings may be called during the summer if a full board request is submitted and quorum can be met.

At the beginning of each academic semester, the IRB Chair will contact all current IRB members to obtain their schedules and availability. The Chair will then identify the day and time during which a meeting can predictably meet quorum requirements (½ + 1 members). Meetings will be scheduled during the first week of each month at this designated time.

Submissions for Full Board Review (see 1.4.1e) must be received within 2 weeks of the scheduled meeting. If Full Board submissions have been received, the Chair will notify the Committee that a meeting will take place and distribute the submitted protocols, meeting agenda, and any other applicable materials including minutes from the previous meeting.

If no submissions are received by the deadline, the Chair will notify the Committee and ask if there is any administrative business to discuss. If the Chair or other IRB member wishes to discuss administrative business, the Chair will notify the Committee of the scheduled meeting and distribute the meeting agenda and materials. If no business is brought forth, the scheduled meeting will be cancelled.

The IRB must meet at least once per semester, regardless of whether any full board submissions are received.

1.2.2 Conducting Meetings

The Chair will call the meeting to order and take roll. The IRB Administrator will record the minutes and ensure quorum is met throughout, including the presence of at least one nonscientist. The Chair will moderate the meeting and ensure that the agenda is followed, which may include: reviewing and voting

on previous minutes, reviewing and voting on submitted protocols, discussing any administrative business, training, and closing of meeting.

ACU IRB meetings are closed and confidential. Principal Investigators or other guests will not be permitted to attend the meeting unless they receive an invitation from the Chair and sign a non-disclosure agreement. The Chair will make every effort to ensure that the Committee is prepared to reach a decision on a protocol at the meeting, to avoid tabling a protocol for insufficient information. The Chair will solicit questions and comments from the Committee and request responses from the Principal Investigator prior to the scheduled meeting. The Principal Investigator may also supply a telephone number for contact during the meeting should any other unresolvable issues arise.

If at any time quorum is broken, either due to fewer than ½+1 members present or due to lack of a non-science member, the IRB Administrator will notify the Chair and the Chair will halt the meeting until which time quorum can be restored. If quorum cannot be restored within a reasonable break, the Chair will close the meeting and reschedule.

Alternates may replace any member in a full board meeting, when alternates are needed to meet quorum.

At the conclusion of the meeting, the IRB Administrator will complete the minutes, the Chair will review, and the Committee will vote to approve or modify at the following meeting.

IRB PROCEDURES 1.3

1.3.1 INITIAL REVIEW

STATEMENT/PURPOSE

If participants or researchers are ACU faculty, staff or students and the research -- whether external or internal -- involves human subjects, the project director or principal investigator (PI) must submit a Research Review Request to the Institutional Review Board (IRB). He or she must obtain approval **before** beginning the research. If the PI has received IRB approval from another institution with which he or she is affiliated, the IRB application and approval should be attached to the email submission of the completed ACU Research Review Request or IRB Authorization Agreement.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, whether on-campus or off-campus, as part of their duties or studies at ACU. This policy also applies to any non-ACU researchers who wish to use ACU faculty, staff, students, or organizations as research subjects.

POLICIES & PROCEDURES

1.3.1(a) Requirements for Review

Any research study that involves human participants must be reviewed initially and periodically by the IRB, unless the study qualifies for **exempt status** under very specific conditions. These requirements are to ensure that human participants are treated in an ethical manner that respects their rights and welfare. ACU's IRB policies and procedures are based on the federal regulations outlined in the "Common Rule" (45 CFR 46). The Common Rule outlines a set of policies and procedures for all IRBs that oversee studies receiving federal funding or operating under a Federalwide Assurance. Because of this, many IRBs have adopted these policies and procedures for their general practice. The ethical guidelines outlined in the Common Rule are the standard for human research ethics today.

The Common Rule defines ***Research*** as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, projects that are not systematic investigations (such as case studies) or are not designed to contribute to generalizable knowledge (such as class projects, program evaluations, or community service) may not require IRB oversight.

Human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or

(2) Identifiable private information." Studies that do not involve human subjects also may not require IRB oversight.

Any study that meets both of the above definitions must receive IRB review and approval **before** enrolling any participants and beginning the work, even if that study may qualify as "Exempt" status (See Section d below). Studies that do not meet either of the above definitions do not require review; however, researchers may wish to have an external reviewer make that determination for assurance and/or for publication purposes (See Section c below). When in doubt, the investigator may submit an application to the ORSP office to determine whether the study qualifies as research or human subjects research.

Investigators should use the tools on the IRB website and the Department of Health and Human Services (DHHS) website to determine whether to complete the non-research/non-human research (Section c below), exempt (Section d), expedited (Section e), or full-board (Section f) application forms. However, ultimately, the ORSP Office or an IRB member will make the final determination as to the level of IRB review required.

1.3.1(b) Training Requirements

Prior to designing or conducting research in which there are human participants, it is important that all investigators and faculty advisors (when applicable) have sufficient training and knowledge with regard to pertinent federal regulations and ethical guidelines. The NIH Office of Extramural Research provides an online course which should be used to obtain and document basic training. This training must be completed by all research team members at least once every 5 years (and by IRB members annually).

In addition, all research team members must complete EthicsCORE Responsible Conduct of Research (RCR) Training. Investigator should make sure to register under the ACU group when creating an account. RCR training should be conducted once every 4 years at minimum.

Upon completion of the training, investigators should save the Certificates of Completion to provide the IRB documentation of their training.

All training modules are accessible via a Canvas Research Training Course. Investigators may request access to the classroom by emailing orsp@acu.edu.

1.3.1(c) Non-Research and Non-Human Research

Any study that does not meet the definitions of ***Research*** and/or ***Human Subjects*** as defined in Part (a) above is not within the purview of the IRB. However, at times such judgments may be difficult for the Principal Investigator to make with confidence. At other times (or in addition), proof of IRB review may be required by another entity (e.g., the study site, hosts of a meeting, a journal, etc.). In such cases, it may be beneficial for another person, not involved in the study, to make the determination of Non-Research or Non-Human Research.

Investigators who require review of Non-Research or Non-Human Research studies may submit an application to the IRB Office using the applicable forms for this review. Such requests are received by the Chair who will review the materials submitted and determine if the study meets the requirements for the non-research/non-human research designation. The Chair may also designate an IRB member or alternate to make this determination. If the requirements are met, the researchers will receive a letter from the IRB Office stating this designation and exempting the study from further IRB oversight. Researchers will be notified that should the details of the study change such that it no longer qualifies for this designation, the researchers should contact the IRB again.

If the Chair, or designated reviewer, determines that the study does not meet the requirements for this designation, the appropriate review will be recommended and forwarded as appropriate.

1.3.1(d) Exempt Research

An exempt study is human-subjects research which does not require ongoing IRB oversight. The determination of Exempt status **must** be made by the IRB Office or a designated IRB reviewer, not by the researcher/s. Exempt research is defined by 45 CFR 46.104. The study must be minimal risk and fall into one of 8 categories. Briefly, those categories are research involving 1) standard educational practices in an educational setting; 2) minimal risk surveys, tests, interviews, or observations; 3) benign behavioral interventions; 4) existing data or specimens that are either publically available or deidentified; 5) public benefit programs supported by a federal agency; 6) taste and food quality; 7) Storage or maintenance for secondary research for which broad consent is required; 8) Secondary research for which broad consent is required. Further detail and stipulations for these categories may be found on the DHHS website.
These exemptions do not apply to studies using prisoners as participants. Exemptions involving children are allowable with certain restrictions.

Investigators who require review of Exempt Research may submit an application to the IRB Office using the applicable forms for this review. Such requests are received by the Chair who will review the materials submitted and determine if the study meets the requirements for exemption. The Chair may also designate an IRB member or alternate to make this determination. If the requirements are met, the researchers will receive a letter from the IRB Office stating this designation and exempting the study from further IRB oversight. Researchers will be notified that should the details of the study change, such that it no longer qualifies for this designation, the researchers should contact the IRB again.

Some of the exempt categories may require a limited review. In such cases, the researcher should complete the limited review section in order to satisfy the requirements in .111(7) and/or (8).

If the Chair, or designated reviewer, determines that the study does not meet the requirements for this designation, the appropriate review will be recommended and forwarded as appropriate.

1.3.1(e) Expedited Review

An expedited review is one conducted by a single IRB member, as opposed to being discussed at a convened meeting of the entire IRB (See Full Board Review, Section f, below). The expedited reviewer may request clarifications and revisions and may approve the research. An expedited reviewer cannot fail to approve a study. In such a case where an expedited reviewer does not feel he/she can approve the study, even with revisions, the study must be brought to full board review.

Expedited research is defined by 45 CFR 46.110. The study must fall into one of 7 categories. Those categories are described in full on the DHHS website and, briefly, include 1) Qualifying clinical study of drugs or medical devices; 2) Qualifying collection of blood samples; 3) Collection of biological samples by noninvasive methods; 4) Noninvasive data collection using procedures routinely employed in clinical practices; 5) Research involving data or samples that were collected for nonresearch purposes; 6) Voice, video, digital, or image recordings; 7) Research on individual or group behavior or using surveys or interviews that don’t otherwise qualify for exemption.

Studies approved by expedited review must still follow the IRB’s policies and procedures for informed consent, amendments, reporting unanticipated problems or deviations, and inactivating a study, as described in other sections of this Handbook.

Investigators who require an Expedited Review may submit an application to the IRB Office using the applicable forms for this review. Such requests are received by the Chair or IRB Administrator who will review the materials for completeness. If items are missing or there are questions about the application, the IRB office may contact the investigator for further information before continuing the review. Once the application package is determined to be complete, the IRB Office will forward a copy to the primary reviewer within 1 week of the completed proposal being received. The primary reviewer will review the protocol and make a determination within 2 weeks of receipt.

A list of all studies approved via expedited review will be submitted to the full IRB committee at the end of each academic semester.

If the Chair, or designated reviewer, determines that the study does not meet the requirements for this designation, the appropriate review will be recommended and forwarded as appropriate.

1.3.1(f) Full Board Review

Full board review is considered the default type of review. The other classifications and review types (e.g., exempt and expedited) represent special cases with specific parameters that must be met.

Investigators who require a Full Board Review may submit an application to the IRB Office using the applicable forms for this review. Such requests are received by the Chair or IRB Administrator who will review the materials for completeness. If items are missing or there are questions about the application, the IRB office may contact the investigator for further information before continuing the review. Once the application package is determined to be complete, the IRB Office will forward a copy to the primary reviewer within 1 week of the completed proposal being received. The primary reviewer will then confirm the designation and call the protocol to full board review. If the Chair, or designated reviewer, determines that the study meets the requirements for another review type, the appropriate review will be recommended and forwarded as appropriate.

A protocol that was submitted on an expedited request form may also be called to full board for two reasons: 1) The IRB Office or IRB reviewer determined that the study did not, in fact, meet the criteria for expedited review, or 2) the reviewer did not feel that he/she could approve the study, even after revision. 45 CFR 46 does not permit disapproval of a study under expedited review, but instead requires that it go to full board for consideration. Note that if a reviewer believes that a study that otherwise qualifies for expedited review is more than minimal risk and needs full review, the burden of proof is on the reviewer to justify this claim.

ACU's IRB will meet a least once a semester and monthly, as needed. Full board meetings are generally scheduled within the first week of each month during the academic year. If a complete full board request is received at least 30 days before the meeting, it will be assigned to that meeting, space allowing. Protocols received between 30 days and 2 weeks prior to the meeting will be assigned to the next scheduled meeting if: 1) the protocol is determined to be complete at least 2 weeks prior to the meeting, and 2) space allowing. The IRB Office cannot guarantee an assignment at the next meeting and may assign the protocol to a later meeting. Protocols received fewer than 2 weeks prior to the meeting will automatically be assigned to the following month to allow for appropriate preparation by the IRB. The PI and Point of Contact named in the protocol will receive notice of full board review and the date assigned for review.

The Chair will make every effort to ensure that the Committee is prepared to reach a decision on a protocol at the meeting, to avoid tabling a protocol for insufficient information. The Chair will solicit questions and comments from the Committee and request responses from the Principal Investigator prior

to the scheduled meeting. The Principal Investigator may also supply a telephone number for contact during the meeting should any other unresolvable issues arise.

1.3.1(g) Review Process, Potential Actions, and Requests for Changes

Review Process

The IRB must determine that 9 criteria, when applicable, are met in order to approve a human subjects research study:

1. The risks to subjects have been minimized by: a) Using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and/or b) Using procedures already being performed on the subjects for diagnostic or treatment purposes
2. The risks to subjects are reasonable in relation to the anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
3. The selection of subjects is equitable, considering the purposes of the research, the setting in which it will be conducted, and any special problems related to vulnerable populations (such as children, prisoners, pregnant women, mentally disabled person, 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 §46.116 (which includes conditions under which waivers or alterations may be granted).

   The general requirements of consent cannot be altered. These are: participants must be given sufficient time; language must be readable on an appropriate level, free of technical language, and free of exculpatory language; participants must be given reasonable information in order to make a decision; and the format must be a concise presentation of key information to facilitate understanding

   Consent must include: 1) a statement that this is research and the purpose of the research; 2) descriptions of the procedures involved and the frequency and duration of participation; 3) descriptions of the risks and benefits anticipated; 4) any alternative treatment that may be available instead of the research treatment, if applicable; 5) any efforts that will be made to protect privacy and confidentiality; 6) if there will be any treatments or compensations made in the event of an injury; 7) whom to contact for questions, issues regarding welfare and rights, and in the event of an injury; 8) a statement that participation is voluntary, and the participant may decline to participate or withdraw at any time without penalty or loss of benefits to which they are otherwise entitled.
   In some cases, additional statements may also need to be added when appropriate to the study, including: 1) the possibility of unforeseen risks; 2) any situations whereby the investigator may withdraw the participant; 3) any costs that the participant may incur; 4) any natural consequences that may occur if the subject withdraws (e.g., withdrawal side effects of a study medication); 5) if any findings that occur during the study may affect the participant's willingness to participate and how that will be communicated; 6) the number of participants to be enrolled; 7) A statement that biospecimens may be used for commercial profit and whether the subject will or will not share in the profit; 8) A statement regarding whether clinically relevant results will or will not be shared with subjects and if so, under what conditions; 9) disclosure if biospecimens will be used for whole genome sequencing; 10) a statement informing participants if their data MAY or WILL NOT be stripped of identifiers and used in future research without consent; and 11) if technology will be used capable of generating identifiable private information/biospecimens, a statement including this in the description of research.

The IRB can grant an alteration or waiver of the consent procedure in certain cases. The research has to be minimal risk, can't be practicably carried out without the alteration, and the alteration must not adversely affect the rights and welfare of the participants. In cases like deception, the researchers are often required to provide the participants additional information at the end of their participation.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117 (which includes conditions under which waivers or alterations may be granted).

   Documentation of informed consent is a general requirement for all studies, either requiring a signature on the full consent form or a short form confirming that the consent process was done orally. However, there are conditions under which the IRB can waive this requirement. The first condition is when breach of confidentiality is the primary risk of the research and the consent document is the only identifier. The second is when the research is minimal risk and involves no activities that would otherwise require consent documentation. Finally, waiver of documentation of consent can be granted if the participant or their legal representative is a member of a community for which signature is not the cultural norm. This waiver must be justified and include a method of documenting consent.

6. The research plan make adequate provisions for monitoring the data collected to ensure the safety of subjects, when more than minimal risk and when appropriate.
7. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.
8. When Limited Review is required by .104(d)(7), the IRB need not make the determinations above, and shall make the following determinations: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained; (ii) Broad consent is appropriately documented or waiver of documentation is appropriate; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
9. If some or all of the subjects are vulnerable populations likely to be susceptible to coercion or undue influence, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

These requirements are further detailed in 45 CFR 46, which the reviewers will utilize to determine if the conditions for approval are met. In addition to the regulations in 45 CFR 46, the IRB also has to consider other laws and regulations, for instance HIPAA and FERPA laws related to medical and educational records, respectively.

Potential Actions

During an Expedited Review, the reviewer may take the following actions: 1) Research approved; 2) Approved with requested modifications; 3)Requests for further information/modifications before a decision can be made; 4) Recommend that the proposal be reviewed by the full IRB.

During a Full Board Review, the Committee may take the following actions: 1) Approve as submitted; 2) Approve with minor modifications; 3) Table- Request further information/clarification and resubmission of the proposal; 4) Not approved as submitted/ Request Major Modifications for: a) Inadequately observing the Standards for Utilizing Human Subjects in Research; or b) Excessive use of specific groups or classes that may have recently participated in other research. A simple majority will constitute decision of action on the proposal, after a full deliberation of controverted issues. If minor revisions are required,

the committee will identify who will be responsible for confirming that the revisions meet the requirements. This may be the Primary Reviewer assigned, the Chair, or another designated reviewer. If major revisions are required, the protocol will be brought back to full board at a later meeting. This meeting will be assigned once the revisions have been received by the IRB Office.

Researchers will be notified, in writing, of the decided action and any requests for changes (see below). Researchers are notified of their responsibilities on the Signature and Assurance Form which must be submitted with the application. In addition, upon final approval, researchers are reminded of their responsibilities in the approval letter.

Requests for Changes

During any of the review procedures, the Chair, designated reviewer, or IRB Committee may request changes in order to bring the protocol in line with the policies set forth in this Handbook and 45 CFR 46. In such cases, the researchers will be notified in writing, typically via email and notation on the electronic protocol, of the requested changes. It is recommended that requested revisions be completed within 2 weeks of notification and resubmitted to the IRB Office. Revisions must be made directly to the reviewed application forms and in a distinguishable text, such that the reviewer can identify the changes.

For exempt determinations: Once the IRB Office has received the edits, the Chair, or designated reviewer, will determine if the revisions meet the requirements of this policy and 45 CFR 46.

For expedited reviews: Once the IRB Office has received the edits, the protocol will be returned to the reviewer for final determination. The reviewer is provided another 2 weeks for this final review.

For full board reviews:

Approved with Minor Revisions: If the study was approved with minor revisions, the committee has a set of small revisions requested that do not require a reconvening of the full board once those changes are made. The Chair, primary reviewer, or other designated reviewer will review the revisions once submitted, and if they are in line with what the committee has requested, the approval letter will be provided to the PI.

Tabled/Request for Further Information: The IRB reviewers strive to have all questions answered prior to convening the full board. However, if a question arises during the meeting, and the research team is not available to answer the question, the study may have to be tabled until a later meeting after the additional information has been gathered. In such cases, the request for more information will be made in writing, typically via email. The protocol will be assigned to a later meeting and the research team notified of the date and time.

A study may also be tabled if the IRB meeting fails to establish or maintain quorum. If quorum is not met at any point, all deliberations and voting must cease until quorum can be established or reestablished. The IRB strives to schedule meetings at times when quorum can be met and maintained, but if quorum is lost, the IRB may have to reschedule study discussions to a later meeting. In such cases, no further information may be required. The researchers will be notified in writing of the situation, as well as the rescheduled date and time.

Not approved as submitted/ Request Major Modifications: A study is not approved when it requires substantial revisions in order to meet the criteria for approval and/or the revisions requested by the committee will require a reconvening of the full board in order to review. When a study is not approved, the PI will receive in writing the reason(s) for the decision and a statement regarding any revisions that may be required or requested. The researcher(s) may choose to address said reasons with a

revision of the protocol and resubmit. The study will always go back to full board review in these cases. Upon resubmission, the researchers will be notified of the date and time of the meeting during which the protocol will be reconsidered. The IRB has the final determination on disallowing a particular study. Such a decision cannot be overturned by institutional officials.

In some cases, multiple revision iterations may be required if the revisions bring up new issues. No research may be initiated on any proposal that was returned for revisions or has not been approved by the IRB.

1.3.1(h) Establishing an Effective Date and Expiration Date

Effective Dates for new protocols will be the date on which the designated reviewer or IRB Committee confirms final approval to the IRB Office. If a protocol is approved without changes, the effective date is the date of the meeting or initial decision. If a study is approved with minor revisions, the effective date will be the date on which the designated reviewer confirms that the revisions are sufficient to meet the requirements of this policy and 45 CFR 46. For protocols that are tabled or require major revisions, the effective date will be the date of the meeting at which it is finally approved or if further revisions are required, the date upon which the designated reviewer confirms the revisions are sufficient to meet the requirements of this policy and 45 CFR 46.

The expiration date, when required, will be one year after the effective date, except when the IRB determines that a protocol must be reviewed more frequently than once per year. The Committee shall take this under consideration when 1) the protocol is more than minimal risk, and 2) potential risks are Serious and Likely. The Committee will consider the number of serious risks, the degree of severity, and the degree of likelihood when determining how frequently to review a high risk protocol. The greater these variables, the more frequently the IRB should review the protocol. The Committee may elect to review a protocol as often as necessary to ensure the protection and welfare of human subjects, including but not limited to every 6 months, quarterly, or monthly. Likewise, if the committee determines that risks are greater than originally anticipated, they may elect to increase the frequency of review. Such changes will be communicated, in writing, to the researchers.

Researchers will be notified in writing when their protocol is approved. This notification will include the expiration date for the study and the PI's responsibilities following approval.

1.3.1(i) Appeals

If the researcher(s) disagree with the actions of the IRB or the requested changes, they may file an appeal in writing to the IRB Office. The appeal should state the actions being disagreed with, reasons for the disagreement, and any proposed resolutions. The Chair will review the appeal and contact the researchers, if necessary, for further information. When appropriate, the Chair will communicate the request to the designated reviewer or full committee to determine a resolution. The final decision of the IRB will be communicated to the researchers in writing.

1.3.2 CONTINUING REVIEW

STATEMENT/PURPOSE

All studies that were previously approved by expedited or full board review and that continue beyond the expiration date assigned at approval must undergo continuing review until inactivated. As per 45 CFR 46, reviews must be completed, at minimum, once per year for on-going studies. Studies with a high degree of risk may be reviewed more frequently at the IRB's discretion.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by expedited or full board review. This policy also applies to any non-ACU researchers who received approval from ACU's IRB.

POLICIES & PROCEDURES

1.3.2(a) Principal Investigator Responsibilities

It is the Principal Investigator's responsibility to ensure that his/her ongoing studies do not expire or have a lapse in approval. Researchers are notified of this responsibility on the Assurance Form and the protocol approval letter.

1.3.2(b) Review Process, Potential Actions, and Requests for Changes

Review Process

The IRB Office will contact researchers approximately 60 days prior to expiration to notify them of the pending expiration and their responsibilities to file a Continuing Review Request. Researchers will be informed which documents to submit and the timeframe within which to submit them. The Continuing Review Form and any other applicable forms, as directed, should be submitted to the IRB Office approximately 30 days prior to the expiration date. Just as with the initial review, the IRB must determine that the same 9 criteria are met in order to approve a human subjects research study (See 1.3.1(g)).

The Continuing Review documents will be submitted to the expedited reviewer or full board within one week of receipt. Committee members will be informed of the pending expiration date and their right to access all study-related documents upon request.

If a reviewer feels that an expedited study requires continuing review, the burden of proof is on the reviewer to justify this need at the time of initial review.

Studies that were originally approved by full board will also undergo full board review at renewal unless one or more of the following conditions applies according to 45 CFR 46:

1) The research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects.
2) No subjects have been enrolled and no additional risks have been identified.
3) The remaining research activities are limited to data analysis.
4) The research is not conducted under an investigational new drug application or investigational device exemption and where the expedited categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Continuing reviews will be conducted in the same manner outlined in sections 1.2 and 1.3.1.

Potential Actions & Requests for Changes

Potential Actions and Requests for changes are the same as with an initial review:

During an Expedited Review (only when documented and required), the reviewer may take one of the following actions: 1) Research approved; 2) Approved with requested modifications; 3) Requests for further information/modifications before a decision can be made; 4) Recommend that the proposal be reviewed by the full IRB.

During a Full Board Review, the Committee may take the following actions: 1) Approve as submitted; 2) Approve with minor modifications; 3) Table: Request further information/clarification and resubmission of the proposal; 4) Not approved as submitted/ Request Major Modifications for: a) Inadequately observing the Standards for Utilizing Human Subjects in Research; or b) Excessive use of specific groups or classes that may have recently participated in other research.

Researchers will be notified, in writing, of the decided action and any requests for changes. The procedure for requesting changes is the same as that outlined in 1.3.1(g). When a Continuing Review is approved with modifications, the new expiration date will apply and the study may continue.

If the researchers disagree with the actions of the IRB or the requested changes, they may file an appeal in writing to the IRB Office in accordance with 1.3.1(i).

1.3.2(c) Determining Continuing Expiration Date

Continuing Review dates and new expiration dates are set in the same manner described in 1.3.1(h), except when the review occurs within 30 days of the original expiration date. In such cases, a fixed expiration date may be used. Researchers will be encouraged to submit Continuing Review requests approximately 30 days prior to expiration in order to maintain the fixed expiration date.

1.3.2(d) Lapses in Approval

If a study expires before being re-approved by the IRB, all research activity on that protocol must halt immediately. The only exception is if it is determined that it is in the best interests of the participants who are already enrolled to continue the activities of the study. The decision may initially be made by an investigator and perhaps by a physician, but as soon as possible, the Primary Investigator should submit a request that the IRB approves. The decision may be made by the IRB Chair or another member of the IRB. Such an instance still requires that the IRB approve a continuing review before new participants can be enrolled in the study.

Whenever lapses occur, the IRB should document the reason for the lapse and steps planned/taken to prevent future lapses. The IRB will notify the researchers when a study has expired with instruction to halt all activity on the protocol.

1.3.2(e) External Verification

45 CFR 46 requires that the institution have procedures for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review. This section outlines when such verification is required, the procedures for conducting such verification, and the actions that may be taken when such changes have been identified.

Situations in which external verification may be required include:

- Studies with unusual levels/types of risk
- Studies in which noncompliance is suspected or when concerns have been raised that material changes have been made without prior IRB approval
- Studies in which one or more researchers has a history of noncompliance
- Studies in which complaints have been made by participants or others
- During internal auditing of study-related records and procedures
- Any other situation in which the IRB Chair, Institutional Official, and/or convened IRB Full Board determine that external verification is necessary

An external verification process may be initiated by the Institutional Official, IRB Chair, or convening of the full IRB board, as defined in 1.2 of this policy. Any person may report suspicions/concerns of noncompliance to the Institutional Official or IRB Chair. Reports should detail what activity is suspected or any issue of concern and any evidence available. The confidentiality of the individual filing a report will be protected to the extent possible, and there will be no repercussions for filing a report in good faith. Upon receipt of such a report, the IRB Chair and Institutional Official will review the report and determine if external verification is needed.

If an external verification is initiated for any of the above reasons, the following process will be followed:

- The IRB Chair will convene a committee of at least 3 members. This committee may be comprised of IRB members, other ACU faculty or administrative staff, or non-ACU consultants. The committee shall not be comprised of any member of any of the researchers' departments or other individuals who may have a conflict of interest.
- The committee may review the IRB records for the affected study and the researchers' study records and may observe the conduct of study procedures (such as obtaining consent, running study trials, etc., to the extent that such observance will not materially affect the outcome of the study).
- The committee will determine if the study is being conducted in accordance will the filed IRB protocol and will prepare a report of these findings. The report shall be signed by a majority of those conducting the review and submitted to the IRB Chair.
- The IRB Chair and Institutional Official will review the report and determine if there have been any deviations from the IRB protocol.
- In the case of such deviations, a noncompliance report shall be filed (by the investigators, when possible; otherwise by the Chair) and appropriate actions taken in accordance with the policy on noncompliance (see 1.3.4).

1.3.3 AMENDMENTS TO EXISTING PROTOCOLS

STATEMENT/PURPOSE

For any study that was previously approved by expedited or full board review, any and all proposed changes to the study, no matter how minor (including changes to personnel, methodology, or consent forms), must receive prior approval by the IRB before being implemented (45 CFR #46.108(a)(3)) (except when the change was made to eliminate an apparent immediate hazard to the participants).

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by expedited or full board review.

POLICIES & PROCEDURES

1.3.3(a) Requirements for Review

It is the Principal Investigator's responsibility to ensure that their ongoing studies are conducted in accordance to the approved IRB protocol and that any proposed changes are submitted to the IRB **before** being implemented. Researchers are notified of this responsibility on the Assurance Form, as well as the protocol approval letter.

All proposed changes, no matter how minor, to active non-exempt human subjects research must be reviewed and approved. Changes that do not increase risk to participants, or seek to further minimize risk, can often be reviewed by an expedited procedure. Changes that significantly increase risk to subjects must go to full board review.

In cases in which changes were implemented prior to review, a noncompliance report should accompany the amendment request. In cases in which changes were implemented to eliminate an apparent immediate hazard to the participants, an unanticipated problem report should be filed in addition to the amendment form.

For studies previously determined to be non-research, non-human research, or exempt, amendments to the protocol do not have to be reviewed by the IRB unless the change increases risk or otherwise affects the study status. If the changes to the study may cause a classification change, such that it no longer qualifies for exemption, please submit the amendment for review.

Reviews for Amendments will follow the same policies and procedures as outlined in 1.3.1(e,f). Amendments submitted during the study period do not constitute a continuing review and will not affect or change the expiration date, except in circumstances in which the degree of risk is increased and the IRB determines that more frequent review is required.

If the researchers disagree with the actions of the IRB or the requested changes, they may file an appeal in writing to the IRB Office in accordance with 1.3.1(i).

1.3.3(b) Administrative Changes

Changes in, addition, or removal of personnel, address or contact changes, and other minor administrative changes may be requested and approved through the IRB Office. Such changes do not require expedited or full board reviews by IRB Committee members. The IRB Chair will review the requested change, ensure that the required training is met by all research team members, and issue the approval.

1.3.3(c) Minor Changes

Minor changes are defined as the addition of minimal risk procedures or change in procedures that does not increase risk category and/or the addition or change in procedures aimed at reducing risk. Such changes may be reviewed by the IRB Chair or a designated reviewer through the expedited procedure as defined in 1.3.1(e).

1.3.3(d) Major Changes

Major changes are defined as substantial changes to the study design, additional procedures that are more than minimal risk, and/or change in procedures that results in increased risk.

If the study was originally reviewed via the expedited procedure **AND** the proposed changes do not alter that status, then the amendment will be sent to an IRB member for expedited review via the procedures outlined in 1.3.1(e).

If the study was originally reviewed via full board or the proposed changes alter the status of the study such that it no longer qualifies for expedited status, then the proposed amendment will be reviewed by full board via the procedures outlined in 1.3.1(f).

1.3.4 UNANTICIPATED PROBLEMS AND NONCOMPLIANCE

STATEMENT/PURPOSE

If a researcher encounters an unexpected event that is probably related to the research and potentially increases the risk profile of the study or if there is a deviation from the approved protocol, no matter how small, the researcher must **report this** to the IRB in accordance with 45 CFR 46.108(a)(4).

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by expedited or full board review.

POLICIES & PROCEDURES

1.3.4(a) Requirements for Review

What Must Be Reviewed

It is the Principal Investigator's responsibility to ensure that their ongoing studies are conducted in accordance to the approved IRB protocol and that any unexpected events or deviations are reported to the IRB in accordance with this policy and 45 CFR 46. Researchers are notified of this responsibility on the Assurance Form, as well as the protocol approval letter.

If a researcher encounters an unexpected event that is probably related to the research and potentially increases the risk profile of the study, there is a complaint from a participant that suggests there may be an increased risk to the study, or there is a breach of confidentiality, the researcher must **report this** to the IRB. In addition, any deviation from the approved protocol, no matter how small, must be **reported** to the IRB. If the reported deviation is a permanent change, it must be accompanied by an **amendment** request form.

For studies previously determined to be non-research, non-human research, or exempt, unexpected events or deviations from the protocol do not have to be reviewed by the IRB **unless** 1) the unexpected event is a serious UPIRSOs (Unanticipated Problems Involving Risk to Subjects or Others), 2) the unexpected event suggests that the risk involved in the study is higher than anticipated and the study may no longer qualify for exemption, or 3) the protocol deviation increases risk or otherwise affects the study status. If any unexpected event or deviation may cause a classification change, such that the study no longer qualifies for exemption, please submit the report for review.

How Quickly Must it be Reported

Unanticipated problems that are serious UPIRSOs should be reported within 7 days of learning of the event, unless the UPIRSO is potentially lethal, then it should be reported within 2 days. Other unanticipated problems should be reported within 14 days of learning of the event. Deviations from the protocol/Noncompliance must be reported following the same timeline as **unanticipated problems**, with the exception that minor deviations that do not affect safety, increase risk, or violate rights and welfare of participants may be reported on the continuing review.

1.3.4(b) Procedure for Review

Reports of unexpected event or noncompliance will be initially received and reviewed by the IRB Chair. In cases of minor problems or deviations (defined as those that do not increase risk category) and in which it is not a situation of continuing noncompliance, the Chair may make a determination on the report and issue any requirements for compliance. The Chair may also consult with the Institutional Official and/or one or more IRB members in making this determination.

Reports involving serious events or deviations or cases of continuing noncompliance by a single researcher or group of researchers will be brought before the full IRB board. The Chair may consult with the Institutional Official and/or one or more IRB members in making this determination. Reports will be reviewed by full board as outlined in 1.2. Determinations and requirements for compliance will be determined by a majority vote of the members in attendance, having met quorum.

Any person may report suspicions/concerns of problems or noncompliance to the Institutional Official or IRB Chair. Reports should detail what activity is suspected or an issue of concern and any evidence available. The confidentiality of the individual filing a report will be protected to the extent possible, and there will be no repercussions for filing a report in good faith. Whistleblower protections are posted in the Employee Handbook (421). Upon receipt of such a report, the IRB Chair and Institutional Official will review the report and determine if external verification is needed. In such a case, external verification will be conducted as outlined in 1.3.2(e), and if a problem or noncompliance is found, a report will be filed and reviewed as outlined herein.

1.3.4(c) Potential Actions

Researchers should detail in their report any actions they have already taken to correct the problem. The IRB will review these reports to determine if these actions are sufficient. Otherwise, the IRB may require the following corrective actions:

1) A protocol amendment including but not limited to changes in methods/procedures, modification of inclusion/exclusion criteria, changes to safety monitoring plan
2) A revised Consent Form
3) Notification of the problem to current and/or past participants
4) Additional training
5) Requirement of external verification at Continuing Review
6) A temporary suspension on research activities until problems/concerns can be addressed
7) Permanent termination of study activities
8) Removal of a researcher's or group of researchers' privilege to conduct human subjects research at ACU (typically only in the case of serious misconduct or continued noncompliance)

Corrective actions shall be in line with the severity of the reported problem and the degree of risk involved. Such actions will always be taken in the interest of protecting the rights and welfare of the past, current,

and future participants. No study may be suspended or terminated unless approved by the majority of IRB members convened at a full board meeting in which a quorum is met. Removal of research privileges at ACU may be recommended by the IRB, but shall not be implemented without the approval of the Institutional Official and the Provost. Regardless of the required corrective actions, at any time, the IRB may determine that it is in the best interests of the participants who are already enrolled to continue the activities of the study.

Findings will be reported to the researchers in writing, including a statement for the reasons for any IRB actions (e.g., suspension or termination). If the researchers disagree with the actions of the IRB or the requirements for compliance, they may file an appeal in writing to the IRB Office in accordance with 1.3.1(i).

1.3.4(d) Institutional and External Reporting Requirements

45 CFR 46.108(a)(4) requires "prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval." In such cases, the Chair of the IRB will prepare a report to the ACU Institutional Official. In addition, when the study is funded by federal sources, falling under ACU's Federal Wide Assurance, the Chair and/or Official will also notify the funding agency and Office for Human Research Protections (OHRP) and prepare any necessary reports as required. In such cases, the agency or OHRP may investigate the report, as well as issue their own suggestions for corrective actions.

When the event is serious, a preliminary report will be submitted to OHRP, when required, within 7 days of being notified of the event. When the event is less serious, but still reportable, a preliminary or final report will be submitted within 2 weeks. A final report will be submitted when the review is complete.

When possible and appropriate, corrective actions will be implemented institution-wide in order to prevent future occurrences of similar incidents.

1.3.5 INACTIVATION AND RECORD STORAGE

STATEMENT/PURPOSE

All studies that were previously approved by expedited or full board review must be inactivated upon completion of the study in order to fulfill record-keeping requirements in 45 CFR 46.115(b).

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, with an active protocol that was previously approved by expedited or full board review.

POLICIES & PROCEDURES

1.3.5(a) When Can a Study Be Inactivated

Inactivation should be completed when enrollment is closed, data is no longer being collected, and analysis is complete or involves only de-identified data, in other words, when all human subjects activity has ceased. Note that if the study is federally funded or if you are the lead site on a multi-center trial with active sites, you must keep the protocol open and submit continuing reviews at least annually per your approval letter.

1.3.5(b) Record Storage

Data and records related to human subjects research must be kept by the research team and the IRB for at least 3 years after the date of inactivation of the study in accordance with 45 CFR 46.115(b). These records are auditable and must be produced in a "reasonable amount of time." Thus, ACU requires that a faculty member keep these records, in some form, on campus. This can be in electronic or paper form, as long as it is appropriately secure and available upon request.

IRB: 1.4 ADDITIONAL POLICIES RELATED TO HUMAN SUBJECTS RESEARCH

STATEMENT/PURPOSE

The policies in this section fall outside the purview of 45 CFR 46; however, they address important concerns or other regulatory requirements related to the use of human subjects in research and non-research studies.

APPLICABILITY

This policy applies to any ACU faculty, staff, students and organizations that are engaged in human subjects research, and in some cases non-research involving human participants, whether on-campus or off-campus, as part of their duties or studies at ACU. This policy also applies to any non-ACU researchers who wish to use ACU faculty, staff, students, or organizations as participants.

POLICIES & PROCEDURES

1.4.1 Non-Research Classifications using Human Participants

45 CFR 46 defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, projects that are not systematic investigations (such as case studies) or are not designed to contribute to generalizable knowledge (such as class projects, program evaluations, or community service) **may** not require IRB oversight. Project leaders who are unsure whether their study fits into this classification may submit an application form as outlined in 1.3.1 to receive a determination by the IRB Office. However, certain issues should be carefully considered when requesting a non-research determination.

Certain activities are specifically named as NOT research, including: Scholarly and journalistic activities, oral history, biography, literary criticism, journalism, historical analysis, certain public health surveillance activities, criminal justice & national security activities

The following activities should be determined on a case-by-case basis: quality assurance and program improvement activities. Some of these activities may still be research, depending on the intent and goals of the project.

45 CFR 46 states clearly that all human subjects research must receive IRB approval **before** beginning the research. Therefore, it is the policy of the ACU IRB not to provide retroactive approval of studies (i.e., approving a study after data collection has already begun/been completed). Project leaders should consider their long-term intentions and possibilities when deciding whether their project is for research or non-research purposes. If there is any possibility that you may wish to use your data for research purposes in the future, you should proceed with the appropriate IRB application. This policy applies to prospective

data collected for a study. It does not apply to information collected purely for clinical purposes which may or may not be reviewed retrospectively in the future.

Classroom Projects

A classroom project is defined as one in which the purpose is to teach content, not contribute to generalizable knowledge. These projects may be designed to teach research methodology, and so may look very much like research. Such projects do not require IRB approval; however, ACU does require that students follow the ethical guidelines in 45 CFR 46 in the conduct of such projects. Therefore, the following requirements must be met:

Data collected for class purposes 1) cannot be used for research purposes outside of the classroom, 2) must follow all ethical guidelines for human subjects research, and 3) must be destroyed at the end of the class. Course instructors are responsible for ensuring these standards are met. Again, this exemption should be used wisely. Retroactive approval will not be granted. Course instructors should guide students to an appropriate decision as to whether to apply for IRB approval or not. If the student thinks he/she may wish to use the data outside of the course, the appropriate IRB application should be prepared.

Because course instructors are responsible for ensuring that ethical standards are met, they should contact the IRB Office for ethical training requirements.

Quality Improvement/Program Evaluation

Quality Improvement and Program Evaluation studies may or may not be research. The intent of the study and how the project leaders intend to report the results are important. Guidance published by OHRP suggests that the intent to publish, alone, does not make a project research. Likewise, obtaining a non-research designation does not preclude one from ever publishing or reporting the results. However, the intention behind the report does matter. If the intention of the study is **only** to assess the program's ability to meet objectives and/or assess change meant to improve the specific program, then it may be non-research. Project leaders may report their process and findings (e.g., what we did and what we found). However, if the intention is to develop a program or process of change that may be generalizable and applied at other institutions or organizations, then this is research and should go through the IRB.

1.4.2 HIPAA and FERPA in Human Subjects Research

HIPAA

To collect data

Medical records include protected health information (PHI) that is covered by the Health Insurance Portability and Accountability Act (HIPAA). In general, accessing medical records for research purposes requires a consent to access and disclose PHI. Researchers should prepare a HIPAA/PHI consent to disclose form in addition to or as part of the research consent document. In limited cases, a waiver of such consent can be granted if the PHI disclosure represents no more than minimal risk and the research could not be conducted without the waiver. The researcher will need to justify this need and explain why obtaining consent to access and disclose PHI is not practicable. In all cases, researchers should take care to only look at and collect the minimum PHI necessary to achieve the goals of the research and any personal identifiers should be destroyed as soon as possible.

For participation selection

Sometimes we cannot know from whom to seek permission without accessing the records. In such cases, a waiver of consent requirement can be approved if the PHI disclosure represents no more than minimal risk and the research could not be conducted without the waiver. In all cases, researchers should take care to only look at and collect the minimum PHI necessary to achieve the goals of the research and any personal identifiers should be destroyed as soon as possible.

FERPA

Educational records include private information that is protected by the Family Educational Rights and Privacy Act. In general, accessing educational records for research purposes requires consent, even if the educational information is something the researcher typically has access to (such as a teacher/professor having access to their students' grades). FERPA requires a signed consent in all but very limited situations, even if you just need to view the information for participant selection. A signed disclosure authorization is required unless one of the following conditions are met: 1) You will only be viewing/collecting directory information; 2) The study is for, or on behalf of, the institution to either develop, validate, or administer predictive tests; administer student aid programs; or improve instruction; 3) The study involves only de-identified records, including the removal of all direct and indirect identifiers. Studies on behalf of the institution require a written agreement between the institution and the researcher which includes the stipulations outlined in 34 CFR §99.31(a)(6)(iii). In all other cases, researchers should prepare a FERPA consent to disclose form in addition to or as part of the research consent document.

Authorizations

Authorizations should include : 1) What is being accessed (what protected information will be viewed and/or collected), 2) Who is accessing the information and/or to whom is it being given, 3) Why– for what purpose, and 4) How Long– for how long will access to (or retaining of) identifiable protected information be required. Additionally, it is recommended to include: a statement of the right to refuse or revoke authorization, if any treatments or benefits are conditional on authorization, a statement regarding risk of accidental disclosure.

Ultimately, it is the responsibility of the institution releasing the protected data and the researchers accessing the data to ensure compliance and authorization for the release of protected information. However, ACU's IRB will review HIPAA/FERPA compliance issues and is granted the authority to provide waivers of authorization when the appropriate conditions are met.

1.4.3 Off-Campus Research by ACU Affiliates

ACU researchers who wish to conduct their studies at a different location (another business, organization, or institution) should seek the permission of that site prior to conducting their studies. Prior to approval, the ACU IRB will request at minimum that researchers contact the site and inquire about their approval process. In some cases, this may only require a verbal or written affirmation. In other cases, a contract or IRB review may be required. It is up to the site to determine what they require in order to grant ACU researchers access to their site and people/potential participants. It is the researcher's responsibility to ensure they are following the policies of that site.

Other academic institutions typically require that external researchers go through their IRB in some fashion. Therefore, ACU researchers conducting studies at other academic institutions will be required to contact the other institution's IRB prior to approval. This will ensure that the ACU researcher is following the policies required by the other institution. It is not sufficient to rely on the approval of a faculty

member or administrator at the institution, as these employees may not be fully aware of the institution's IRB policies on external research. The Chair of the IRB or Human Research Protections Officer will typically be familiar with such requirements.

1.4.4 External Research Requests by non-ACU Affiliates

If a researcher from another institution wishes to have access to ACU faculty, staff or students as potential participants -- whether ACU is engaged or not engaged in the research -- the project leader or principal investigator must submit the appropriate application to the IRB or a signed Authorization Agreement. If the PI has received IRB approval from another institution with whom he or she is affiliated, the IRB application and approval should be attached to the email submission of the completed ACU IRB Request or IRB Authorization Agreement. Generally, Authorization Agreements are preferred when the affiliated institution has an approved FWA number with the OHRP. Authorization Agreements should be signed by officials at each institution who have the authority to enter into such agreements. At ACU, Authorization Agreement requests are reviewed by the Chair of the IRB and submitted to the Institutional Official for signature.

ACU does not guarantee external researchers that access will be granted. Each request is addressed on a case-by-case basis depending on the topic of the research; whether participation by ACU is in the best interest of the institution and our faculty, staff, and students; whether an Authorization Agreement can be made and/or the IRB has sufficient resources to consider an external review.