PREFACE

Institutional Authority and Role of the University of Central Oklahoma Institutional Review Board (UCO IRB)

The UCO IRB was established in 2000 under the authority of the Provost to be administered by the Dean of the Graduate College. In 2008, the UCO IRB became a part of the Office of Research and Grants, and beginning July 2010, it became part of the Office of Research Compliance (ORC), a freestanding unit of Academic Affairs. In October of 2014, the ORC became part of the Office of Research and Grants, which changed to the Office of Research and Sponsored Programs in 2015. In 2015, the ORC changed to the Office of Research Integrity and Compliance (ORIC). The Provost has granted the UCO IRB the authority and responsibility to meet and administer the federal regulations as set forth by the US Department of Health and Human Services as specified in the Federal Register (45 CFR 46) in alignment with the procedures specified by the Office of Human Research Protection (OHRP). UCO was granted Federal Wide Assurance (FWA) by the U.S. Department of Health and Human Services (DHHS) Office of Human Research Protections on 4/19/2011, FWA00017185.

The Provost has empowered the UCO IRB with the protection of human subjects involved in research activities conducted at or sponsored by UCO, including research activities (a) by faculty, staff, and students, (b) performed in UCO facilities, or (c) otherwise supported by University resources or facilities which are under the control of UCO officials. The principles that govern the UCO IRB are those set forth in the Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979).

Although the UCO IRB obtains its institutional authority from the Provost and communicates the results of any investigation, sanctions, suspension or termination of approval, or other serious or continuing noncompliance by investigator(s), no administrative official or other individual may intervene in the proceedings or rulings of the IRB.

The UCO IRB has ties to other entities within the university and communicates the general operations of the IRB to those other entities. The Manager of Research Integrity and Compliance is a member of the Research Advisory Council (RAC) and the Undergraduate Research and Creative Activities Team (URCAT).

The following abbreviations are used throughout the Manual:

IRB-Institutional Review Board
Application- UCO IRB Application for Review of Human Subjects Research
Chair- UCO Institutional Review Board Chair
GP&P- UCO Institutional Review Board *Guidelines, Policies and Procedures for the Use of Human Subjects in Research Activities* (located under "IRB Policies" on the ORIC website)
PI /Co-PI-Principal Investigator/Co-Principal Investigator

Staff- Staff of Office of Research Integrity and Compliance
COI-Conflict of Interest
SOP-Standard Operating Procedure
ORIC-Office of Research Integrity and Compliance
RAC-Research Advisory Council

Links referenced throughout the Manual:

Office of Research Integrity and Compliance (ORIC) website:
https://www.uco.edu/academic-affairs/office-research-integrity-compliance/

The Belmont Report:
https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Federal Guidelines:
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#

UCO SOP MANUAL
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RC 800: Reporting Non-Compliance
801 Reports of Non-Compliance

DD 900: Data Disposition
901 Final Data Disposition

SOP 101
Training

1.0 POLICY

All members of the IRB are required to undergo training in Protecting Human Participants in Research consistent with federal regulations, Oklahoma state law, UCO institutional policies, and all requirements for IRB membership. The training shall consist of education in UCO IRB policies and procedures and completion of the basic online course in Protecting Human Participants in Research, with recertification to take place every three (3) years.
IRB members will not be allowed to review research proposals nor vote on IRB matters, nor will potential investigator(s) be allowed to conduct or assist in research until documentation of the completion of all required training has been submitted and approved.

2.0 RESPONSIBILITIES

2.1 The Chair shall provide training for new IRB members.
2.2 The Chair shall provide continuing education for IRB members.
2.3 Each IRB member shall maintain current (every 3 years) Protecting Human Participants in Research certification.
2.4 The Manager of Research Integrity and Compliance shall provide training for the university community.
2.5 The ORIC Office will verify that all investigator(s) and research team members working with human subjects have current Protecting Human Participants in Research certification.
2.6 The Chair will attend external professional IRB training as it is necessary.

3.0 PROCEDURES

3.1 Board members will be given initial and continuing education on HHS regulations.

3.1.1 Initial education will be given to new members as they join the IRB.
3.1.2 At least annually, the Chair will provide continuing educational updates at regularly scheduled or special board meetings.
3.1.3 As specific issues are raised, the Chair will provide current regulations and materials to IRB members.
3.1.4 Each member will be given an IRB Member Handbook.
3.1.5 Copies of the federal regulations will be made available to each member.
3.1.6 Members will have access to books and manuals kept in the IRB Office.

3.2 IRB training sessions will be offered to the university community.

3.2.1 Campus-wide training sessions will be offered at least annually.
3.2.2 Individual departments or colleges will be encouraged to request more targeted training sessions.

3.3 IRB members are required to complete the online Protecting Human Participants in Research training and send a copy of their certificate to the IRB Office.

3.3.1 The office staff will keep a record of the current status of each member and notify them as new certification is needed (after 3 years). The UCO IRB will accept training completions and requirements of other assured entities that are collaborating with UCO researchers.

3.4 All Continuing Review applications will be checked to assure that certification is current.

4.0 REFERENCES

Department of Health and Human Services (DHHS) Human Subjects Research regulations as specified in 45 CFR 46.107 and 21 CFR 56.107.

5.0 APPENDIX

ORIC webpage

SOP 102
Maintenance of SOPs

1.0 POLICY

All operations and actions shall proceed according to approved policies defining and regulating all aspects of IRB operations at UCO. These policies must clearly detail requirements for IRB operations and membership, types of research to be submitted for IRB review, procedures for conducting IRB review, responsibilities of investigator(s) conducting and/or assisting in research, and the utilization, security, and disposition of data.

Developing and maintaining current SOPs shall be the responsibility of the UCO IRB Chair, and other such persons appointed for the purpose. These policies must be submitted for annual review to ensure continuing compliance with applicable federal policies, laws, and regulations, and with UCO policies regarding UCO IRB operations.

2.0 RESPONSIBILITIES

2.1 The Chair and IRB staff shall review all SOPs annually.
2.2 The Chair shall develop new SOPs as needed.
2.3 The IRB shall approve all new SOPs prior to implementation.
2.4 The Chair shall provide the most current, approved version of the UCO SOP Manual to the university community and the Provost.

3.0 PROCEDURES

3.1 The Chair and Manager of Research Integrity and Compliance will review all SOPs annually to insure alignment of current procedures and policies.
3.2 The Chair and Manager of Research Integrity and Compliance will review and update individual SOPs as revisions are needed.

3.2.1 Proposed revisions will be placed on the agenda for the next IRB meeting.
3.2.2 Copies of the revised SOPs will be sent to IRB members five (5) working days in advance of the meeting.

3.3 The IRB will review and approve the initial and all subsequent changes to the UCO SOP Manual.
3.4 An updated copy of the UCO SOP Manual will be available on the ORIC website and in the IRB Office.
3.5 An updated copy of the UCO SOP Manual will be provided to the Provost annually.

4.0 REFERENCES

45 CFR 46.103 (b).

5.0 APPENDIX

ORIC webpage
UCO SOP Manual

SOP 103
Conflicts of Interest

1.0 POLICY

A conflict of interest (COI) may occur when an investigator or IRB member may have a financial, fiduciary, or other interest, which has the possibility of yielding a tangible personal and/or professional benefit having the potential to exert an improper influence on the individual's professional judgment, introducing an unethical bias into the exercise of their roles as reviewers or investigator(s).

2.0 RESPONSIBILITIES

2.1 IRB members must declare any possible or real COI for matters brought before the IRB as soon as it becomes known.

2.2 IRB members acting as assistant to the Chair shall report any potential or real COI on any IRB application they have been asked to review.

2.3 The Chair will not act on any IRB business where there is a possible or real COI.

2.4 Investigator(s) must declare any real or potential conflicts of interest related to the protection of human subjects for their project in the IRB application as well as notify participants on the informed consent.

3.0 PROCEDURES

3.1 IRB members will recuse themselves for discussion and voting on matters which they have a COI. IRB members will leave a meeting under the following circumstances:

1) Presentation of an application on which the member is named as an investigator or research team member
2) Discussion of an application from a student for whom the member serves as a mentor, chair, or thesis committee member
3) Discussion and voting on violations or non-compliance issues involving colleagues with whom the IRB member has a relationship that would make it difficult to provide objective judgment

3.2 The Chair will not review or make decisions on applications on which the Chair is a named investigator or research team member.

3.2.1 The application will be reviewed and processed by one of the IRB members serving as an Assistant Chair [See SOP 202].

3.2.2 An IRB member will be selected by the IRB to carry out investigations of alleged IRB violations in which the Chair might have a role or COI (Chair must be absent).

3.2.3 A current Assistant Chair shall serve as acting Chair during the proceedings related to the above.

3.3 An Assistant Chair shall notify the Chair and recuse themselves from reviewing an application in which they might have a role or COI as soon as it becomes known.

3.4 Investigator(s) must declare any real or perceived COI regarding their financial interests at the time of application.

3.4.1 Any COI should be stated in the IRB Application or accompanying email at the time of submission of the IRB Application.

3.4.2 Subjects need to be informed of any COI in the consent document.

4.0 REFERENCES

42 CFR 50 Subpart F (regarding grants)
45 CFR 46.107(e)
45 CFR 94 (regarding contracts)

5.0 APPENDIX

SOP 202

SOP 104
Activities that Require IRB Review

1.0 POLICY

The UCO IRB is established and empowered by the Provost to provide protection for research involving human subjects. The UCO IRB operates in accordance with the Belmont Report and all current federal regulations as set forth by the Department of Health and Human Services (DHHS) for the protection of the rights and welfare of human subjects. All research activities involving human subjects conducted at or sponsored by the University of Central Oklahoma, including research activities (a) by faculty, staff, and students, (b) performed in UCO facilities, or (c) otherwise supported by University resources or facilities which are under the control of UCO officials is subject to these regulations. This includes both sponsored and unsponsored research activities at the University of Central Oklahoma.

Research is defined as "*any systematic investigation designed to develop or contribute to generalizable knowledge.*" Activities which meet this definition constitute "research" whether or not they are regularly called "development," "demonstration," "instruction," or another term.

A human subject is defined as "*a living individual about whom an investigator conducting research obtains either data through intervention or interaction with the individual, or identifiable private information.*" An intervention can be both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

2.0 RESPONSIBILITIES

2.1 The Provost shall grant authority to the IRB to establish a review process for all research activities involving human subjects in accordance with federal regulations.

2.2 The Provost shall provide the IRB with the resources necessary to fulfill their duties.

2.3 The IRB shall review all research-related activities to determine which are exempt and which require IRB approval.

2.4 The Chair shall provide assistance to investigator(s) regarding the documentation necessary to make a determination regarding review.

3.0 PROCEDURES

3.1 The Provost shall provide assurance to DHHS of the intention of the university to establish an IRB in accordance with federal regulations and the principles of the Belmont Report.

3.2 The Provost shall communicate to the university community the necessity for IRB oversight.

3.3 The IRB Office will publish the Policies and Standard Operating Procedures online to assist investigator(s) with the process.

3.4 The Chair will provide assistance and information to the university community about the process of IRB review.

3.4.1 The Manager of Research Integrity and Compliance will hold an educational presentation no less than annually, open to the university community to advise investigator(s) about the IRB process.

3.4.2 The Manager of Research Integrity and Compliance will be available to meet individually or in small groups with investigator(s) for advice about the IRB process as requested.

4.0 REFERENCES

45 CFR 46.109-111

5.0 APPENDIX

The Belmont Report
Appendix D

SOP 105
Personnel Management

1.0 POLICY

The university is required to provide the IRB with sufficient resources and support to carry out its duties. It will be the responsibility of the Office of Research and Sponsored Programs to hire and supervise the administrative personnel necessary for the daily operations of the IRB.

2.0 RESPONSIBILITIES

2.1 The Office of Research and Sponsored Programs shall hire a Manager of Research Integrity and Compliance and a Coordinator to assist with daily operations of the IRB Office.
2.2 The Manager of Research Integrity and Compliance shall be responsible for managing the IRB Office.
2.3 The Coordinator shall be responsible for the reception, communication, and documentation of the IRB Office.
2.4 The Chair will appoint one or more IRB members to serve as an Assistant Chair.

3.0 PROCEDURES

3.1 The Office of Research and Sponsored Programs shall follow university regulations regarding employment and evaluation of IRB personnel.
3.2 The Office of Research and Sponsored Programs shall provide training and supervision to the administrative staff to complete their duties.
3.3 The Coordinator shall be responsible for intake, data entry, initial review of applications to insure completeness, and other record keeping as required.

4.0 REFERENCES

45 CFR 46.103(b)(2)

SOP 201
Composition of Board

1.0 POLICY

The composition of the UCO IRB is designed to meet regulatory requirements and to ensure the complete review of all projects submitted. The IRB will be composed of no less than eight (8) regular members, including a legal, community, and scientific representative with at least one member having no affiliation with the university (alternates will be in place for each required representation), and the Chair of the IRB. The Assistant Vice-President of the Office of Research and Sponsored Programs and Manager of the Office of Research Integrity and Compliance shall serve as *ex-officio members*, with non-voting status to provide administrative support and guidance in carrying out its duties.

The Chair shall be selected and appointed by the Provost for an indefinite period. The Chair serves at the pleasure of the Provost, and can be removed by such for violations of or failure to uphold the policies and procedures or failure to carry out the necessary duties of the IRB.

Members shall be appointed by the Provost, on the recommendation of the Chair. The length of the membership will continue as long as the individual is willing to serve, but be no less than three years. Appointments will balance representation across colleges and expertise in matters related to IRB issues.

When necessary or desired, the Chair of the IRB may determine one or more advisors with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals shall not have the right to vote with the IRB membership.

At the discretion of the Chair, visitors may be invited to attend IRB meetings to witness or discuss the general business of the IRB, but may not be present for deliberations or voting on issues regarding specific submissions, proposals, investigators, or study participants.

2.0 RESPONSIBILITIES

2.1 The Chair shall insure that the composition of the IRB meets regulatory requirements.

2.2 The Chair shall solicit names of interested, qualified individuals for openings on the IRB as needed.

2.3 The Chair shall recommend to the Provost individuals to serve on the IRB as openings become available.

2.4 An IRB member shall notify the Chair at least 30 days in advance if they intend to step down from the IRB.

2.5 The Chair shall notify all members of the IRB in advance of a scheduled meeting of the identity of any visitor and reasons for their visit, and to insure the confidentiality of IRB proceedings.

3.0 PROCEDURES

3.1 Upon authorization of the Provost, the Chair shall notify the member of their appointment to the IRB.

3.2 The Manager of Research Integrity and Compliance shall report the IRB composition to the appropriate federal authorities.

3.3 The Chair shall contact IRB members at the end of their term to determine their continuing desire to serve.

3.3.1 Prior to the start of the academic year in which a member's term ends, the member will be contacted by email to inquire of their desire to continue service on the IRB.

3.4 A member who wishes to step down from the IRB shall notify the Chair in writing.

3.5 The Chair will report any violation of IRB policies or breach of ethics that would compromise the integrity of the IRB process to the Provost as soon as determined.

3.6 After an investigation by the Chair, the member shall either be cleared or required to step down from the IRB.

4.0 REFERENCES

45 CFR 46.107

SOP 202
Management of Board

1.0 POLICY

The UCO IRB is a university standing committee that reviews, approves, and has oversight of human research for the purpose of protecting the rights and welfare of the subjects. The IRB operates in alignment with the Office for Human Research Protections under the Department of Health and Human Services and under the authority of the UCO Provost. It is managed by the Office of Research Integrity and Compliance. Daily operations are managed by the Manager of Research Integrity and Compliance and IRB Chair.

2.0 RESPONSIBILITIES

2.1 The Chair shall inform the IRB of all activities of substance on a monthly basis.

2.2 The Chair shall select an IRB member with expertise in a particular area to be the secondary reviewer for the applications to be presented by the Chair or Assistant Chair at the meeting.

2.3 Each IRB member agrees to serve as an Assistant Chair for two semesters during their three year tenure on the IRB.

2.4 The Chair shall appoint an IRB member to serve as Interim Chair if the Chair will be away from the university for more than five (5) working days.

2.5 Each IRB member and IRB staff will sign a Confidentiality Agreement.

3.0 PROCEDURES

3.1 Matters of substance will be placed on the agenda of the next regularly scheduled meeting of the IRB for discussion. [See SOP 303]

3.1.1 This will include a report of the number of exempt and expedited applications, and any other issues of importance.

3.2 Assistant Chair will review applications and make recommendations to the Chair for a minimum of two semesters during their tenure on the IRB.

3.2.1 Upon receipt of those reviews, the Chair will compile and forward a letter of action to the investigator(s).

3.2.2 The assistant reviewers will receive feedback about the intermediate and final disposition of the applications they review.

3.3 Absences of the Chair lasting more than five (5) working days will be covered by a designated IRB member selected by the Chair.

3.3.1 The designated Interim Chair shall perform all of the duties of the Chair with the cooperation and consultation of the IRB staff.

4.0 REFERENCES

45 CFR 46.115
45 CFR 46.103

5.0 APPENDIX

Pledge of Confidentiality
SOP 303

SOP 301
IRB Submission Requirements

1.0 POLICY

The IRB shall review all research involving human subjects conducted at or sponsored by UCO, including activities undertaken (a) by any UCO faculty, staff, and students, (b) performed in UCO facilities, or (c) otherwise supported directly or indirectly by University resources or facilities which are under the control of UCO officials, except for institutional assessment activities.
The procedures and safeguards herein shall apply to all sponsored and unsponsored research activities of UCO.

2.0 RESPONSIBILITIES

2.1 Investigator(s) are responsible for submitting information to the IRB of their intent to conduct research activities involving human subjects with sufficient time prior to starting the research to enable the IRB to make a determination of the required procedures and to process the paperwork.

2.2 The Chair will provide assistance to investigator(s) for determining the necessity for and completion of required paperwork.

2.3 Upon receipt, IRB Office staff will conduct a pre-review of submission and either request more information from the researcher to make a complete submission or forward the submission to the Chair.

3.0 PROCEDURES

3.1 All faculty, staff, or students planning on engaging in research involving human subjects will contact the IRB Chair of their intent, in advance of beginning those activities, in one of the following ways:

1) Complete the electronic IRB Application (available at ORIC website) and submit through the IRB managing software

    a) Letter or email authorization to recruit from groups, businesses, or organizations
    b) Copies of all surveys, tests, or other data collection instruments
    c) Protocol or description of research activities
    d) Informed Consent Form, Information Sheet, Assent Form, or Waiver of Consent (Waiver of Documentation if needed)
    e) Copies of current (within 3 years for all UCO research members) online Protecting Human Participants in Research training

certification for all investigator(s) and team personnel working directly with subjects or identifiable data

2) Contact the IRB Chair or Manager of the Office of Research Integrity and Compliance by phone, email, or in person with specific questions regarding the necessity for IRB approval

3.2 **Determinations:** If a researcher believes that his or her project is possibly not human subjects research he or she can submit a determination checklist. The Manager of Research Integrity and Compliance can assist investigator(s) considering whether efforts might be considered research with human subjects.

3.2.2 The Chair will provide individual assistance with completion of paperwork.

3.2.2.1 Upon receipt, the Chair will review a Checklist and determine if the effort is human subjects research and calls for completion of an IRB Application. If it determined not to be human subjects research the researcher will receive a determination letter.

3.2.2.2 If requested, the Chair will meet or talk by phone with investigator(s) to answer questions regarding the necessity for IRB approval for a project or assistance in completion of an application.

3.3 The IRB Office staff will check submissions for required attachments and ensure that the submission is complete (if not complete the submission will be returned to the researcher to address deficiencies) and assign a sequential number to the submission.

4.0 REFERENCES

45 CFR 46.109

5.0 APPENDIX

Appendix C

SOP 302
Determination and Documentation of Exempt Research

1.0 POLICY

Any research project which is conducted with an expectation that the results of the project will be made public through any type of publication, including a thesis or dissertation, or presentation at a meeting, must be reviewed and approved by the IRB before the project can begin. Under Federal regulations (45 CFR 46.101(b)), there are three categories of review of research projects involving human subjects: exempt, expedited, and full board review.

Exempt research refers to specific categories of activity that meet the definition of research but may be exempt from full board review. **This determination must be made by the IRB after review of the research proposal.**

Such research must be certified as exempt, but exempting an activity from review does not absolve the investigator(s) from ensuring that the welfare of subjects is protected and that methods used to gain subject consent and provide information are appropriate. Exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.

Criteria for exempt research are as follows:

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as on:

    a) regular and special education instructional strategies, or
    b) the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless**:

    a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
    b) any disclosure of subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or

observation of public behavior that is not exempt under the above paragraph (1.2), **if**:

a) The human subjects are elected or appointed public officials or candidates for public office **or,**
b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, **if** these sources are publicly available **or if** the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

a) public benefit or service programs
b) procedures for obtaining benefits or services under those programs,
c) possible changes in or alternatives to those programs or procedures, **or**
d) possible changes in methods or levels of payment for benefits or services under those programs

6) Taste and food quality evaluation and consumer acceptance studies, **if**:

a) Wholesome foods without additives are consumed **or,**
b) A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2.0 RESPONSIBILITIES

2.1 The PI must complete and submit an Application for IRB approval. [See SOP 301]
2.2 The Chair will review and determine the category of the review of research activities.
2.3 The Chair will notify the PI of any stipulations that need correcting or of the approval of the project.

2.4 The Chair will certify to the PI in writing that the research is exempt and provide the criteria number for the determination.
2.5 It is the responsibility of the researcher to inform the IRB of any modifications to the study which may move it from exempt status.
2.6 The PI will notify the ORIC of closure of the project file.

3.0 PROCEDURES

3.1 The PI shall complete either an IRB Application or the IRB Checklist and consult with the IRB Chair prior to beginning the project.

3.1.1 Sufficient time must be given to the IRB to review and approve research projects.
3.1.2 The IRB Checklist is not a substitute for the IRB Application but is designed to identify those projects that involve human subjects' research. If a positive determination is made, an application and approval is required. If a negative determination is made, no further IRB action is needed. Checklists are kept on file.

3.2 The Chair may assign the application to the appropriate individuals for review.
3.3 The Chair will notify the PI by email of any stipulations that need additional information or of approval.

3.3.1 Final email approvals will be followed by a letter via campus mail.
3.3.2 Approved, stamped copies of the Informed Consent Forms will be sent to the PI by campus mail.

3.4 The Chair will certify to the PI in writing those projects exempt from review and indicate the criteria number.
3.5 The PI will complete an application if changes necessitate.
3.6 The PI will notify the ORIC and complete a Closure Form when the project is complete.

4.0 REFERENCES

45 CFR 46.101

5.0 APPENDIX

Appendix C
IRB Checklist
IRB Closure Form
SOP 301

SOP 303
IRB Meeting Administration and Communication

1.0 POLICY

The IRB shall review and have authority to approve, approve conditionally requesting the completion of required changes to secure approval, defer, or reject research activities involving human subjects which are conducted at or sponsored by UCO, including research activities (a) performed by UCO faculty, staff, and students, (b) performed in the University of Central Oklahoma facilities, or (c) otherwise supported by University resources which are under the control of UCO officials.

The IRB will convene for regularly scheduled monthly meetings during the academic semesters and as needed during the summer. The IRB will review all applications requiring full board review and any amendments or continuing review requests from previous full board review approvals.

IRB members will be provided with relevant materials necessary to conduct informed discussions and votes. The deliberations of the IRB will be recorded and disbursed to members, who will have an opportunity to review the minutes of the previous meeting and to make corrections as needed. All minutes of meetings, discussion, deliberations of the IRB will remain confidential.

2.0 RESPONSIBILITIES

2.1 The Chair shall set the time and date of IRB meetings and call special meetings as needed.

2.2 The Chair will determine the category of review and forward materials to all board members for those applications deemed to need full board review.

2.3 The Chair will send out an agenda for the meeting no later than 48 hours prior to the meeting.

2.4 The Primary Reviewer and Secondary Reviewer will provide a summary of each application to be discussed and voted on. [See SOP 202]

2.5 IRB staff will attend and record minutes of the meeting and distribute to members of the IRB.

3.0 PROCEDURES

3.1 A monthly meeting time and day will be established each semester to accommodate members' schedules.

3.1.1 Members will be notified no later than one week in advance of upcoming meetings.

3.2 Electronic copies of documents and supportive materials will be available to members no later than 48 hours in advance of the meeting, preferably one week in advance of the meeting.

3.3 The agenda will be sent to each member no later than 48 hours in advance of the meeting, preferably one week in advance of the meeting.

3.4 The UCO IRB requires five voting members present, one of which must be a community member, for a quorum.

3.5 Each application to be considered by the IRB at the meeting, will be presented by the primary and secondary reviewer, who will provide a summary of the application.

3.5.1 Primary Reviewers can only be either the Chair or Assistant Chair

3.5.2 Members shall discuss and vote on one of the following actions:

1) **approve** as extant when no changes are needed
2) **conditional approval** where the Chair is authorized to request numerous stipulations and approve when all are met
3) **defer** in those cases where extensive revisions are needed and set another date for full board review
4) **reject** in those cases where no amount of modification would make an application approvable.

3.5.3 Actions on an application require a majority vote of the board, defined as "Yes" votes by simple majority of the number of voting members present. Abstentions shall be counted as "Present", constituting neither "Yes" or "No" votes. Failure to obtain a majority vote shall automatically defer an application until the next board meeting.

3.6 IRB staff will type and send minutes to Chair.

3.6.1 Once proofed, minutes are sent to each member.

3.6.2 At the following meeting, corrections are solicited.

3.6.3 Final copies are kept by the Chair and IRB staff.

4.0 REFERENCES

45 CFR 46.111

5.0 APPENDIX

SOP 202

SOP 401
Policies and Procedures for Initial IRB Application Review

1.0 POLICY

The IRB review shall judge whether all submissions are in compliance with federal regulations, and will assess in particular issues involving risk/ benefit, informed consent, procedures used to identify and select potential subjects, including members of vulnerable populations, privacy and confidentiality, and conflicts of interest.

2.0 RESPONSIBILITIES

2.1 Each individual PI shall submit an application to the Office of Research Integrity and Compliance and have it approved prior to beginning any research related activities.
2.2 IRB staff will process the application and deliver to the Chair.
2.3 The Chair will review to determine the category of review required (exempt, expedited, full board).
2.4 The Chair will select reviewers of the application.
2.5 The Chair will communicate the outcome of the reviews and final approval to the investigator(s).

3.0 PROCEDURES

3.1 The PI shall complete and submit the IRB application.
3.2 IRB Office staff will log the application into the database and forward to the Chair and other designated reviewers.

3.2.1 Each application is time stamped.
3.2.2 Each application is given a consecutive number.
3.2.3 IRB Office staff will keep and update an electronic database for new submissions, and paper copy file system of all previous applications and related documentation and communications until it is no longer necessary to maintain them.

3.3 The Chair will make a preliminary review to determine if the project is exempt, requires expedited, or full board review.

3.3.1 For Exempt Projects, see Appendix C, SOP 302.
3.3.2 For Expedited Projects, see Appendix C, SOP 302.
3.3.3 All other projects will receive full IRB Board review. Those include research involving vulnerable subject populations (depending on the

intervention) and or all studies that are more than minimal risk to subjects. Minimal risk is defined as "*the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or the performance of routine physical, psychological examinations or tests*" [45CFR46.102(i)]

3.4 The IRB Office will verify that the application is complete, including the following required documentation:

1) Letter or email authorization to recruit from groups, businesses, or organizations
2) Copies of all surveys, tests, or other data collection instruments
3) UCO Office of Information Technology approval for on-line research activities that require it
4) Informed Consent Form, Information Sheet, or Waiver of Consent (Waiver of Documentation, if needed)
5) Documentation of completion of training in Protecting Human Participants in Research.

3.5 Reviewers will review and send written comments to the IRB Office who will compile.

3.6 The Chair will communicate with investigator(s) about approval or necessary changes. [See SOP 601]

3.6.1 Initial communications with investigator(s) are via email.

3.6.2 Final approvals are communicated by email and followed with a signed letter and stamped, approved ICF or Assent Forms.

3.6.3 Investigator(s) whose applications require full board review are notified and invited to attend the IRB meeting to answer questions.

4.0 REFERENCES

45 CFR 46.109
21 CFR 56.109

5.0 APPENDIX

Appendix C
SOP 302
SOP 601

SOP 402
Policies and Procedures for Continuing Review

1.0 POLICY

The IRB will conduct continuing review of all research activities that were approved at a Full Board meeting and do not fit within the criteria of Expedited Review. Intervals of review will be specified by the IRB upon initial approval, but at least by the one year anniversary of initial approval. At the point of continuing review, it is the responsibility of the Primary Investigator to submit all relevant documentation consistent with initial approval, in addition to the request for continuance. If approval expires before continuing review is approved, all research activities must cease until approval is reinstated. Considerations regarding continuing review will include assessment of success in recruitment, preliminary research results, evaluation of methods and procedures, and determinations regarding compliance with federal and UCO policies about privacy, risks, data security, and consent.

2.0 RESPONSIBILITIES

2.1 The IRB Office will notify each investigator at least 60 days and 30 days prior to the anniversary date of approval that a Continuing Review Form or Closure Request Form must be completed and returned at least two weeks prior to the anniversary date. Studies not approved by the anniversary date must suspend all data collection activities.

2.2 Studies that have expired and no Continuing Review Form has been submitted may be closed administratively after 30 days.

2.3 Investigator(s) must notify the IRB in writing or by email of the status of their project and the need to continue or close the project by the anniversary date.

2.4 The IRB Chair will review the documents and communicate with investigator(s) by email regarding approval of their request, the need for further information or documents, or the scheduled presentation at the next IRB meeting.

2.5 IRB Office staff will update files and database.

2.6 Failure to comply will result in activation of procedures for non-compliance. [See SOP 404]

3.0 PROCEDURES

3.1 Investigator(s) will complete and submit the necessary form by the anniversary date.

3.1.1 If the project is still active, they will complete the IRB Continuing Review Form.

3.1.2 If the project has been completed, they will complete a Closure Request Form.

3.2 The IRB Chair will schedule a time at the next IRB meeting to discuss and vote.

4.0 REFERENCES

45 CFR 46.109(e)
21 CFR 56.109(f)

5.0 APPENDIX

Closure Request Form
Continuing Review Form
SOP 404

SOP 403
Policies and Procedures for Amendments to an Approved IRB Application

1.0 POLICY

Any changes to an approved IRB application require approval before implementation. Changes may not be implemented without the prior review and approval of the IRB, except where there may be risks or hazards too immediate to secure IRB approval. In the latter case, the PI must submit a written report explaining the immediacy of the hazard and justifying the deviation from the IRB-approved protocol. When it is determined that an amendment to an approved IRB is necessary, the PI shall submit a form requesting an amendment to an approved IRB to the Chair of the IRB. It is the responsibility to the Primary Investigator to provide all relevant information justifying the necessity for the amendment and documentation.
Minor changes may be submitted for expedited review. Amendments that do not meet the criteria for expedited review must be reviewed by a convened IRB. Amendments to an approved IRB application usually do not affect the approved dates of the research project unless the amendment specifically requests an extension.

2.0 RESPONSIBILITIES

2.1 The PI shall complete and submit Amendment Form to the IRB office.
2.2 The Chair will review and determine the type of review necessary.
2.3 The IRB Chair shall notify the PI of approval or need for additional documentation.
2.4 IRB staff will update records to reflect the amendment.

3.0 PROCEDURES

3.1 The PI shall provide justification and documentation for all changes including:

1) Number of subjects
2) Recruitment sites
3) Recruitment materials
4) Other materials or procedure
5) Research team members
6) Informed Consent or Assent Form
7) Any other substantive changes to the protocol.

3.1.1 If changes involve the Informed Consent or Assent Form, a copy of each of the following should also be submitted:

1) revised version with changes highlighted

2) final copy of revised form

3.1.2 If changes involve materials and procedures, a copy of each of the following should also be submitted:

1) revised version with changes highlighted
2) final copy of revised form

3.2 The Chair shall determine the type of review.

3.2.1 If full board review is needed, the Chair shall schedule the amendment review for the next meeting.

3.2.2 If the initial review is expedited, the Chair or designated reviewer will review the amendment request.

3.3 The Chair shall notify the PI by email of approval or need for additional documentation.

3.4 The Chair shall direct staff to update paper and electronic files accordingly.

4.0 REFERENCES

45 CFR 46.110
21 CFR 56.108 (a) (3) and (4)

5.0 APPENDIX

IRB Amendment Form

SOP 404
Policies and Procedures for Adverse Events or Unanticipated Problems

1.0 POLICY

In the conduct of human subjects research all team members are required to report any unanticipated problems or adverse events to the IRB for investigation. An adverse event is defined as:

> *Any untoward or unfavorable occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms and can occur in the context of medical or social and behavioral research.*

When there is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research, and the adverse event increases the risk to a subject involved in the research, a report shall be filed with the IRB. The IRB is then mandated to investigate that event. These events can be serious in nature, but are not always serious. It is important to identify a case for the seriousness of the event.

2.0 RESPONSIBILITIES

2.1 All study personnel are required to report an unanticipated problem or serious adverse event to the IRB Office within 48 hours of occurrence.

2.2 Upon initial investigation, the Chair will determine if the event is unanticipated, and if so, will investigate all aspects of the incident. (Anticipated adverse events will be dealt with as specified in the approved protocol.) [45 CFR 46.103(a) and 46.103(b)(5)]

2.3 The Chair will make a report to the IRB at the next scheduled meeting.

2.4 The IRB shall discuss and vote on any necessary sanctions or follow-ups.

2.5 If actionable, the Chair will report the result of the investigation and action(s) of the IRB to the Provost and other appropriate administrators or officers.

3.0 PROCEDURES

3.1 Reports of an adverse event should be sent to the IRB Chair.

3.2 The Chair will interview all of the relevant parties involved in or affected by the incident.

3.2.1 Interviews will be conducted by telephone or in person when possible.

3.3 The Chair will complete an Unanticipated Problem Report.

3.3.1 The report will be kept in the study file.

3.4 The Chair will summarize the findings of the investigation for the IRB and make all investigation information available as needed.

3.5 If actionable, the Chair will report to the Provost on the investigation and actions of the IRB.

3.6 To the extent possible all information and reports will be kept confidential to protect those involved.

3.7 Any proposed changes to a study in response to an unanticipated problem must be reviewed and approved by the IRB before being implemented, except when necessary to eliminate apparent immediate hazards to subjects

4.0 REFERENCES

45 CFR 46.103(b)(5)
45 CFR 46.103(a)

5.0 APPENDIX

Adverse Event Report
Serious Adverse Event Report
Unanticipated Problem Report

SOP 405
Policies and Procedures for Study Completion

1.0 POLICY

The Investigator is responsible for notifying the IRB when a research project is complete. This may occur at any time or at the anniversary of the approval (or the specified monitoring interval). If the approval has expired and no action is taken by the Investigator, the IRB may administratively close the file after 30 days.

2.0 RESPONSIBILITIES

1.1 The Investigator shall promptly notify the IRB of the completion of a study.
1.2 When notified of the anniversary of the approval (or the specified monitoring interval) the PI shall notify the IRB that the project has been completed and that all identified data have been disposed of in the manner approved in the IRB Application.

3.0 PROCEDURES

1.1 Prior to the anniversary date or specified monitoring period, when a study has been completed, the Investigator shall submit a Closure Request Form.
1.2 Upon notification of the anniversary of the approval (or the specified monitoring interval) Investigator(s) will submit a Closure Request Form.
1.3 The IRB will send email to PI acknowledging receipt of Closure Request Form and confirming file closure.
1.4 If the PI does not notify the IRB within 30 days of the approval expiration, the IRB may administratively close the file. The IRB will send an email notifying the PI that the file has been closed. A new IRB application will have to be submitted in order to continue research.

4.0 REFERENCES

45 CFR 46.115 (b)

5.0 APPENDIX

Closure Request Form

SOP 501
Research Involving Vulnerable Populations

1.0 POLICY

Current federal regulations recognize three groups of vulnerable subject populations for whom additional guidelines have been prepared. These are: children, pregnant women and fetuses, and prisoners. Additional groups recognized as needing added protection are the mentally, cognitively or developmentally impaired, and the elderly. Although some exemptions apply for research involving these subjects, full board review will be required for most research projects.

2.0 RESPONSIBILITIES

2.1 The Investigator shall notify the IRB of research involving vulnerable populations before submitting an application.
2.2 The Chair shall determine the type of research review required.
2.3 The Chair will assign reviewers as needed.
2.4 The Chair will notify the PI of any additional information needed or changes necessary.
2.5 The Chair will notify the PI of IRB decisions in writing.
2.6 The Chair shall provide the IRB with an update of applications previously discussed by the IRB.

3.0 PROCEDURES

3.1 The Chair will make a preliminary review to determine the type of research review required: exempt, expedited, or full board. (Those targeting vulnerable populations usually require full board review.)
3.2 Exempt or expedited research will be reviewed by the Chair and one or more IRB members for consulting purposes.

3.2.1 Projects involving prisoners will be reviewed by the IRB member with expertise as a prisoner advocate.
3.2.2 When necessary, outside reviewers with specialized knowledge will be asked to review.

3.3 Applications needing full board review will be scheduled by the Chair for the next IRB meeting.

3.3.1 The Chair will notify the PI of the requirement for full board review, the time, and date.

3.3.2 The Chair will invite the PI to attend the IRB meeting to answer questions, if desired.

3.4 The Chair will provide a copy of an application needing full board review to IRB members prior to the meeting. [See SOP 303]

3.5 The reviewers will summarize the issues for the IRB members. All IRB members will be given the opportunity to discuss the application.

3.6 The IRB will vote to approve, contingently approve with required stipulations, defer, or reject the application.

3.7 The Chair will notify the PI of all stipulations that need changing and a summary of comments or discussion (without attribution) from the IRB meeting.

3.8 The Chair will notify the PI by email and in writing of the final approval or other actions.

4.0 REFERENCES

45 CFR 46 Sub-Part B, C, D

5.0 APPENDIX

Appendix C
SOP 303

SOP 502
Research Carrying Higher Than Minimal Risk

1.0 POLICY

Research involving humans must be assumed to carry at least some risks, such as to health, privacy, or physical, emotional, psychological, economic and legal risks. It is the duty of the investigator(s), as well as one purpose of the IRB, to ensure that the risks are identified, justified, and minimized. This is especially important when the research involves vulnerable populations. Risks must be evaluated according to federal guidelines and subjects must be informed of all risks as well as benefits to them directly. In the case of higher than minimal risk where there is no direct benefit to the subject, the burden lies with the investigator to justify the research to the IRB and any participants, and in all cases to take great care in the consenting process to insure as much disclosure of risks as possible.

The Board will consider the following in approving any projects involving more than minimal risk:

1) Risks to subjects will be minimized:

    a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
3) Selection of subjects is equitable.
4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
5) Informed consent will be appropriately documented, in accordance with, and to the extent required.
6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2.0 RESPONSIBILITIES

2.1 The Chair shall make a preliminary review of applications to determine the level of risk.
2.2 The Chair will assign additional reviewers with relevant expertise as needed.
2.3 The Chair will notify the PI of the need for full board review and add the application to the agenda of the next IRB meeting.

2.3.1 The PI shall be notified of the time and date of the meeting and invited to attend to answer questions.

2.4 The IRB Full Board will review and vote on all applications involving more than minimal risk.
2.5 The Chair will notify the PI of the IRB decision(s) or actions of the IRB in writing.
2.6 The Chair will notify the PI in writing when all stipulations are satisfactorily met.

3.0 PROCEDURES

3.1 The Chair and any secondary reviewers will prepare a summary for the IRB.
3.2 The IRB may decide to monitor the subjects by requiring a continuing review of less than one year, proportionate to the degree of risk involved.
3.3 The IRB will insure that the risks are minimized as much as possible
3.4 The IRB will vote to approve, contingently approve with required stipulations, defer, or reject the project.
3.5 The Chair will notify the PI of all stipulations that need changing and a summary of comments or discussion (without attribution) from the IRB meeting.
3.5 The Chair will notify the PI by email and in writing of the final approval.

4.0 REFERENCES

45 CFR 46.111 (a) and (b)
45 CFR 46.201 (Pregnant women, fetuses and neonates)
45 CFR 46.301 (Prisoners)
45 CFR 46.401 (Children)
21 CFR 56.111(b)

5.0 APPENDIX

Appendix C

SOP 503
Research Involving Deception or Incomplete Disclosure

1.0 POLICY

Research activities that involve giving false information (deception) or withholding information about the real purpose or nature of the research (incomplete disclosure) to subjects carry more than minimal risk and in most cases are subject to a full board review and additional measures to mitigate the effects of such procedures. Deception and incomplete disclosure shall only be used in research when necessary to prevent the confounding of the data. Deceptive techniques intended to entice subjects to participate will not be allowed and subjects cannot be deceived about aspects of the study that pose greater than minimal risk.

If feasible, potential subjects should be advised in the consent form that the information they are given is not complete and that they will be debriefed after the procedures are complete. The debriefing should include a detailed description of the way in which deception was used and why it was necessary. Subjects should be allowed to express their reaction to the debriefing and an effort should be made to insure that they do not leave in a distressed state. Subjects should be given the option to withdraw their data upon being debriefed. In those limited cases where debriefing would be harmful to the subjects, the investigator must provide justification for withholding the debriefing.

2.0 RESPONSIBILITIES

2.1 The investigator will specify in the application that deceptive or incomplete disclosure procedures are part of the protocol of the study and provide justification.

2.2 The Chair will make a preliminary review of the application and determine if full board review is needed.

2.3 The Chair will schedule the application for the next IRB meeting or will complete an expedited review when appropriate.

2.4 The degree of deception or withholding and the steps to mitigate any effects, are considered in making the final decision about a proposal.

2.5 The investigator will modify procedures as required by the IRB.

3.0 PROCEDURES

3.1 The investigator shall indicate in the application those instances where deception or withholding information exist, provide a justification for them, and explain what steps will be taken to reduce any distress they might cause to the subject. Note that withholding information does not apply to statements of the specific hypothesis being tested.

3.1.1 The use of deceptive techniques can be justified **if**

1) the benefits outweigh the costs, **and**
2) the study could not otherwise be conducted

3.1.2 No deception can be included in the Informed Consent Form.
3.1.3 The deception or withholding shall be explained to the subjects as soon as possible.
3.1.4 Subjects will be given the option of withdrawing their data.
3.1.5 Subjects must be frequently and careful monitored for indications of stress or harm
3.1.6 Steps will be taken to mitigate any stress or harm.

3.2 The Chair will review an application to determine the type of review necessary. In most cases involving deception or withholding information, full board review is required but in those cases where incomplete information is minimal, and subjects are told that information is being withheld, an expedited review is possible. The chair will explore possible non-deceptive alternatives with the PI.

3.3 In cases where deception is more than minimal the board shall consider:

1) the value and probability of the outcome of the study
2) the likelihood of stress, distress, or harm to subjects
3) measures to mitigate the effects
4) a shorter continuing review period to monitor the effects

3.4 After approval, IRB staff will monitor the project as specified by the IRB SOP regarding Continuing Review. [See SOP 402]

4.0 REFERENCES

45 CFR 46.116(d)

5.0 APPENDIX

Continuing Review Form
SOP 402

SOP 504
Research at External or Multiple Sites

1.0 POLICY

The UCO IRB is responsible for the review of all research involving human subjects conducted by faculty, staff and/or students, whether that research was conducted onsite at UCO, at offsite locations and/or multiple sites. Research conducted by UCO research personnel, acting as PI or Co-PI, in concert with investigators from other institutions should be done under the home institution's IRB, with that board acting as the IRB of Record, and it is the responsibility of UCO research personnel to ensure that they are in full compliance with all relevant policies and procedures. Where there is disagreement between policies, it is the duty of UCO-affiliated personnel to abide by the policies of the IRB of Record. Permission to deviate from any UCO IRB policy must be submitted in writing for full board review by the UCO IRB prior to the commencement of any research by UCO-affiliated personnel.
If UCO is not the IRB of Record, all UCO investigators, acting as PI or Co-PI, are nevertheless expected to act in full compliance with UCO IRB policies and procedures. External or multiple site IRB(s) must provide to the UCO IRB documentation of Federal-Wide Assurance for that research site.

2.0 RESPONSIBILITIES

2.1 UCO research personnel, acting as PI or Co-PI who are engaging in external or multiple site research shall provide to the UCO IRB contact information of coordinators and of local IRB's, if present.

2.2 If there is no local IRB or similar body, the UCO IRB must serve as the coordinating body (IRB of Record) for the research and a UCO-affiliated investigator must serve as PI.

- 2.2.1 The PI(s) shall ensure full compliance with all UCO IRB policies.
- 2.2.2 The PI(s) shall ensure effective communication among research sites.
- 2.2.3 The PI(s) shall ensure security of research data.
- 2.2.4 The PI(s) shall ensure propriety of the informed consent.
- 2.2.5 The PI(s) shall provide documentation that all non-UCO investigators have the appropriate training and certification to conduct human subject research.

2.3 If there are local IRB's, and UCO does not serve as IRB of Record, UCO investigators, acting as PI or Co-PI, are permitted to cooperate in human subject research, and expected to conduct research in compliance with UCO IRB policies and procedures.

2.4 Any research proposal which includes UCO personnel, acting as PI or Co-PI, must be submitted for review by the UCO IRB in addition to any review undertaken by other IRB's and UCO personnel will be expected to comply with any directives or modifications recommended by the UCO IRB regarding the conduct of research.

3.0 PROCEDURES

3.1 Investigator(s) will submit a completed IRB application of the IRB of Record including, any existing proposal or project description and supporting materials.
3.2 Investigator(s) will submit a copy of an approval letter from the IRB of Record.
3.3 Investigator(s) will not involve human subjects in the proposed research until UCO IRB approval is obtained.
3.4 UCO IRB chair will review the application to determine the type of review necessary.
3.5 UCO IRB chair will verify the application is complete and includes the required documents.
3.6 UCO Chair will communicate with investigator(s) about approval or necessary changes. [See SOP 601]
3.7 After approval, UCO IRB staff will monitor the project as specified by the IRB.

4.0 REFERENCES

45 CFR 46.114; 21CFR46.114

5.0 APPENDIX

Appendix C
SOP 601

SOP 505
Research at International Sites

1.0 POLICY

All research involving human subjects conducted at international sites (outside the United States borders or territories) by UCO researchers, acting as PI or Co-PI, must follow all UCO IRB regulatory and ethical policies and procedures, and must be submitted for approval by the UCO IRB, unless it is determined not to meet the criteria. This applies regardless of the site(s) where the actual research is conducted or the source(s) of funding. For international research, special considerations must be given to ensure compliance with UCO, state, and federal regulations in addition to any local policies that may exist. Participants in the research are entitled to the same rights and protections enjoyed by study participants in the United States, regardless of local law or custom.

2.0 RESPONSIBILITIES

2.1 Research to be conducted by UCO investigators, acting as PI or Co-PI, at international sites must be submitted for full board review by the UCO IRB. At the discretion of the Chair, full board review may be waived in favor of expedited review, but it is the responsibility of the researcher(s) to the make the case for waiver. Any study involving vulnerable populations, greater than minimal risk, or deception must receive full board review.

2.1.1 It is the responsibility of the investigator(s) to be in compliance with all UCO, state, and federal regulations and to provide appropriate documentation attesting to full compliance.

2.1.2 It is the responsibility of the investigator(s) to have sufficient knowledge of local customs and cultural norms to make informed decisions regarding the conduct of research, recruitment of study participants, and special considerations regarding study participants who are members of vulnerable populations.

2.1.3 The investigator is responsible for ensuring that the process for obtaining informed consent complies with UCO IRB policies as well as local customs; this is of particular importance in avoiding conflicts of interest.

2.1.3.1 Investigators must demonstrate awareness of local literacy levels in the obtaining of informed consent.

2.1.3.2 Investigators must take special care in obtaining informed consent where the study involves deception.

2.1.3.3 The proposal must reflect knowledge of country-specific guidelines for the conduct of human subjects research. [See

OHRP: International Compellation of Human Research Standards, 2012 Ed.]

2.2 The UCO PI or Co-PI investigator is responsible for data safety, monitoring, storage, and eventual disposal consistent with UCO IRB policies and compliance with U.S. and local laws.

2.2.1 Data exported to the U.S. must meet Export Control regulations established by the U.S. government. [See http://exportcontrol.org/links/1355c.aspx]

2.3 The UCO PI or Co-PI investigator is responsible for determining if there is a local IRB, ethical board, or similar body which reviews research, and for obtaining local approval and following local requirements in addition to UCO IRB policies and procedures. [See SOP 504]

2.3.1 A letter from such an entity should accompany an IRB Application.

2.4 If there are local IRB's, and UCO serves as IRB of Record, UCO investigators, acting as PI or Co-PI, are permitted to cooperate in human subject research, but are expected to conduct research in compliance with UCO IRB policies and procedures.

3.0 PROCEDURES

3.1 The investigator must submit a Checklist for International Research along with the study proposal for IRB review in time for full board review.
3.2 The documents will be reviewed by the IRB Chair in advance of the meeting to determine any needed stipulation changes or variances in the review process.
3.3 The full board will discuss and vote on each application and proposal prior to any research being undertaken or consent solicited.
3.4 Applications will be approved for one year and will require a Continuing Review thereafter if they were approved as requiring Full Board review. [See SOP 402]
3.5 Any amendments, reports of adverse events, or protocol violations must be submitted consistent with UCO IRB policies and procedures. [See SOP 402, 403,404]

4.0 REFERENCES

45 CFR 46.101 (h)
45 CFR 46.114
OHRP: International Compellation of Human Research Standards, 2012 Ed.

5.0 APPENDIX

SOP 402
SOP 403
SOP 404

SOP 506
Outside Researchers on UCO's Campus

1.0 POLICY

Institutions and organizations outside UCO that may wish to conduct research on the UCO campus, whether in concert with UCO faculty, staff, or students, or through recruiting as study participants anyone affiliated with UCO, must submit their requests to do so to the UCO IRB for evaluation. In most cases, such requests can be expedited, particularly if the inquiring institution has federal-wide assurance (FWA). The outside researcher(s) submitting the proposal already have secured IRB approval from their home institution, and the study population does not include any vulnerable populations. However, the UCO IRB evaluation of such requests may determine that a full board review be conducted prior to approval, regardless of the type of review the proposal received at the home institution. In any case, no IRB-related research may be initiated on the UCO campus by outside entities without UCO IRB approval. The UCO IRB will require sufficient documentation to substantiate the legitimacy of the research, the relationship of the researcher(s) to the inquiring institution, and to ensure that outside researchers understand the policies of UCO and of the UCO IRB and agree to be compliant with those policies. It is the responsibility of UCO research personnel who may be participating in such studies to ensure that they remain in full compliance with all relevant UCO IRB policies and procedures, regardless of policies and procedures at other institutions. Where there is disagreement between policies, it is the duty of UCO-affiliated personnel to abide by UCO policies. Permission to deviate from any UCO IRB policy must be submitted in writing for full board review by the UCO IRB prior to the commencement of any research by UCO-affiliated personnel.

2.0 RESPONSIBILITIES

2.1 Outside institutions wishing to conduct research on the UCO campus, whether or not in concert with any UCO-affiliated personnel, must submit their proposal to the UCO IRB for evaluation prior to the initiation of recruitment or data-gathering.

2.2 If the inquiring institution has FWA, UCO IRB acceptance of the project may be granted and might require the inclusion of an Authorization Agreement Form.

2.3 If the inquiring institution does not have FWA, the UCO IRB may request that a UCO IRB Application be completed and submitted, with all requested supporting documentation, prior to the initiation of recruitment or data-gathering.

2.4 UCO IRB evaluation of the request will follow the same guidelines and procedures as the evaluation of any UCO-originated proposal.

2.5 Outside researchers are responsible for providing any documentation requested by the UCO IRB regarding the proposal or their qualifications as researchers, and

such documents must be submitted and approved by the UCO IRB prior to the initiation of the research.

2.6 Any changes made to the research as it is conducted on the UCO campus, whether or not such changes apply to the approved research at the originating institution, must be submitted in writing to the UCO IRB for review and approval prior to their implementation.

2.7 Outside researchers are responsible for providing documentation of the completion of Protecting Human Participants in Research training, to be submitted with the materials when requesting to do research on the UCO campus.

2.8 Any UCO-affiliated personnel who will be acting as Co-PIs or research assistants must abide by UCO and UCO IRB policies regardless of policies at the originating institution.

2.9 Outside researchers are responsible for being familiar with UCO policies and for acting at all times in compliance with them. Failure to do so will constitute noncompliance and may result in the withdrawal of approval to conduct the research at UCO. [See SOP 801]

2.10 Reports of any violations of UCO policy by outside researchers will result in an investigation by the UCO IRB Chair and the Institutional Official. If it is determined that a violation has taken place, at a minimum UCO approval of the research will be withdrawn, all activities connected to the research will be suspended, and all documentation regarding the research as it was conducted at UCO will become the property of UCO. Reports of any violations of UCO policy by outside researchers will result in an investigation by the UCO IRB Chair and the Institutional Official. If it is determined that a violation has taken place, at a minimum UCO approval of the research will be withdrawn, all activities connected to the research will be suspended, and all documentation regarding the research as it was conducted at UCO will become the property of UCO.

2.11 The outcome of an investigation will be made a part of the permanent record of that study, a formal letter from the UCO Provost will be sent to the designated official of the originating institution.

3.0 PROCEDURES

3.1 Outside investigator(s) will submit the completed IRB application, Approval Letter and Informed Consent form from their originating institution, including any existing proposal or project description and supporting materials.

3.2 The UCO IRB Chair will evaluate the request and supporting documents.

3.3 Research activities at UCO may not commence without UCO IRB prior approval.

3.4 Outside investigators will provide to the UCO IRB Chair upon request any documents regarding the research or the qualifications of the researchers.

3.5 The UCO IRB Chair will communicate to the outside investigators the outcome of UCO IRB review of the proposal.

3.6 Any modifications of the proposal requested by the UCO IRB must be implemented prior to the initiation of any research activities.

3.7 Reports of potential violations of UCO or IRB policy will be investigated according to UCO procedures. [See SOP 801]

4.0 REFERENCES

45 CFR 46.114; 21 CFR 45.114

5.0 APPENDIX

Appendix C
SOP 801

SOP 601
Communication and Notification to Investigator(s)

1.0 POLICY

The IRB is responsible for communicating with investigator(s) about the results of the IRB application review and any stipulations needed, final approval, amendment requests, continuing review requests, and reports of violation investigations in a timely manner. All communications will be by email (unless otherwise requested) and a signed letter of final approval and stamped, approved ICF will be made available and must be used.

2.0 RESPONSIBILITIES

2.1 The Chair shall notify the PI in writing of the results of the review(s) and needed changes or additions.
2.2 The Chair shall notify the PI of the necessity of full board review. [See SOP 501; SOP 502; SOP 503]
2.3 The Chair shall notify the PI of the final approval or action of the IRB.
2.4 IRB administrative staff shall maintain records of all communications.
2.5 The administrative staff shall notify the PI of upcoming anniversary dates necessitating Continuing Review or Closure.

3.0 PROCEDURES

3.1 For exempt or expedited applications the Chair will notify the PI as soon as the application has been reviewed.

3.1.1 The Chair will email the PI about changes and additions as soon as reviews are completed and compiled.

3.2 The Chair will notify the PI by email and in writing as soon all stipulations have been satisfied and the application has been approved.
3.3 Where required, the Chair or IRB staff will send a copy of the approved, stamped consent document to the PI by campus mail for use in the consent process.
3.4 If the application requires full board review, the Chair will notify the PI at the initial stage of review.

3.4.1 The PI will be informed of the time and date of the IRB meeting and invited to attend to answer questions, if desired.
3.4.2 Following transcription of the minutes of the meeting, the Chair will notify the PI of the actions of the board, including a summary of

comments or discussion (without attribution) and a list of stipulations needing change.

3.5 The Chair will notify the PI by email and in writing of the final approval.

3.6 Administrative staff shall notify the PI of approaching anniversary of approval and need for Continuing Review or Closure at 60 and 30 days. [See SOP 402]

3.7 The administrative staff will keep electronic files of:

1) all IRB applications and their current status
2) all email communications to and from investigator(s)
3) paper copies of applications and supplemental documents, review notes, letter outlining stipulations required, letter of final approval and ICF or AF, as needed.

3.8 Paper records will be maintained for at least 3 years following the closure of the project. Documents will then be archived electronically and kept indefinitely.

4.0 REFERENCES

45 CFR 46.109

5.0 APPENDIX

IRB Application
Closure Request Form
Appendix C
SOP 402
SOP 501
SOP 502
SOP 503

SOP 602
Communication and Notification to Administration

1.0 POLICY

The sponsoring institution and the IRB are jointly responsible for maintaining open and effective communication. It is necessary that staff, investigator(s) and research subjects have the means to communicate and solicit information relevant to the activities of the IRB at all times, and it is the responsibility of the sponsoring institution to provide adequate resources and technologies for the conduct of research. It is necessary that the IRB members have open access to the Provost or others of authority within the institution who are designated to act in behalf of the institution to support and sustain the activities of the IRB.
The IRB will report to the Provost any serious or continuing noncompliance or other matters. The results of any investigation of noncompliance and the sanctions voted on by the IRB will be reported to the Provost and other appropriate administrators or officers.

2.0 RESPONSIBILITIES

2.1 The Chair shall notify the Provost of policy violations or noncompliance after the IRB has reviewed the evidence from the investigation and made its decisions regarding actions and/or sanctions. [See SOP 801]
2.2 The Chair shall notify other appropriate administrators as directed by the IRB.
2.3 The IRB staff will maintain documentation pertinent to cases of policy violations or noncompliance.
2.4 The Chair shall provide the Provost with a summary of the annual evaluation report.

3.0 PROCEDURES

3.1 The Chair will request an in person meeting with the Provost to discuss a case of non-compliance after the board has met.
3.2 The Chair will inform the Provost in writing of the actions and/or sanctions directed by the IRB.
3.3 The Chair will inform other appropriate administrators in writing about the case, as directed by the IRB.

3.3.1 IRB staff will keep copies of all communications with administrators in applicant file.

4.0 REFERENCES

45 CFR 46.108; 112

5.0 APPENDIX

Appendix C
Reviewer Checklist
SOP 801

SOP 701
General Requirements for Informed Consent

1.0 POLICY

The need for informed consent and the development of a legally effective consent document is a vital step in the design of research involving human subjects. Except as detailed below, regulations require that the investigator obtain the informed consent of the subject, or the subject's legal representative, prior to involvement in the research. This applies to all categories of research.

The basic elements to be included in a legally effective informed consent document are as follows:

1) A statement describing the study, its purpose, the duration of the subject's participation, and a description of procedures.
2) It is the responsibility of the investigator to detail the risks involved, explain the degree of risk involved and to justify the degree of risk against potential benefits to the participant. It also is the responsibility of the investigator to keep all participants informed during the study of any new or unforeseen risks which may have arisen, and their potential impact on the safety and welfare of participants. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and if so, where further information may be obtained.
3) A statement describing the measures to protect the privacy of the subject(s) and the confidentiality of the data.
4) A statement of whom to contact for answers to pertinent questions about the research subject's rights.
5) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is entitled, and the subject may refuse to answer questions or discontinue participation at any time without penalty or loss of benefits.

2.0 RESPONSIBILITIES

2.1 The PI will provide details of the consent process in the IRB application.
2.2 The PI will provide subjects with information about the study as outlined above.
2.3 The Chair and other reviewers will review all materials and make the determination to approve or modify the consent process as requested.
2.4 The Chair or IRB staff will send copies of the stamped, approved consent form(s) (and assent form(s) where required) to the PI by campus mail.
2.5 The PI will only use the stamped, approved consent/assent forms.

2.6 The PI will complete an amendment form to make any changes to the consent documents.

2.6.1 Amendments for applications that initially required full board review will need to be approved by the full board.

3.0 PROCEDURES

3.1 The PI will document who will be consented and where the consenting will occur, and provide one of the following: [See SOP 702; SOP 703; and SOP 704]

1) an Informed Consent Form (and Assent Form where necessary), or
2) a Waiver of Documentation of Consent, with justification, or
3) a Waiver of Informed Consent, with justification.

3.2 The PI shall provide a copy of the information sheet, introductory script, or other summary information to be provided to subjects for whom a waiver of consent is requested.

3.3 The Chair will insure that all of the basic elements of a legally effective informed consent document are present.

3.4 The Chair will send stamped approved copies of consent documents to the PI.

3.5 The PI will obtain formal approval of any changes before implementation of those changes. [See SOP 403]

4.0 REFERENCES

45 CFR 46.116
21 CFR 50.20

5.0 APPENDIX

Appendix C
IRB Review Documentation: Waiver of Informed Consent
IRB Review Documentation: Waiver of Documentation of Consent
SOP 403
SOP 702
SOP 703
SOP 704

SOP 702
Documentation of the Informed Consent Process

1.0 POLICY

Except as outlined below, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either of the following:

1) A written consent document that embodies the elements of informed consent required by 45 CFR 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; **or**
2) A short form written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

2.0 RESPONSIBILITIES

2.1 The investigator shall provide a written, signed informed consent in all but the above described cases.
2.2 The Chair or other reviewers shall determine that subjects are given adequate information for their voluntary consent.
2.3 The investigators shall keep signed consent forms in a secure, identified location for at least three years after the project closure.
2.4 Investigators shall make those documents available to the IRB upon request.

3.0 PROCEDURES

3.1 The application shall include either a written, signed consent form or some other form of information on which to base their agreement to participate.
3.2 Copies of the approved consent form shall be stamped and sent to the investigators to be used in the study.

3.3 The investigator will only use those consent documents that have been approved and stamped by the IRB Office.

4.0 REFERENCES

45 CFR 46.116

SOP 703
Waiver of Consent

1.0 POLICY

No investigator may involve a human being as a subject unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. However, investigator(s) may request a Waiver of Informed Consent in situations where: a) the research in its entirety involves no greater than minimal risk, b) the waiver of consent will not adversely affect the rights and welfare of the subjects, AND c) it is not practicable to conduct the research without the waiver/alternation. The waiver can include part or all of the consent document and regulations also permit an IRB to waive parental permission.
Investigator(s) may also request a Waiver of Documentation of Consent in situations where the only record linking the subject or the research is the consent document and the principal risk is from a breach of confidentiality, OR the research involves no more than minimal risk and involves no procedure for which written consent is normally required outside of the research context.
In cases where either consent or documentation of consent is waived, the investigator will be required to prepare a statement (information sheet/script) for distribution to the subjects, containing the basic elements of the consent form and describe the study.

2.0 RESPONSIBILITIES

2.1 Investigator(s) shall request a waiver and provide appropriate justification in the application for IRB approval.

2.2 Researcher will complete the appropriate form, either:

1) IRB Review Documentation: Waiver of Informed Consent, or
2) IRB Review Documentation: Waiver of Documentation of Consent

2.3 A stamped approval copy of information sheet will be sent to the PI.

3.0 PROCEDURES

3.1 Investigator(s) will provide copies of the consent documents or information sheet/script to be presented to the subjects along with justification.

3.2 The IRB will grant approval for a waiver when the following stipulations apply:

1) Waiver of Consent:

a) the research involves no greater than minimal risk,

b) the waiver of consent will not adversely affect the rights and welfare of the subjects
c) it is not practical to conduct the research without the waiver, AND
d) whenever appropriate the subjects will be provided with additional pertinent information after participation

2) Waiver of Documentation of Consent:

(a) where the only record linking the subject to the data is the consent document and the principal risk is from a breach of confidentiality, **OR**
(b) the research involves no more than minimal risk and no procedure for which written consent is normally required outside of the research context.

3.3 Chair or IRB staff will send stamped, approval copies of consent documents to the PI.

3.4 The PI will obtain approval of any changes before implementation of those changes. [See SOP 403]

4.0 REFERENCES

45 CFR 46.116(c) or (d)

5.0 APPENDIX

Appendix C
SOP 403
Waiver of Informed Consent Form
Waiver of Documentation of Consent Form

SOP 704
Assent of Minors

1.0 POLICY

The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. The IRB has the discretion to determine the appropriate manner, if any, of documenting child assent. Based on such considerations as the child's age, maturity, and degree of literacy, the IRB should decide what form of documentation, if any, is most appropriate. If adolescents are involved in research where a consent form would have been used if the subjects were adults, it would generally be appropriate to use a similar form to document an adolescent's assent.

If young children are involved who are as yet unable to read, documentation should take a form that is appropriate for the purpose of recording that assent took place. The IRB may also decide that documentation of assent is not warranted.

The assenting may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

2.0 RESPONSIBILITIES

2.1 The investigator shall provide an Assent document or justification for its absence.

2.2 The Chair or other reviewers shall consider the ability of the children to give true informed consent.

2.3 Where necessary, documentation of the process will be required.

3.0 PROCEDURES

3.1 Investigators shall include a means of informing children and receiving assent from them or providing justification for its absence.

3.2 The reviewers shall base approval on the ability of children to give true informed consent.

3.2.1 Where necessary an outside expert shall be consulted regarding the feasibility of the process.

3.3 If written consent is not given, the IRB can consider documentation of oral consent, or justification of why it is not necessary.

4.0 REFERENCES

45 CFR 46.408

SOP 801
Reports of Non-Compliance

1.0 POLICY

It is the responsibility of the UCO IRB to insure that approved protocols are followed and that subjects' rights and privacy are protected. If the IRB receives a report that non-compliance or misconduct has occurred, it is obligated to act on the allegation. The Chair is required to conduct an investigation and report the findings to the IRB at the next meeting. The IRB must then determine if the allegation has been proven, and if so, the degree of seriousness of the violation, and the appropriate sanctions or actions. The results of the investigation and sanctions are reported to the Provost and other appropriate administrators or officers.

2.0 RESPONSIBILITIES

2.1 Once notified of a potential violation or non-compliance, the Chair shall conduct an investigation of the allegations. [See Appendix B]

2.1.1 With the assent of the Provost, the Chair may appoint another full member of the IRB to conduct an investigation. This person shall have the full authority of the Chair for the purposes and duration of the investigation, and shall have access to all personnel and documents deemed necessary to arrive at a determination regarding the allegation(s). Upon completion of the investigation, this person shall report to the Chair and then to the full board at the next scheduled meeting of the IRB. All documents and information generated during the investigation shall be turned over to the Chair or Provost and shall be the property of the university. Such reports which are required to be submitted shall be completed by the appointed investigator and the Chair.

2.2 The Chair shall report the findings of the investigation to the IRB at the next scheduled meeting.

2.3 The IRB shall discuss and vote on the outcome of the investigation and any necessary sanctions or follow-up. [See UCO Appendix B]

2.4 The Chair shall report the results of the investigation and the actions of the IRB to the Provost and other appropriate administrators or officers.

3.0 PROCEDURES

3.1 As part of the investigation, the Chair will contact all of the parties involved in or affected by the alleged non-compliance.

3.1.1 Interviews will be conducted by telephone or in person when possible. If unfeasible, questions will be sent to involved parties by email.

3.2 The Chair will summarize the findings for the IRB and make all investigation information available as needed for the IRB.

3.3 If warranted, the Chair will report to the Provost and other administrators or officers a written summarization of the interviews, and the discussion, vote, and authorized sanctions or actions of the IRB.

3.4.1 All information gathered for purposes of investigation and any discussion of such matters by the IRB are strictly confidential and will not be shared with any of the parties involved.

3.4.2 Care will be taken to protect the identity of any informant as much as is possible.

3.4.3 Any IRB member with a COI relationship to any of the involved parties will recuse themselves from the IRB meeting during the discussion and disposition of the case. [See SOP 103]

3.5 Cases where no further action is required will be reported to the board at the next meeting.

4.0 REFERENCES

45 CFR 46.103; 123
45 CFR 76
21 CFR 56.108 (b); 120-124

5.0 APPENDIX

Appendix B
SOP 103

SOP 901
Final Data Disposition

1.0 POLICY

The institution is required by the HHS regulations to retain records related to each approved application in some form for at least three (3) years after the completion of the study. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner.

Investigators must keep documentation of the informed consent of the subjects—either the signed informed consent form or the short form and the written research summary—and records related to conducted research for at least three years after completion of the research, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent. In the event that the PI leaves the university, other entities, including the Co-PI or the IRB, can be designated to serve that role.

The IRB Office is required to retain all records of IRB activities and certain other records frequently held by investigators for at least three years after completion of the research. These may be kept as paper or electronic documents.

Study completion is defined by the following:

> *all research-related interventions or interactions with human subjects have been completed, **and** all data collection and analysis of identifiable private information described in the IRB-approved research plan has been finished*

Once a study has been completed, the investigators are no longer required to obtain continuing review and approval of that study by the IRB. Investigators may keep the data they collected, as long as it is de-identified, except in cases where the IRB has approved a research plan approving the retention of identifiable private data that can be retained indefinitely. Investigators should continue to honor any confidentiality protections of the data. Investigators should honor any other commitments that were agreed to as part of the approved research, for example, providing information about the study results to research subjects, or honoring commitments for compensation to research subjects for research participation.

2.0 RESPONSIBILITIES

2.1 The investigator is required to notify the IRB of the study's completion within 30 days of the completion of a study.

2.2 The investigator shall notify the IRB of the location of the retained data and any subsequent changes.

2.3 The investigator shall maintain the records for at least three (3) years.

2.4 At the end of the retention period, the investigator shall dispose of the records as specified in the approved IRB protocol.

2.5 The IRB Office shall maintain all records related to IRB applications for at least three (3) years.

2.6 Investigators wishing to retain identifiable data indefinitely shall amend their approved IRB application to request such arrangements. [See SOP 403]

3.0 PROCEDURES

3.1 Investigator(s) must complete a Closure Request Form and notify the IRB by letter or email that the project should be closed.

3.2 Following receipt and review, the IRB Office shall notify the investigator of the closure of the project.

3.3 The investigator shall notify the IRB if alternative arrangements for document retention are needed. That will be necessary when:

1) a student PI graduates, whereupon the faculty mentor/sponsor Co-PI is responsible for record keeping
2) a faculty or staff PI leaves the university, the IRB or another designee shall be appointed to keep those records

4.0 REFERENCES

45 CFR 46.115(b)
45 CFR 46.117

5.0 APPENDIX

Closure Request Form
SOP 403

Appendix A
Guidelines for Human Subject Research Involving Children
(45 CFR 46.401-409)

Definition

Children are persons who have not attained the legal age (18) for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. The secretary of the DHHS has set 18 as the age of adulthood in the absence of other guidelines.

Informed Consent

The general requirements for obtaining informed consent, the elements to be included, and the provisions for waivers all apply to research involving children as subjects. The regulations require that the assent of the child be solicited when, in the judgment of the IRB, they are capable of providing assent. The process of obtaining informed consent for children is complicated by the issues of the child's age, ability to understand, and the relationship with the parents or guardians. When evaluating consent procedures for children the following guidelines are generally applied:

Parental Consent

For research involving children under 18 years of age, investigators must obtain written consent from at least one parent or guardian for participation of the child in the project. If the project involves more than minimal risk, as described below, signatures of both parents or guardians will be required.

Child's Assent

Children are legally unable to give consent either orally or in written form to participate in a research activity. From about middle school onward, children can comprehend a properly written form requesting their consent. Therefore, a written assent from the child (in addition to a required written parental/guardian consent) may become appropriate. While written assent is not legally binding, it does provide an optional documentation of the subject's being "informed" of the research activity.

The assent explanation should be worded to match the reading comprehension level of the children. Elementary school age children should provide oral assent to participate. The explanations to the children should match the level of comprehension of the children being solicited for research participation. A script copy of the explanation to be given should be provided to the IRB.

Some of the criteria defining exempt research change when children are the subjects of research. The following research is categorized as exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as

(a) research on regular and special education instruction strategies; or

(b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) if information taken from those sources is recorded in such a manner that subjects cannot be identified (directly or through identifiers linked to the subjects).

3. Research involving the observation of public behavior so long as the investigator does not participate in the activities being observed. Observations must be recorded in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subject. Moreover, the observations recorded about the individual, if they became known outside the research, should not place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing or employability. Finally, the research should not deal with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified (directly or through identifiers linked to the subjects).

Although categorized as exempt for adults, surveys and interviews with children must be reviewed by IRB members and are categorized for either expedited or full board review.

Research Categories Involving Children

The regulations define four categories of research involving children. Each category addresses a different order of risk and benefit for the child. As such, each category also has special review criteria. These criteria are in addition to the review criteria applied by the IRB to adult projects.

1. Minimal Risk: Minimal risk means that the risks of harm anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine physical psychological examinations or tests. If the proposed research involves only minimal risk, then it may be approved if the project makes

adequate provisions for soliciting assent of the children and permission of their parents or guardians.

2. Greater than Minimal Risk with Direct Benefits: The IRB may approve a project in which the procedure or intervention offer the child subject greater than minimal risk if there is the prospect of direct benefit to the child, and if it meets the following criteria.

(a) The risk must be justified by the anticipated benefits to the subject;

(b) The relationship of the anticipated benefit to the risk is at least as favorable as that presented by available alternative approaches; and

(c) The project makes adequate provision to solicit the child's assent and permission of parents or guardians.

3. Greater than Minimal Risk with No Direct Benefit: If a project offers the child subject greater than minimal risk without prospect of direct benefit from the intervention or procedure, then the IRB may approve it only if it meets the following criteria:

(a) The risk represents only a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to the child subject that are reasonably commensurate with those inherent in actual medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition, information which is of vital importance for understanding or ameliorating the subject's disorder or condition; and

(d) The project makes adequate provision to solicit the children's assent and permission of the parents or guardians.

4. Research Not Otherwise Appropriate: Research that the IRB cannot approve under one of the above categories may be permitted if it meets stringent criteria. This category of research is extremely rare. If you feel that your research project does not meet any of the above categories, please contact the IRB office for guidance.

Appendix B
Non-Compliance Policies & Procedures
Developed and approved by the UCO IRB on February 13, 2009

Explanation

The goal of the UCO-IRB is to promote research and protect subjects, researchers, students, and the university. The role of the IRB is to insure that all UCO-associated research activities comply with the regulations set forth by the Department of Health and Human Services Code of Federal Regulation Title 45 Part 46. To that end, it is the responsibility of the IRB to insure that the approved protocols are followed and that subjects' rights and privacy are protected.

If the IRB receives a report that non-compliance or misconduct has occurred, it is obligated to act on the allegation. The Chair is required to conduct an investigation and report the findings to the IRB Board at the next meeting. The Board must then determine if the allegation has been proven, if so, the degree of seriousness of the violation, and the appropriate sanctions or actions. The results of the investigation and sanctions are then reported to the Provost and other appropriate administrators or officers.

Definitions

Non-compliance is defined as a failure to follow IRB policies which can include:

1. not applying for IRB approval prior to involving humans as subjects in research activities

2. not obtaining final IRB approval for a project prior to engaging humans as subjects in research activities

3. not following an approved protocol or application

4. making changes in procedures, personnel, recruitment, number or type of subject groups, or Informed Consent Forms without prior approval

5. not obtaining Protection of Human Research Subjects training certification before

6. beginning research involving human subjects

Sanctions or corrective actions

Sanctions or corrective actions are based on the seriousness of the violation and the degree of risk to subjects that has resulted. Sanctions or corrective actions can include (but are not limited to) the following:

1. temporary suspension of some or all research activities

2. prohibition of further use of the data

3. prohibition of future on-campus research funding

4. prohibition of mentorship privileges

5.required completion of on-line research ethics training

6. formal acknowledgement of violations and assurance of future compliance

7. informing appropriate administrative personnel

8. violation report to funding agency

9. preparation of IRB application or other forms

10. modifying the protocol or Informed Consent Form

11. requiring current subjects to re-consent to the project

12. modifying the continuing review schedule

13. terminating the research project

Appendix C
Definitions and Elaborations

The definitions and elaborations herein are designed to conform to Title 45 Code of Federal Regulations (CFR) Part 46 as implemented by United States Department of Health and Human Services (DHHS) "Final Regulations Amending Basic HHS Policy for the Protection of Human Subjects," revised June 18, 1991. They also apply to the 17 common Rule Agencies. (USDA, DOE, NASA, DOC, CPSC, HUD, DOJ, DOD, DEd, VA, HHS, NSF, DOT, EPA, AID, OSTP, SSA, and CIA)

University of Central Oklahoma will comply with DHHS requirements regarding cooperative research projects. When sponsored research is conducted at or in cooperation with another entity, all provisions of this policy shall remain in effect for that research. University of Central Oklahoma may accept, for the purpose of meeting IRB review requirements, the review of an IRB establishment under another assurance of compliance with DHHS. Such acceptance must be in writing, and approved and signed by the designated official of each of the other cooperating institutions. Specifically, we require that application for approval be filed with the UCO IRB and that Cooperative agreement and an approval letter from the other institution be attached.

I. Definitions

For Purposes of this policy, the following definitions shall apply:

"Research" or "research activity" means any systematic investigation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute "research" whether or not they are regularly called "development," "demonstration," "instruction," or another term.

"Unsponsored research" means research that is supported solely by the University of Central Oklahoma. "Sponsored research" means research that is supported in whole or partly by any other institution or individual.

"Human Subject" means a living individual about whom an investigator conducting research obtains

1. data through intervention or interaction with the individual, or

2. identifiable private information.

3. "Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

"Interaction" includes communication or interpersonal contact between investigator and subject. "Private Information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

The idea of interaction with a human being is perhaps key in determining whether or not the human being is a subject with respect to the regulations. All forms of interaction are included by the regulatory definitions. Among the most common types of research interactions are:

1. Mailed or Internet questionnaires or surveys

2. Personal interviews, structured or unstructured, with or without recognized instruments.

3. Personal (i.e., face-to-face) surveys

4. Telephone interviews and surveys

5. Classroom instruments, evaluations or exercises

6. Examination of private records (e.g. medical, psychological, or school records as well as pathological specimens).

7. Observation of public behavior by identifiable individuals (e.g., in a classroom, in a mall).

"Research investigator" or "investigator" means any faculty, staff, or student member of the University of Central Oklahoma Campus who engages in any research activity involving the use of human subjects. Please note that there are exceptions for educational activities. See the Appendix D for specific details.

"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Risks of daily life mean those risks encountered in the daily lives of the subjects of the research, considering their actual life situations, as opposed to the daily life of "normal persons" or of "healthy volunteers" as the case may be.

II. Common Forms of Research Requiring Submission to IRB

From the list of types of interaction, we can see that many common forms of research that present little, if any, risk to human beings nevertheless require either review or certification of exemption simply because they are research and have human subjects. Some of the more common types are:

1. Oral history

2. Case studies of events or individuals, if interviews are involved

3. Workplace and school observations, whether activities are controlled or uncontrolled

4. Surveys for information, attitudes, opinions, and similar matters for publication or for report to a federal state, or local governmental agency

5. Classroom research which will later be disseminated to the public.

III. Exempt Research

The following types of research may be considered exempted from the requirements of 45 CFR 46 and approval under the regulations of the DHHS and this policy, except under the conditions noted and except when the subjects have not obtained their legal majority (18 years of age as of application date) in Oklahoma or in the locale where the research is to be performed. All research involving legal minors as human subjects must be submitted to the IRB for review and approval prior to the involvement of any subject who is a legal minor.

The IRB may, at the discretion of the chair, review the following types of research, when they involve legal minors, via the expedited review. THE DETERMINATION OF WHETHER OR NOT RESEARCH WOULD BE CONSIDERED EXEMPT FROM REVIEW WILL BE MADE BY THE IRB. Note that, when support is being requested from a non-DHHS sponsor which has more restrictive or elaborate requirements for the protection of human subjects, a review must be performed on that project in accordance with the regulations of that sponsor. Investigators should complete an IRB Checklist and send it and supporting materials to the IRB for determination.

Educational Practices Research

Research in conducted in established or commonly accepted educational settings, involving normal educational practices, is exempt. Examples of such research are:

1. Research on regular and special education instructional strategies.

2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Educational Testing Research

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) is exempt, provided that information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Survey Research

Research involving survey or interview procedures is exempt, except where all of the following conditions exist:

1. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.

2. The subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.

3. The research deals with sensitive aspects of the subject's own behavior such as psychological testing, illegal conduct, drug use, sexual behavior, or use of alcohol.

All research involving survey or interview procedures is exempt, without exception, when the respondents are elected or appointed public officials or candidates for public office.

Observational Research

Research involving the observation (including observation by participants) of public behavior is exempt, except where all of the following conditions exist:

1. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects.

2. The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability.

3. The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

Collection or Study of Existing Data

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects, is exempt.

Public Benefit or Service Program Research

Unless specifically required by statute, research which involves the study, evaluation or other examination of programs under the Social Security Act, or other public benefit or service programs is exempt from review. This includes research of procedures for obtaining program benefits or services, possible changes in or alternatives to those programs or procedures, and possible changes in methods or levels of payment for benefits or services under those programs.

However, if it determined that a research or demonstration project which would be considered exempt under these criteria presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project, written informed consent of each participant or subject must be obtained before any federal funds may be expended.

Investigational New Drugs or Devices

The IRB is responsible for complying with the federal guidelines for investigational new drug or device certification requirement (21 CFR 312.22-23). The following procedures will be used to meet this requirement:

1. The IRB will identify the test article (i.e., drug, biologic, or device) in the certification to DHHS when the proposal involves a test article and will state whether the 30-day interval required for test articles has elapsed or was waived by the Food and Drug Administration (FDA).

2. If the 30-day interval has expired, the IRB will state whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human subjects.

3. If the 30-day interval has not expired and a waiver has not been issued, the IRB will send a statement to DHHS upon expiration of the interval.

IV. Tests for Research

When dealing with data gathering within the context of training, demonstration, or service projects, you may want to ask yourself several questions to determine if any aspect of your work is research as it might be related to human subjects for review:

1. Do you anticipate in advance of conducting the project that you will analyze, interpret, and disseminate the findings or your investigation?

2. Will you seek out subjects (or settings that contain subjects) for your training, demonstration, or service project, rather than the subjects seeking the service or training from you in their normal pursuit of professional services?

3. Might the knowledge you gain from your encounter with the subjects be applied beyond the service of training project to similar encounter so as to lead a new procedure or process?

If you answer yes to any of these questions, then your training, demonstration, or service project has a research component. See IRB Checklist at ORIC webpage.

V. Instances of Non-research

There are numerous forms of data gathering from human beings that do not constitute research within the context of human subjects review regulations. Some examples are:

1. Data gathering for classroom training in research methods for which the only foreseeable purpose is teaching. In other words, neither the instructor nor the student can foresee or anticipate any dissemination of the data gathered beyond the classroom situation. See Appendix D: Student Research Activities.

2. Data gathered for administrative purposes alone within the context of the normal efforts of a department or an institution to find out what is happening or how to improve services or operations. In other words, no dissemination of the information outside the unit or institution is foreseen or anticipated.

3. Evaluation data gathered for a contractor about a project or operation for which he or she is responsible, if neither the researcher nor the contractor intends or anticipates the dissemination of the data.

All these categories of data gathering fail to be research because there is no foreseeable dissemination of the data. Any record of the data (or interpretations and analyses of the data) remains private (used only for purposes that are appropriate to the class, institution, or agency in the normal conduct of its work).

VI. Types of Expedited Research

Types one (1) through nine (9) pertain to both initial and continuing IRB review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which an investigational device exemption application (21 CFR part 812) is not required; or

(c) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and the health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(a) hair and nail clippings in a non-disfiguring manner;

(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

(c) permanent teeth if routine patient care indicates a need for extraction;

(d) excreta and external secretions (including sweat);

(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;

(f) placenta removed at delivery;

(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the success is accomplished in accordance with accepted prophylactic techniques;

(i) mucosal and skin cells collected by bucccal scraping or swab, skin swab, or mouth washings;

(j) sputum collected after saline mist nebulization

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from DHHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows where:

(a) 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;

(b) no subjects have been enrolled and no additional risks have been identified;

(c) the remaining research activities are limited to data analysis.

9. Continuing review or research, not conducted under an investigational new drug application or investigational device exemption where 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 that minimal risk and no additional risks have been identified.

VII. Criteria for IRB Approval of Research

Prior to approving research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized

(a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In

evaluating risks and benefits the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

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 this policy.

5. Informed consent will be appropriately documented in accordance with, and to the extent required by this policy.

6. Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects.

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

8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect the rights and welfare of these subjects.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review-expedited or convened-utilized by the IRB.

Preemption of Laws

The informed consent requirements in this policy are not intended to preempt any application federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

APPENDIX D
STUDENT RESEARCH ACTIVITIES

Independent Study Projects and Research, Scholarly, & Creative Activities (RCSA) Grant Projects

All research at UCO that involves human subjects, including undergraduate and graduate student projects, are required to obtain Institutional Review Board (IRB) approval prior to beginning the research (see IRB Application webpage for instructions and form). IRB approval is required regardless of whether the activity is funded or not. Failure to obtain IRB approval prior to beginning data collection could jeopardize your data, prevent you from publishing the results, and place the university and yourself in violation of federal regulations, which could imperil all federal funding to the university.

All students will need a Faculty mentor as a Co-PI on the IRB application. The faculty mentor must review and approve the IRB application and assume responsibility for the protections specified in the application.

All researchers including students will be required to complete online Protecting Human Participants in Research training before IRB approval for the project will be granted. Copies of the certificate for all project personnel should accompany the IRB application.

Research Assistants

Students assisting a faculty member on a research project that has already received IRB approval can be added to the project by addendum. The faculty member should write or email the UCO IRB and indicate the student's name, indicate in what capacity they will be working, and verify that the student has completed Protecting Human Participants in Research training (forward a copy of the certificate).

For students working on a side project directly related to a faculty member's approved research project, an addendum to the original IRB application with the updated information can request that the side project be added to the original approved study. All relevant changes and additions specified in the application should be outlined in an accompanying letter from the faculty mentor.

Education and Training:

In-class Activities

Some classroom exercises do not meet the definition of research and do not fall under the auspices of the UCO IRB. These include in-class activities where 1) the students use each other as subjects, 2) the intent is for educational purposes only and not to add new or expanded knowledge, 3) where the results will not be made public outside the classroom, AND 4) there is minimal risk. These should be projects already developed by the instructor.
When the data are collected from students in class there could still be potential privacy issues, so students should be instructed about the protecting the confidentiality of human subjects' data. Information should be included in the syllabus specifying what the expectations for students are and instructors should be sensitive to potential issues that might arise and have a contingency plan in place. Feel free to discuss these issues with the IRB chair.

Independent Projects

For courses where each student designs and implements an independent project (under the direction of the instructor) and collects identifiable information from human subjects, each student will need to submit an individual IRB application with the course instructor as Co-PI (see Independent Study Projects above).

Group Projects

Group research projects, where groups of students enrolled in a course work together to collect data from individuals outside the classroom, should be submitted with course instructors as the PI and include a list of names and signatures of all group members indicating that they have read and understand the project and rules for protecting human subjects and agree to abide by the IRB regulations. Documentation of training in Protecting Human Participants in Research is needed for Group Projects.

Masters Theses or Projects

A special class of data record that is always research is the thesis or project. By accepting a thesis or project, the University disseminates its contents for use by others. Therefore, a thesis or project that involves the use of human subjects must always be submitted for review or for certification.

APPENDIX E
STUDENTS AND EMPLOYEES AS PARTICIPANTS

Students and employees recruited as research subjects are more vulnerable to coercion because of the possibility that they may perceive grades, employment, or other benefits as dependent upon or affected by their participation in research. Students and employees are at greater risk of experiencing negative ramifications related to an inability to maintain strict confidentiality and because more information is known about these individuals than is collected during the course of the research project.

The IRB considers these individuals to be more vulnerable to coercion (real or perceived) and to issues related to confidentiality than individuals not affiliated with the University and, therefore, will apply additional safeguards to protect their rights and welfare.

Students as Research Participants

Note: For Classroom-Based Research Projects Conducted by University Students, refer to SOP Appendix D: Student Research Activities.

1. Justification for Targeting Students. Investigators who plan to conduct research with only students as participants must be able to provide a rationale, other than convenience, for restricting the research project population to students and must show that the recruitment method does not lead potential subjects to think they will be penalized by not participating or receive preferential treatment by participating. Examples of such rationale include: a) participation as a valuable educational experience demonstrated by a substantive plan for debriefing, b) the need for an alternative mechanism for research project compensation (e.g. class credit or extra credit) due to lack of monetary resources, c) the existence of a formal student subject pool and related departmental policy. Neither Investigators nor Class Instructors may impose penalties on students who fail to show up for scheduled research-related appointments. Recruitment materials should minimize the potential for undue influence or coercion.

2. Direct Recruitment. Investigators may make research project-related announcements (such as research project title and investigator contact information) or provide recruitment materials (such as fliers) to students in University classrooms, so long as the Investigator is not also the Class Instructor.

3. Indirect Recruitment. IRB-approved recruitment materials may be posted on the University campuses after the Investigator has received the appropriate permission, if necessary.

4. Mass Email Recruitment. Investigators seeking approval to email recruitment materials or research project announcements to students must explain this recruitment method in the protocol. Once approved by the IRB the email blast must be sent to Academic Affairs for approval, then sent to IT for implementation.

5. Consent. A student may not be compelled to participate in research as part of a course requirement. Investigators must ensure that students know that they may choose not to participate in the research and that their decision will not affect their grade, class standing, or relationship with any instructor. Similarly, research participants must be made aware that their participation will not lead to any preferential class-based treatment.

6. Course Credit. If research participation is required as part of the course assignments, an alternate means of earning equivalent course credit for an equivalent commitment of time and effort must be made available for those who cannot or choose not to participate in a research project.

* If extra credit is offered for participation in a research project, the opportunity to participate must be made available to all students. The amount of extra credit must reflect the amount of time required for research participation.

7. Use of Class Time. IRB submissions proposing the use of class time for research should include an explanation of the benefit of the research to all of the students, especially those who choose not to participate in the research project. Specifically, the Investigator should explain how participation in the research would be a learning experience for the students and how the research project is relevant to the course being taught in that class. An alternative activity should be provided for students who choose not to participate.

8. Use of Class Assignments in Research. Instructors who use their students' class assignments (e.g., journals, term papers) in research projects will be required by the IRB to obtain consent from the students who are willing to be research participants. The Investigator must make arrangement for the consent process to occur after the class grades are posted or to be conducted by another member of the research team.

9. Additional safeguards may be required to protect the privacy and confidentiality of University student research participants. Certain additional protections for students and parents are required by federal regulations. For example, the proposed use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA). If any University records of the research participants are to be used, then the research participant must give permissions for records access in the consent documents. It is the responsibility of the Investigator to comply with any additional federal, state, or local regulations.

Student Research "Pools"

1. In some departments, University students are offered the opportunity to participate in research projects. Examples include participation for course credit as part of a course requirement, participation for "extra credit" in a course, or participation in exchange for compensation.

2. A University student may not be required to participate in research for course credit unless a comparable non-research alternative is also offered. To minimize the potential for coercion, alternatives to participating in research for course credit that are offered must be comparable in terms of time, effort, and fulfillment of course requirements. Examples may include reading and/or writing research papers, attending research presentations offered by faculty, or observing performance of research studies.

3. All research participants, including University students, must be free to withdraw from participation at any point in research project without penalty. University students who withdraw from a research project offered for course credit must receive the full course credit offered for participation. When compensation is offered, a pro-rated amount of compensation must be given to a University student who does not complete the entire research project.

4. Every University student participating in a research project must give informed consent for that specific research project as described by SOP 702: Documentation of the Informed Consent Process; federal regulations; and IRB policies. Parental permission and assent are required for any University students (including high school students taking University courses) who meet the regulatory definition of minors.

Recruitment of Employees

1. Justification for Targeting Employees. Investigators who plan to include only University employees must be able to provide a rationale, other than convenience, for restricting the research project population to employees and must show that the recruitment method does not lead potential subjects to think they will be penalized by not participating.

2. Direct Recruitment. Investigators may make research project-related announcements or provide recruitment materials to employees at regular meetings. However, recruitment methods should permit employees to self-identify as interested in participation in a way that maintains confidentiality. For example, employees should be provided with contact information for a research project team member whom they may

contact for more information. When possible, employees should not be recruited for participation by their direct supervisor.

3. Indirect Recruitment. IRB-approved recruitment materials may be posted on the University campuses after the Investigator has received the appropriate permission, if necessary.

4. Mass Email Recruitment. Investigators seeking approval to email recruitment materials or research project announcements to employees must explain this recruitment method in the protocol.

5. Consent. An employee may not be required to participate in research as a condition of employment. Investigators will ensure that employees know that they may choose not to participate in the research and that their decision will not affect their employment or benefits at the University. Similarly, research participants must be made aware that their participation will not lead to any preferential employment treatment.