

Institutional Review Board Policies and Procedures (Internal)

- I. Purpose and Governing Principles: The Institutional Review Board (IRB) at Barton College exists to protect the rights and welfare of human participants in research. All faculty, students, and staff are expected to comply with the following IRB policies and procedures which have been established in the spirit of the federal regulations of the U.S. Department of Health and Human Services, policy on the Protection of Human Participants (45 CFR § 46).

- II. Authority: The Institutional Review Board was established in October 2004 under the authority of the Office of the President and the Board of Trustees of Barton College. The Institutional Review Board is a workgroup of the Office of the President and as such reports to the President or his designee. The Institutional Review Board is charged with reviewing research studies, approving those which comply with standards for ensuring human participant protections, and, when necessary, suspending or terminating studies that violate ethical principles. Only research studies (as defined below) must be submitted to the IRB for approval consideration.

- III. Membership: The Institutional Review Board will have a sufficient number of members to represent the welfare of the participants, the investigators, and the institution. In addition, membership will reflect regulatory recommendations in terms of member qualifications and representation (including gender, ethnicity, profession, affiliation, and degree of scientific training).

- IV. IRB Management:
 - A. IRB Director:
 1. Selection and appointment: To ensure compliance with applicable federal and state laws and regulations and with College policies and guidelines involving the protection of the safety, rights and welfare of human subjects in research, the President is designating the position of IRB Director. The position will be filled by the Institutional Research Director.
 2. Length of term/service: The IRB Director will have a continuous appointment with no term limit.
 3. Duties:
 - a) The Director is responsible for identifying and helping to resolve regulatory, procedural, and ethical issues related to human subjects research. The Research Director works with the IRB, its executives, and researchers to address research protocol and compliance issues.
 - b) The Director will be charged with directing audits that are conducted to assess the Investigator's compliance with federal, state, and local law and policies, identify areas for improvement, and suggest recommendations based on existing policies and procedures.

- c) The Director will also be charged with halting any project approved by the IRB Board that is deemed in non-compliance with the rules and regulations set forth in the national IRB guidelines. Halted projects by the IRB Director will need to be re-examined by the full IRB Board.
 - d) The IRB Director is a non-voting regulatory agent.
 - e) The Director will serve as the “President’s designee” to solve IRB issues and concerns.
 - f) The IRB Director may recommend policy changes for approval by the President if necessity arises.
4. Removal: The Director may be replaced by the President at the end of his/her contract year or the position may be reassigned if a need arises.

B. Chairperson:

- 1. Selection and appointment: The IRB Chair is selected by the President in consultation with the IRB members based on qualifications and ability to lead. The appointment is at the invitation of the Office of the President and will occur prior to the commencement of the academic year.
- 2. Length of term/service: The Chair serves a one year term (August through the end of July) and, at the discretion of the President, is eligible to be appointed for a second term. The maximum term as Chair is two sequential one-year terms. If a member is appointed Chair during the year due to a vacancy in that office, that partial year is not counted in the two-year limit.
- 3. Duties:
 - a) At the beginning of each academic year, the Chair, with the help of the Vice-Chair, will conduct an orientation session for new members of the IRB.
 - b) In collaboration with members of the IRB, the Chair sets the annual meeting schedule.
 - c) The Chair sets the agenda and forwards it, along with all copies of all project proposals, to the Institutional Research Representative seven days in advance of the meeting.
 - d) The Chair will have primary responsibility for conducting the IRB meetings to ensure that they are efficient and effective.
 - e) The Chair will consent to project renewal/termination form letters being sent out by the Institutional Research Representative under his/her name sixty and thirty days prior to the exhaustion of the initial project approval period.
 - f) The Chair serves as the point of primary contact for the IRB, responding to student, faculty/staff, IRB and investigator questions within the same or next business day.
 - g) The Chair will forward to the Institutional Research Representative copies of all correspondence between the IRB and the investigators for storage with project files.
 - h) The Chair, in collaboration with the President or his/her designee, plans and implements annual faculty/staff IRB orientation to be held during FAST Week.

- i) The Chair, in collaboration with the members of the IRB, plans and implements the orientation of new IRB members.
 - j) In collaboration with the members of the IRB, the Chair reviews IRB policies/procedures and makes recommendations for consideration by the President to ensure adherence to commonly accepted and federally mandated IRB practices.
 - k) The Chair must remain current on NIH regulations and IRB issues relating to the protection of human subjects to better inform the functioning and professional development of the IRB and its members.
 - l) The Chair ensures that project decisions, including determinations made outside regularly scheduled IRB meetings, are made and communicated to investigators and other committee members within five days.
 - m) The Chair will review all serious adverse event reports (SAEs) to determine if one or more of the following is needed: A) immediate action to address the safety of the subjects, B) an emergency meeting of the IRB, C) an emergency meeting with the President.
 - n) The Chair, in collaboration with the President, will review and evaluate the performance of the IRB. The President will annually evaluate the Chair.
4. Removal: The Chair may be removed at any time by the President for the benefit of the functioning of the IRB or the institution.

C. Vice Chairperson

- 1. Selection and appointment: The IRB Vice-Chair is selected by the chairperson in consultation with the President based on qualifications and ability to lead. The appointment is at the invitation of the Office of the President and will typically occur prior to the commencement of the academic year.
- 2. Length of term/service: The Vice-Chair serves a one year term (August through the end of July) and, at the discretion of the President, is eligible to be appointed for a second term. The maximum term as Vice-Chair is two sequential one-year terms. If a member is appointed Vice-Chair during the year due to a vacancy in that office, that partial year is not counted in the two-year limit.
- 3. Duties:
 - a. Serves in collaboration with the Chair to assure that the duties of the Chair are fulfilled.
 - b. Fulfills the duties of the Chair in his/her absence.
- 4. Removal: The Vice-Chair may be removed at any time by the President for the benefit of the functioning of the IRB or the institution.

D. Institutional Research Representative:

1. Selection and appointment: The President shall appoint an Institutional Research Representative. The Institutional Research Representative serves as a full voting member of the committee and as IRB secretary. When necessary, the Institutional Research Representative also serves as the President's representative during meetings.
2. Length of term/service: The Institutional Research Representative will have a continuous appointment on the IRB. The individual appointed will serve from August through the end of July and is not subject to a term limit.
3. Duties: The Institutional Research Representative will have the same duties as a regular member and, concurrently, will serve as administrative support for the IRB.
 1. The Institutional Research Representative reserves rooms for all IRB meetings based on annual meeting schedule.
 2. The Institutional Research Representative distributes meeting packets including projects for review and agenda no fewer than ten days in advance of any regularly scheduled meeting.
 3. The Institutional Research Representative will record all minutes of IRB meetings using tape recording technology. Meeting minutes will be sent to all committee members and the Office of the President within two days of the meeting. Tapes of meeting minutes will be reused after the minutes are approved by the committee.
 4. The Institutional Research Representative will receive, document, and forward to the Office of the President all processed packets including processing documents, signed original forms, and signed original letters to investigators indicating IRB determinations within five days of the IRB meeting or Chair determination, in cases of exempt research, where the proposal decisions were determined.
 5. The Institutional Research Representative will send out, under the name of the Chair, project renewal/termination forms sixty and thirty days prior to exhaustion of initial approval period.
 6. The Institutional Research Representative will provide locked storage for IRB documents including communications, project packets, and official records.
 7. The Institutional Research Representative must maintain a current listing of proposals considered and their status for the IRB and the Office of the President.
 8. The Institutional Research Representative must remain current on NIH regulations and IRB issues relating to the protection of human subjects in support of the IRB.
4. Removal: The Institutional Research Representative may be replaced or substituted at the discretion of the President.

E. General Members:

1. Selection and Appointment: General members of the IRB are selected by the President based on qualifications, commitment, and ability. The appointment is at the invitation of the Office of the President and will occur prior to the commencement of the academic year.
2. Length of term: Each member serves from August to the end of the following July. Members of the IRB serve staggered two-year appointments. Members must rotate off the IRB after two consecutive terms and are eligible for reappointment after a one-year hiatus from serving on the committee. If a member is appointed in mid-term to fill a vacancy, that partial year does not count against the two-year term limit.
3. Duties: Members of the IRB must remain current on NIH regulations and IRB issues relating to the protection of human subjects.
4. Attendance Requirements: The important nature of the IRB requires that all members strive to fully participate in the work of the committee. As such members are strongly encouraged to attend all meetings. Lack of attendance or participation may prove cause for removal.
5. Removal: Members may be removed at the discretion of the President.

F. Training of IRB Chair and members:

1. Orientation: All IRB members are required to complete IRB training prior to voting on research submissions. Members are to complete online training offered at either <http://ohsr.od.nih.gov/IRBCBT/intro.html> or http://cme.cancer.gov/clinical_trials/learning/human_participant-protections.asp.
2. Training of New IRB Members: The Chair and the Vice-Chair will conduct an orientation session for all new IRB members.
3. Continuing education: All IRB members are encouraged to remain current in their knowledge of issues and topics of concern to institutional review boards at the local, state, national, and international levels. Continuing education can be accomplished by subscribing to the IRB Forum listserv, participating in annual online IRB training, or reading specialized publications such as the *IRB Advisor*, *IRB Ethics and Human Research*, or *Human Research Report*.
4. Reference materials (IRB library): A copy of *Institutional Review Board Member Handbook* by Robert Amdur, MD. is available for any IRB member to review from the Office of the President.

G. Compensation of IRB members: Serving as a member of the Barton College IRB is on a voluntary basis. Institutional members may use their service as part of their Professional Development Plan and evaluation materials, including, where applicable, for purposes of promotion and tenure.

H. Liability coverage for IRB members: In general, liability coverage for IRB members is provided by the umbrella liability policy of the institution.

- I. Resources (e.g., meeting area, filing space, reproduction equipment, and computers): Institutional Review Board meetings will be held on campus in venues providing sufficient space for members to confer about study submissions. The official copies of all records and files will be maintained in a locked file cabinet in the Office of Institutional Research. In addition, electronic copies of minutes, agendas, training sites, and policy manuals and protocols will be maintained in both the Office of Institutional Research and the Intranet in a limited access IRB folder. Information necessary for investigators will be housed on the Intranet in an IRB folder that may be accessed by the Barton community.

- V. Conflict of interest policy: Members of the IRB who have a conflict of interest regarding a specific project must recuse themselves during the review of that project. This restriction extends to participation in both the deliberation of and voting on the project.

- VI. Function of the IRB:
 - A. Conduct of Reviews: The function of the IRB is to conduct initial and continuing reviews of research studies performed by members of the Barton College community and by those external to the college seeking to conduct research at or in affiliation with the college.
 - B. Review Frequency: The IRB is responsible for determining whether a study may require more frequent (greater than annually) review.
 - C. Reporting: The IRB reports its proposal review determinations, as well as study modifications, adverse events, noncompliance, and suspensions or terminations of IRB approval to the President.
 - D. Device Studies: For studies involving devices (such as medical equipment), the IRB must determine during its deliberations whether the device poses a significant or nonsignificant risk.

- VII. Operations of the IRB:
 - A. Meeting Dates: Monthly meeting dates for the year are established by the IRB at the August meeting.
 - B. Meeting Packets: Meeting agenda, proposal packets, and other materials are to be distributed to members at least seven days in advance of the meeting.
 - C. Review Process: An electronic copy and one paper copy of all materials will be sent to the IRB Chair. (If there are items that cannot be sent electronically, then ten copies of those materials will be sent to the IRB Chair.) Upon receipt of a protocol package, the IRB Chair will review the package for completeness and content. If the package is found to be complete, the IRB Chair will begin the initial review process. He/she will check the package for the type of review.
 1. If the investigator has requested an exemption, and if the Chair agrees that that an exemption is appropriate for the project, then the Chair will ask at

least two other IRB members to review the proposal. The Chair will send the electronic copy (and/or paper materials) to the selected IRB members. Each member will inform the IRB Chair of his/her decision concerning the proposal. If the selected members agree that the project should be exempt, then the Chair will notify the IR representative of the decision to approve the request for exemption. All reviewing members will print, indicate approval of exemption, sign, and date the cover sheet and send it to the IR Representative. The IR Representative will notify the investigator of the proposal's approval. If the reviewing members do not agree on an exemption, then the IRB Chair will ask the investigator to submit a proposal for review.

2. If the Chair determines that an administrative (expedited) review seems appropriate for a proposal, he/she will send the electronic copy (and/or paper materials) to at least two other selected IRB members. Each member will inform the IRB Chair of his/her decision concerning the proposal. If all reviewing members agree that the project should be approved, then the Chair will notify the IR Representative of the decision to approve the proposal. All reviewing members will print, indicate approval of the study, sign, and date the cover sheet and send it to the IR Representative. The IR Representative will notify the investigator and all members of the IRB of the proposal's approval. If the reviewing members do not agree on approval, then the IRB Chair will submit the proposal for a full board review.
3. If the Chair determines that a full review seems appropriate for a proposal, he/she will send the electronic copy (and/or paper materials) to all members of the IRB. If there are concerns or needed clarifications, the committee corresponds directly with the principal investigator to resolve the issues. The review process can take anywhere between two and six weeks from initial submission, depending on the complexity of the proposal and the number of issues that require clarification.

D. Voting requirements:

1. Quorum:
 - a. A simple majority of IRB members will be considered quorum for purposes of conducting business.
 - b. A non-scientist member of the IRB must be present in the quorum to conduct business.
2. Voting for study approval or denial will be based on Roberts Rules of Order, whereby a simple majority carries the vote and the Chair casts (or abstains from) the deciding vote.
3. All members of the IRB have full voting rights with the expectation that when a member has a conflict of interest concerning a particular proposal, he or she will abstain from discussion and voting regarding that proposal.
4. Proxy voting, either by writing or telephone, will not be accepted as part of the IRB vote when conducting full board business.

E. Further review/approval of IRB actions: All actions of the IRB are subject to the review of the President in consultation with the Director of the IRB. The President and the Director of the IRB have the authority to override approval decisions of the IRB. The Director of the IRB may not grant approval of a proposal that was denied by the IRB voting members.

F. Communications to/from the IRB:

From	To	Item	Timing
Investigator	IRB Chair	Completed Proposal Packet - submitted as electronic copy and one paper copy or ten paper copies	May be submitted at any time. If the Chair decides that an administrative review is possible, he/she will submit it to at least two other members. If an exemption or approval is given via an administrative review, then it will not be necessary for the proposal to go to the whole committee. If a full review is needed, then the proposal must be received at least ten days prior to the regularly scheduled meeting in order for the proposal to receive a full review at that meeting. If the Chair is unavailable at the time of a project's submission, then the vice-Chair may decide on the feasibility of an administrative review and may oversee the distribution of the materials.
IRB Chair	IR Rep	All information to be contained in meeting packets (for full review.)	Received at least seven days in advance of the scheduled meeting
IR Rep	IRB	Meeting Packets (containing agenda, proposals for consideration, other materials for full committee review)	Distributed seven days in advance of scheduled meeting for items that need a full review. All other items will be sent to at least two IRB members for their consideration of items requesting an exemption or that are eligible for an

			administrative review.
IR Representative	IRB and Office of the President	Meeting Minutes (unofficial)	Mailed within two days of the meeting
IRB members participating in expedited reviews	IRB Chair	Decision on requests for exemptions and administrative (expedited) reviews	Emailed or mailed to the Chair within ten days of receiving the request for a review.
IRB Chair & members participating in expedited reviews	IR Rep	Printed cover page of proposal reviewed. Document should include the reviewer's decision, signature, and date of review.	Delivered to the IR Representative within ten days of distribution of the request for a review.
IRB Chair/IR Rep	Office of the President	Processed Packets (including processing sheets, signed original forms, and signed original determination letters)	Delivered to the Office of the President within five days of the meeting, or Chair determination if an exempt study
Office of the President	Investigator	Notification of the approval, denial, or request for modification of the proposed project	Mailed within two days of receipt of processed packets from Chair and/or IR Representative
Investigator	IRB Chair	Modified Proposal	As necessary (procedural outcome depends on the modifications requested)
Investigator	IRB Chair	Request for Extension of an Approved Proposal	As necessary – Each project approval expires at the end of one year from the date of project approval. If a project extends beyond a year, then an extension must be requested.
IR Representative	Investigator	Project Renewal/ Termination Notice	As necessary

G. Appeal of IRB decision: An investigator may appeal an IRB denial by requesting reconsideration of the proposal first by the IRB Director. The Director will review the materials and make a recommendation to the IRB voting members prompting a re-vote. If the submitter is still not satisfied, an appeal may be presented to the President. The President, in consultation with the Director of the IRB and the Chairperson, will make a written determination. The determination of the President is considered final.

VIII. IRB Record Requirements:

- A. Membership Roster: A membership roster, including member qualifications, will be maintained on the Intranet in the IRB folder and with IRB files in Institutional Research.
- B. Written Procedures: Written procedures for the operation of the IRB will be maintained both on the IRB section on the Intranet and with the Institutional Research Representative. The regulatory document outlining IRB submission procedures will be maintained by the Administrative Assistant to the Vice President for Finance and Administration and available to the college community through the Regulatory Documents link on the college website.
- C. Meeting Minutes: Minutes will reflect members and guests present, a summary of discussion and decisions, as well as a record of member votes by category (for, against, or abstention). Additional notes will be made to the minutes to reflect the results of administrative reviews.
- D. Records Retention: Records relating to all IRB reviewed research (initial and continuing reviews) will be maintained by Institutional Research for a period of three years beyond the completion of the research. This includes communications between investigators and the IRB or Office of the President relating to approved studies.
- E. Adverse Events: The IRB will review and maintain documentation of any reported serious adverse event, subsequent notification to the IRB and President, and IRB or institutional action taken.

IX. IRB Review Procedures:

- A. General Principles: All Barton College researchers (faculty, staff and students) must adhere to strict ethical standards for the use of human subjects in their research. These standards are in place to protect the basic rights of their subjects. Any research that departs from the spirit of these standards violates College policy. Below are some guidelines that the IRB members consider during their reviews to maintain these standards.
 - 1. All research procedures minimize the risks to the subjects.
 - 2. Any risk must be reasonable in relation to the potential benefits from the study.
 - 3. Informed consent must be obtained from the subject before participation. This consent must be in writing unless exempted by the committee.
 - 4. Subjects must be provided with adequate detail regarding the study to make an informed decision regarding their participation. This information should be included on the consent form and should be written in lay language, so that the subjects can make an informed decision regarding participation.
 - 5. Subjects' privacy must be maintained.
 - 6. Subjects need to be made aware that they participate of their own choice and are free to withdraw from the study at any time without penalty.

B. Review Categories: There are three categories (or types of review) for projects that are submitted to the IRB. These are as follows.

1. Exempt from further review.
2. Subject to expedited review.
3. Subject to full review.

Institutional studies for planning and assessment purposes do not require IRB review.

Determination of the type of review (expedited or full review) for studies submitted for IRB review will be made by the Chair of the IRB upon consideration of the submitted materials. If the Chair sends the proposal for an expedited review, and the reviewers determine that there should be a full review, the Chair will then submit the proposal for a full review.

Exempt Review: Studies may be determined by the IRB to be exempt if they fall under the following categories and have no more than minimal risk.

1. Normal educational practices and settings.
2. Anonymous educational tests, surveys, interviews, or observations.
3. Identifiable subjects in special circumstances.
4. Collection or study of existing data.
5. Public benefit or service programs.
6. Taste and food evaluation and acceptance studies.

Expedited Review: Expedited review will typically be conducted on those projects that involve no more than minimal risk. Expedited review involves review by two or three committee members. Review of a project in the expedited review category may take from two to four weeks from initial submission.

Full Review Studies: Full Board Review involves the whole IRB committee and may take four to six weeks from initial submission.

C. Definitions:

1. Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.
2. Human Subject: A living individual, about whom an investigator (whether professional or student) conducting research obtains the following:
 - a. Data through intervention or interaction with the individual or
 - b. Identifiable private information.

3. Intervention: Intervention includes both physical procedures by which data are gathered (for example, venipuncture) 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.
4. Private information: 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order to obtain the information to constitute research involving human subjects.
5. IRB Approval – This term signifies the determination of the IRB that the research has been reviewed and may be conducted at Barton College within the constraints set forth by the IRB and by other institutional and federal requirements.
6. Minimal Risk – Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

X. Review Procedures for Investigators: Described below is the process by which a principal investigator seeks approval from the Barton College IRB for the Use of Human Subjects in Research.

A. Forms: There are four components to a package to be submitted to the IRB for review: the cover sheet, the preliminary questions sheet, the proposal narrative, and the informed consent form. Each of these components needs to be included in the package submitted to the IRB Chair. Incomplete packages will be returned to the principal investigator without review. All necessary forms are located on the Intranet in the IRB folder.

1. Cover Sheet: The cover sheet provides basic information regarding the study under consideration and the principal investigators.
 - a. For research whose principal investigator is a member of the Barton College faculty/staff, this form should be completed and the Barton College faculty/staff member must sign attesting to his or her awareness of the College's policies and procedures for the use of human subjects in research.
 - b. For research whose principal investigator is not a member of the Barton College faculty/staff, the cover sheet should be completed and the principal investigator must sign attesting to his or her awareness of the College's policies and procedures for the use of human subjects in research. Further, a Barton College faculty/staff member must also

sign illustrating that he or she has reviewed the application thoroughly, will oversee the research in its entirety, and acknowledges his or her role as the principal investigator of record. This requirement applies to all student research as well as to other research if stipulated by the IRB after initial review.

2. Preliminary Questions Sheet: The responses to these questions will allow the Chair to quickly place the study in the appropriate review category (exempt, expedited or full review). These questions have been developed to decrease the response time of the IRB.
 3. Proposal Narrative: The proposal narrative is a detailed description of the study. There are seven sections to the narrative that need to be completed: Introduction, Subject Population, Experimental Procedures, Potential Risks, Compensation, Collaborators, and Additional Information. Each of these sections needs to be completed, or if a section does not apply, write “N/A”. Each of these sections contains critical information that will allow the reviewer to evaluate the study. These sections need to be written in lay language, avoiding jargon and acronyms. Proper grammar, including appropriate use of tenses, verb agreement, spelling, and sentence structure, should be utilized. Failure to follow these rules will cause delays in the processing of the submission.
 4. Informed Consent Form: An important component to any submission to the committee is the informed consent form. This form will be used by the researcher to document that the subjects were aware of the requirements of the study and that they were aware that they could refuse to participate or withdraw at anytime. Therefore it is important that this document contain adequate information so that the subjects can make an informed decision regarding participation. As with the proposal narrative, this form should be written in lay language and should avoid jargon and acronyms.
- B. Review: An electronic copy and one paper copy or ten paper copies of all materials should be sent to the IRB Chair. Upon receipt of a protocol package, the IRB Chair will review the package for completeness and content. If the package is found to be complete, the package will then be reviewed. If there are concerns or needed clarifications, the committee will correspond directly with the principal investigator to resolve these issues. The review process can take between two and six weeks from initial submission, depending on the complexity of the proposal and the number of issues that require clarification.
- C. Final Notification: Upon receipt of the notification from the IRB reviewers of the acceptability of the experimental protocol, a letter will be sent from the IRB Chair to the principal investigator stating that the research project has been approved for one year (beginning on the date of the letter). This notification will be sent by the Office of the President to the principal investigator within seven days of the IRB decision.

- D. Extensions: For those projects that require an extension beyond the one year limitation of the IRB approval, the principal investigator must submit a letter to the IRB Chair stating his or her intention to continue the research and documenting any modification to the experimental protocol.

The Institutional Research Representative will send out renewal request reminders under the name of the Chair sixty and thirty days in advance of the expiration of the initial project approval. Renewal submissions should contain a concise overview of the project to date (# of subjects, significant findings, etc.). Upon receipt of this letter, the IRB will conduct a continuation review the protocol at its next meeting. If the committee finds the protocol acceptable, the Office of the President will forward to the principal investigator a letter of approval within seven days of this determination.

- E. Changes to Approved Studies: Any proposed change to an already approved study must be submitted to the IRB prior to implementation. Changes are submitted to the IRB using the “Study Modification/Addendum Request Form.”
- F. Retention of Documentation: A copy of all records relating to the research project (original submitted protocol, all signed consent forms, correspondence with the IRB, etc.) should be retained for at least three years after the completion of the research.