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 & Grants, and beginning July 2010, it became part of the Office of Research Compliance (ORC), a freestanding unit of Academic Affairs. 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).

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 IRB Chair is the Director of Research Compliance, 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 ORC website)
PI/Co-PI-Principal Investigator/Co-Principal Investigator
Staff- Staff of Office of Research Compliance
COI-Conflict of Interest
SOP-Standard Operating Procedure
ORC-Office of Research Compliance
RAC-Research Advisory Council
Links referenced throughout the Manual:

Office of Research Compliance website:
http://broncho2.uco.edu/academicaffairs/Office%20of%20Research%20Compliance.htm

The Belmont Report:
http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

Federal Guidelines:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
UCO SOP MANUAL
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**QA 900: Quality Assurance**
901 Checklists or procedures to measure performance consistency
SOP 101
Training

1.0 POLICY

All members of the IRB are required to undergo training in human subjects 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 course in Protecting Human Research Participants (PHRP) or CITI certification, with recertification to take place every two (2) 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 2 years) NIH-PHRP certification.
2.4 The Chair shall provide annual training for the university community.
2.5 The Chair will verify that all investigator(s) and research team members working with human subjects have current NIH-PHRP certification.
2.6 The Chair will obtain frequent external professional IRB training

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.
3.2.3 The Chair shall publicize the certificate requirements to the university community.

3.3 IRB members are required to complete the PHRP 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 2 years).

3.4 All Continuing Review applications will be checked to assure that certification is current. [SOP 803]

4.0 REFERENCES


5.0 APPENDIX

SOP 803
phrp.nihtraining.com
ORC 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 Office, the 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 will review all SOPs annually to insure alignment of current procedures and policies.
3.2 The Chair 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 ORC website and in the IRB Office.
3.5 An updated copy of the UCO SOP Manual will be provided to the Provost annually.

01/12/2011
4.0 REFERENCES

45 CFR 46.103 (b).

5.0 APPENDIX

ORC 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.

3.0 PROCEDURES

3.1 IRB members will not be present 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 to the Chair [See SOP 202] selected by the full board (Chair must abstain).
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 to the Chair shall serve as acting Chair during the proceedings related to the above.

3.3 An assistant to the 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
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.

Provisions are available for classroom activities involving research (see Policies on Student Research, on our website).

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 Chair will hold at least one educational presentation per semester, open to the university community to advise investigator(s) about the IRB process.

3.4.2 The Chair will be available to meet individually or in small groups with investigator(s) for advice about the IRB process.

4.0 REFERENCES

45 CFR 46.109-111

5.0 APPENDIX

The Belmont Report
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 IRB Chair to hire and supervise the administrative personnel necessary for the daily operations of the IRB.

2.0 RESPONSIBILITIES

2.1 The Chair shall hire an administrative assistant to assist with daily operations of the IRB Office.
2.2 The Chair shall be responsible for managing the administrative assistant and IRB Office.
2.3 The administrative assistant 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 to the Chair.

3.0 PROCEDURES

3.1 The Chair shall follow university regulations regarding employment and evaluation of IRB personnel.
3.2 The Chair shall provide training and supervision to the administrative staff to complete their duties.
3.3 The administrative assistant 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 eight (8) regular members, including a legal or community representative having no affiliation with the university (plus one community alternate); a person specialized in ethics or with a non-science background; and the Chair of the IRB. Both the Vice Provost and the Director of the Office of Research & Grants shall serve as ex-officio members, with non-voting status to provide administrative support 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. Each member will serve a three year term with the possibility of renewal. Appointments will balance representation across colleges and expertise in matters related to IRB issues. When necessary or desired, the Chair of the IRB may appoint one or more ad hoc members 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 Chair 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 Compliance. Daily operations are managed by the Director of Research 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 primary reviewer for the applications to be presented at the meeting.
2.3 Each IRB member agrees to serve as an assistant to the 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 Assistants to the 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. [See SOP 801]

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 log in and establish a file for submitted applications.

3.0 PROCEDURES

3.1 All faculty, staff, or students planning on engaging in research involving human subjects [See SOP 101] will contact the IRB Chair of their intent, in advance of beginning those activities, in one of the following ways:

1) Complete the most current version of an IRB Application (available at ORC website) and submit one electronic (irb@uco.edu) and one signed paper version of the application to the UCO IRB (Office of Research Compliance, 216ADM) including the following required documentation [See SOP 801]:

   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
   e) Required signatures from all investigator(s), Chair, and Dean

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f) Copies of current (within 2 years) NIH-PHRP training certification for all investigator(s) and team personnel working directly with subjects or identifiable data

g) A signed personnel agreement for those members who have not signed the application

2) Complete an IRB Checklist (available at ORC website) and submit an electronic (irb@uco.edu) or paper version (Campus Box 159)

3) Contact the IRB Chair by phone, email, or in person with specific questions regarding the necessity for IRB approval

3.2 The IRB Chair will assist investigator(s) considering research with human subjects.

3.2.1 The assistance will include:

1) Updated news, forms, checklist, and guidelines on the website
2) Annual reminders and new requirements posted to Centralities
3) Annual training sessions for various sectors of the university community

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 contact the investigator by phone and/or email about the decision regarding the necessity for completion of an IRB Application.

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 submitted paper applications for required signatures, time-stamp as received, assign a sequential number to the file, and enter information into the database. Prepared applications or other forms will then be given to the Chair. [See SOP 105]

4.0 REFERENCES

45 CFR 46.109

5.0 APPENDIX

Appendix C

01/12/2011
SOP 801
SOP 102
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 SOPs 301 and 801]

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.

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 full board review and indicate the criteria number.

4.0 REFERENCES

45 CFR 46.101

5.0 APPENDIX

Appendix C
IRB Checklist
SOP 301
SOP 801
SOP 303
IRB Meeting Administration and Communication

1.0 POLICY

The IRB shall review and have authority to approve, approve with caveat, require changes in prior to approval, defer, or disapprove 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 Chair (or other designated reviewers) 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 Hard and electronic copies of documents and supportive materials will be sent to members no later than 48 hours 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.

3.4 Either the Chair or a designated primary reviewer will provide a summary of each application to be considered by the IRB at the meeting.

3.4.1 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 modifications and approve when all are met
3) **defer** in those cases where extensive modifications are needed and set another date for full board review
4) **disapprove** in those cases where no amount of modification would make an application approvable.

3.5 IRB staff will type and send minutes to Chair.

3.5.1 Once proofed, minutes are sent to each member.
3.5.2 At the following meeting, corrections are solicited.
3.5.3 Final copies are kept by the Chair and IRB staff.

4.0 REFERENCES

45 CFR 46.111

5.0 APPENDIX

SOP 202
SOP 401
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 deliver a signed copy of the application to the IRB Office prior to beginning any research related activities. [See SOP 801]
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, which can include the Chair, appointed IRB members, or outside experts.
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 one electronic (irb@uco.edu) and one signed paper version of the Application to the UCO IRB (Office of Research Compliance, 216 ADM). [See SOP 801]
3.2 IRB Office staff will log the application into the database, distribute copies 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, and paper copy file system of all applications and related documentation and communications.

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 and or 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 Chair 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
4) Informed Consent Form, Information Sheet, or Waiver of Consent
5) Documentation of completion of training in human subjects research

3.5 Reviewers will review and send written comments to the Chair 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 601
SOP 801
SOP 402
Policies and Procedures for Continuing Review

1.0 POLICY

The IRB will conduct continuing review of all IRB-approved research at intervals 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. Approved projects can remain active for a total of three (3) years before a new application is needed or a waiver is granted.

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. [See SOP 803] 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 In those cases where the anniversary marks the third anniversary of approval, the Chair will decide if a new application is needed or whether to grant a one year waiver.

2.3.1 The Chair shall waive the need for a new application in those cases where no substantive changes have been made in the protocol.

2.4 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.

2.5 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.

2.6 IRB Office staff will update files and database.

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

3.1 Investigator(s) will complete the necessary form and send a paper copy or email attachment (irb@uco.edu) to the IRB Office by the anniversary date.

3.1.1 If the project is still active, they will complete the IRB Continuing Review Form. [See SOP 802].

3.1.2 If the project has been completed, they will complete a Closure Request Form. [See SOP 805]

3.2 The IRB Chair will make the following determinations:

1) For projects initially approved by exempt or expedited review, requesting continuation of research activities without problems, an email will be sent indicating continuing approval and the next filing date for a continuing review.

2) For projects initially approved by exempt or expedited review, requesting continuation of research activities with a problem, the Chair will contact investigator(s) for further information and will make a determination of the action necessary to remedy the problem. Depending on the information provided, the Chair will either:

   a) Direct investigator(s) to complete a form for Unanticipated Problems (available on ORC website) [See SOP 404] and if the issue(s) are resolved, approve continuation of the approval, or
   b) Schedule a hearing at the next IRB meeting to discuss and vote on further action.

3) For projects initially approved by full board review, the Chair will schedule a time at the next IRB meeting to discuss and vote on further action.

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 803
SOP 805
SOP 403
Preparing and Submitting Amendments to an Approved IRB

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 of 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. In this case, all documentation necessary to make a determination of the appropriateness of the amendment must be submitted ten (10) working days before the monthly IRB meeting. 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 prepare all documents and submit to the IRB by email or campus mail. [See SOP 802]
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 initial review, which will determine the type of amendment 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 assistants 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 802
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 The Chair will complete a Protocol Violation Report or an Unanticipated Problem Report.

3.4 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]

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
Protocol Violation Report Form
Unanticipated Problem Report Form
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 or cognitively 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. [See SOP 801]

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.

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 noted stipulations, defer, or disapprove 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 801
SOP 502
Review of 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 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 noted stipulations, defer, or disapprove 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.
3.6 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

01/12/2011
SOP 503
Research Involving Deception

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.

3.4.1 A notice of the need for a Continuing Review Form shall be sent to the PI.

4.0 REFERENCES

45 CFR 46.116(d)

5.0 APPENDIX

Continuing Review Form
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 sent by campus mail.

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.

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 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.

3.7 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
Appendix C
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 404]

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.

3.4 The Chair will compile and report the results of the annual review of IRB applications by the RAC. [See SOP 901]

4.0 REFERENCES

45 CFR 46.108; 112

5.0 APPENDIX

Appendix C
Reviewer Checklist
SOP 404
SOP 901
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 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.

3.3.1 The reviewer(s) shall complete and sign a Waiver of Informed Consent where appropriate. [See SOP 703]
3.3.2 The reviewer(s) shall complete and sign a Waiver of Documentation of Consent where appropriate. [See SOP 703]

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 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. [See SOP 805]

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

5.0 APPENDIX

SOP 805
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 The Chair and other reviewers 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 practicable 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
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
Initial Submission

1.0 POLICY

When research involving human subjects is to be performed by any UCO investigator, or in any University facility or with the aid of any University equipment or other resource over which he/she has responsibility or control, that investigator must obtain IRB approval or certification that the activities are not regulated by the UCO IRB. This may be done by contacting the Chair of the IRB for assistance in making this determination or completion and submission of an IRB application for approval.

2.0 RESPONSIBILITIES

2.1 The investigator shall notify the IRB of the proposed research by submitting a completed IRB Application, along with supporting materials.

2.2 When research involves vulnerable populations, the investigator will notify the IRB prior to application submission to discuss extra provisions. [see SOP 501]

2.3 The investigator shall not involve human subjects in the proposed research until the IRB has informed him/her of full approval for the use of human subjects in the research. Any specified Caveats must be completely fulfilled before data collection may begin. Only approved, stamped Informed Consent/Assent Forms may be used.

2.4 The investigator shall abide by the decisions of the IRB requiring changes (for approval) or disapproving the research. When the proposed research is to be funded by a federal agency, and the agency’s regulations permit, an investigator may appeal an IRB decision to the appropriate official. However, for research activities not submitted to federal agencies for sponsorship, the decision of the IRB shall be final.

2.5 The investigator shall obtain informed consent from all subjects in accordance with the requirements of this policy.

2.6 The investigator shall ensure that subject consent is documented and retained in the manner prescribed by the IRB for a period of 3 years.

2.7 The investigator shall maintain consent documents signed by subjects in a repository approved by the IRB.

2.8 The investigator shall maintain the confidentiality of data obtained from subjects in the manner required by the IRB.

2.9 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 or that the project is still active. [See SOP 402; SOP 805]

2.10 The investigator shall promptly report to the IRB any proposed changes in the research which would result in a significantly different involvement of human
subjects and shall obtain the approval of the IRB prior to the changes being made, except where necessary to eliminate apparent immediate hazards to subjects. [See SOP 802]

2.11 The investigator shall promptly report any injuries to human subjects resulting from the research to the IRB. The investigator shall also promptly report any unanticipated problems which involve risks to the subjects or others. [See SOP 806]

2.12 The investigator shall promptly report to the IRB any proposed involvement of human subjects in research which previously had no plans, or only indefinite plans, for subject involvement and shall obtain the approval of the IRB prior to the involvement of any subjects.

2.13 The investigator shall promptly report to the IRB any serious or continuing non-compliance with the requirements of this policy or of the IRB on any research with which he/she is associated. [See SOP 404]

2.14 The investigator shall notify the IRB, and cooperate with the IRB in notifying the Food and Drug Administration, when he/she anticipates that an investigational new drug or device exemption will be required.

3.0 PROCEDURES

3.1 Investigator(s) will submit a completed IRB Application including any existing proposal or project description, samples of proposed informed consent forms, and copies of any measurement instruments.

3.1.1 If the investigator is unsure whether the project is research or involves human subjects, they may complete and submit an IRB Checklist to the IRB Office. They will then be contacted for further information or discussion.

3.2 Investigator(s) will not involve human subjects in the proposed research until the IRB has informed him/her of full approval for the use of human subjects in the research.

3.2.1 Any specified Caveats must be completely fulfilled before data collection may begin.

3.2.2 Only approved, stamped Informed Consent forms may be used.

3.3 Upon notification of the anniversary of the approval (or the specified monitoring interval) Investigator(s) will submit a letter or email to the IRB Chair indicating that the project has been completed and that all identified data have been disposed of in the manner approved in the IRB Application and will complete and submit a Closure Request Form. If the project is still active, the PI must complete a Continuing Review Form indicating the continuing status.
3.4 Investigator(s) will report any proposed changes in research by completing an IRB Amendment Form.

3.5 Investigator(s) will complete an Unanticipated Problems Form to report any injuries to human subjects resulting from the research or report any unanticipated problems which involve risks to the subjects or others. Initial inquiries may be verbal but must be followed by submission of the form by email or campus mail.

3.6 Investigator(s) will complete a Protocol Violation/Deviation Report to the IRB for any serious or continuing non-compliance with the requirements of this policy or of the IRB on any research with which he/she is associated.

4.0 REFERENCES

45 CFR 46.101;102;109;111;113

5.0 APPENDIX

Appendix B
Appendix C
Amendment Form, Continuing Review Form, Protocol Violation Report, Closure Request Form, Unanticipated Problem Form, all available at: ORC website
SOP 402
SOP 404
SOP 802
SOP 805
SOP 806
SOP 802
Amendments and Changes

1.0 POLICY

Any changes to an approved research project which would result in a different involvement of human subjects shall require approval of the IRB prior to the changes being implemented, except where necessary to eliminate apparent immediate hazards to subjects. Any proposed involvement of human subjects in research which previously had no plans, or only indefinite plans for subject involvement, shall obtain the approval of the IRB prior to the involvement of any subjects.

2.0 RESPONSIBILITIES

2.1 Investigator(s) shall promptly report to the IRB any proposed changes in the research and shall obtain the approval of the IRB prior to the changes being made, except where necessary to eliminate apparent immediate hazards to subjects. This includes but is not limited to changes in the number or type of subjects to be recruited, changes in procedures used in recruitment or recruitment materials (flyers, etc.), changes to approved research or recruitment sites, changes to the research team (additions or deletions), changes in the procedure(s) including manipulations, assessments, etc., and changes, additions, or deletions to the consent or assent form(s).

3.0 PROCEDURES

3.1 Investigator(s) will request approval for any proposed changes in research by completing an IRB Amendment Form. [See SOP 403]
3.2 Investigator(s) will provide a description and justification for the changes.
3.3 Investigator(s) will provide the required documentation for the proposed changes. These may include signed personnel agreements, letter(s) of permission to recruit subjects from established groups, companies, or classes, a description of experimental procedures, revised recruitment materials (flyers, advertisements, etc.) or revised consent/assent form(s). The latter requires a copy of the original, the revised with changes highlighted, and a clean copy of the revised form.

4.0 REFERENCES

45 CFR 46.103; 111; 116
21 CFR 50.25; 21 CFR 56.108; 111

01/12/2011
5.0 APPENDIX

Appendix C
Amendment Request Form
SOP 403
1.0 POLICY

The IRB is required to monitor the status of each approved research project at least annually. The period of monitoring will be specified at the time of approval depending on the degree of risk to the subjects or other details of the protocol. The period of monitoring may be changed by a vote of the IRB following an investigation of a policy violation, unanticipated event, or non-compliance. Approved projects can remain active for a total of three (3) years before a new application is needed.

2.0 RESPONSIBILITIES

2.1 Upon notification, an Investigator shall notify the IRB for the need to continue an approved research project beyond the anniversary date (or the specified monitoring interval).

2.2 The investigator shall complete the Continuing Review Form when requested.

2.3 The investigator shall cease all research activities if there is a lapse in IRB approval.

3.0 PROCEDURES

3.1 Upon notification of the anniversary of the approval (or the specified monitoring interval), the Investigator will complete a Continuing Review Form indicating the current status. [See SOP 402]

3.2 If the project is completed, the Investigator shall complete the Closure Request Form and notify the IRB by letter or email that the project is complete.

3.3 Projects that will be continued but require changes, will require completion of both a Continuing Review Form and an IRB Amendment Form.

4.0 REFERENCES

45 CFR 46.103(b)(4)

5.0 APPENDIX

Appendix C
IRB Continuing Review Form
IRB Amendment Form
SOP 402
SOP 804
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

2.1 The Investigator shall promptly notify the IRB of the completion of a study.
2.2 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

3.1 Prior to the anniversary date or specified monitoring period, when a study has been completed, the Investigator shall submit:

1) a letter or email to the IRB Chair indicating that the project has been completed and that all identified data have been disposed of in the manner approved in the IRB Application and
2) a Closure Request Form

3.2 Upon notification of the anniversary of the approval (or the specified monitoring interval) Investigator(s) will submit:
1) a letter or email to the IRB Chair indicating that the project has been completed and that all identified data have been disposed of in the manner approved in the IRB Application and
2) a Closure Request Form

3.3 The IRB will send email to PI acknowledging receipt of Closure Request Form and confirming file closure.

3.4 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
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. [See SOP 803]
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 803
1.0 POLICY

In the conduct of human subjects’ research all team members are required to report any 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.

2.0 RESPONSIBILITIES

2.1 All study personnel are required to report an adverse event to the IRB Office as soon as possible.

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 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 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

Unanticipated Problem Report
SOP 404
SOP 901
Procedures for Measuring Performance Consistency

1.0 POLICY

UCO will exercise appropriate administrative review, carried out at least annually, to ensure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of 45 CFR 46 and this policy. This administrative review shall be carried out by members of the Research Advisory Council (RAC). To ensure that reviews are carried out with consistent attention to details, all reviewers will complete a review checklist.

2.0 RESPONSIBILITIES

2.1 The Chair shall initiate an annual review of files from the previous year.
2.2 The RAC shall be given 10 randomly selected files to review.
2.3 The Chair will summarize the data and provide a report for the IRB and the Provost.

3.0 PROCEDURES

3.1 The Chair will meet with the RAC and provide files, instructions, and review forms.

3.1.1 IRB staff will randomly select 10 files from the previous year’s approved files (excluding those from current RAC members).
3.1.2 RAC members will be reminded of the confidentiality of the information and process.

3.2 RAC members will be given 10 days to complete review forms and return all materials to the IRB Office.
3.3 The Chair will summarize the responses and prepare a report on the quality of the review process. The report will be submitted to the IRB and Provost.

4.0 REFERENCES

45 CFR 46.103(a); (e)
45 CFR 76