Institutional Review Board
Health Sciences Section
University of Missouri-Columbia

Standard Operating Procedure

Initial Review

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Approved By: Robert Hall, PhD
Associate Vice Chancellor, Research

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1.0 Purpose
To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting the procedure for review of new applications for the Health Sciences IRB.

2.0 Scope
The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board.
3.0 Policy/Procedure

General Information
In conducting the initial review of proposed research, IRBs must obtain information in sufficient detail to make the determinations required in 45 CFR 46.111. IRBs must determine that:

(1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) 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.

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

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, fetuses and neonates, mentally disabled persons, or economically or educationally disadvantaged persons. In addition, the IRB should take into account the inclusion/exclusion criteria, participant recruitment and enrollment procedures and the influence of payments on participants.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45CFR 46.116 and 21 CFR Part 50 Subpart B – Informed Consent of Human Subjects.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45CFR46.117 and 21 CFR 50.27.

(6) When appropriate*, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111[a][6]). The IRB requires that each new research application include a Data Safety and Monitoring Plan (DSMP) or Data and Safety Monitoring Board (DSMB).

*When monitoring of the data is necessary to ensure subject safety.

- The Investigator is responsible for creating and implementing a data and safety monitoring plan. The plan will need to detail how confidentiality is protected and, to the extent possible, risks are reduced to a minimum. The intensity and frequency of monitoring should be tailored to fit the expected risk level, complexity, phase and size of the particular study.
- The DSMP needs to address:
  a) Items to be monitored (i.e. subject eligibility, adherence to treatment plan, documentation of dropouts, evaluation of primary and secondary...
endpoints, unanticipated problems and, problems with informed consent)

b) Data Management: who is responsible for the collection and storage of data, where will it be stored (i.e. lab notebook, database) and security measures needed to protect the data from inadvertent loss or inappropriate use. Who will perform analysis on the data and how often?

c) A plan to assure compliance with reporting unanticipated problems involving risk to participants or others.

- The IRB will consider the following issues in determining whether the plan is adequate:
  
a) Reporting mechanisms;
  b) The frequency of the monitoring, such as points in time or after a specific number of participants are enrolled;
  c) Who will conduct the monitoring, such as a data monitoring committee, data and safety monitoring board, medical monitor, investigator, independent physician, or IRB;
  d) The specific data to be monitored;
  e) Procedures for analysis and interpretation of the data;
  f) Actions to be taken upon specific events or end points; and
  g) Procedures for communication from the data monitor to the IRB and sites

(7) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- Confidentiality
  a) Strategies to maintain confidentiality of identifiable data, including controls on storage, handling, and sharing data
  b) When appropriate a Certificate of Confidentiality will be applied for.

- Privacy
  a) Consider how the investigator will access information from or about participants
  b) Strategies to protect privacy interests relating to identifying and contacting potential participants
  c) Research procedures should be designed to minimize invasion of privacy of the participant

(8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. For further information see SOP - Recruitment of Special Populations.

(8) HIPAA Authorization will be sought or other HIPAA provisions will be applied to assure the privacy of participants and their information.

In addition, the IRB will evaluate whether the investigator has adequate resources to protect participant rights and welfare. In making this assessment the IRB should take into account the following:

- Access to a population that will allow recruitment of the required number of participants
• Sufficient time to conduct and complete the research within the research period
• Adequate numbers of qualified staff
• Adequate facilities and equipment to perform the research
• Ancillary resources (availability of medical or psychological resources that participants might require as a consequence of the research)

(9) If multi-center study and the lead institution or lead investigator, evaluation of the management and communication of information as it is relevant to the protection of research participants.
(10) All laws beyond federal law are applied as relevant to research involving humans as participants

Submission Requirements
Materials required to assist the IRB in its review of proposed research should include the required number of copies (one) of the relevant information, including:

• Application form (submitted electronically through the eIRB)
• Signature page
• Protocol
• Proposed informed consent document
• Any relevant grant application(s) – accepted in lieu of protocol in most cases
• HIPAA Documentation
• Letters of permission or support from other participating institutions
• Clinical Investigator’s Drug Brochure
• Data safety monitoring plan, if appropriate.
• Any recruitment materials, including advertisements intended to be seen or heard by potential subjects
• Questionnaires, handouts, or any other applicable instruments

IRB Administrative Review
All applications submitted to the IRB office will be reviewed in the order they are received. The IRB administrative office staff will conduct a preliminary review of the submission materials to determine the completeness of the packet; to determine if, in their opinion, the project may qualify for expedited or full-board review; and to request clarification and/or additional materials so as to provide the reviewer with a complete application that meets all regulations and university policies.

Any incomplete submissions will be left in returned status until all required materials are received. The PI or designated contact person will be notified via e-mail that the packet is incomplete and a list of the materials necessary to complete the packet. A project that is incomplete will not be forwarded for review by the IRB until all the necessary elements and clarifications have been received.

Reviewer assignments
For any review, if the primary reviewer feels he/she does not have the necessary expertise to review the project he/she may contact the IRB staff and the project will be assigned to another primary reviewer with the necessary expertise.

If an assigned reviewer has a conflict of interest they should contact the IRB staff and the study will be reassigned.

The primary reviewer for expedited reviews always has the option to contact the IRB staff and request that the project be reviewed by the full board if the reviewer feels the project does not
meet the requirements for expedited review or if the reviewer is more comfortable having the project reviewed by the full board even if the project meets the expedited review criteria.

The HS IRB is comprised of two subcommittees. If the IRB staff determines that there is not at least one person in this particular IRB subcommittee with the appropriate scientific and scholarly expertise to conduct an in-depth review, the IRB staff will rely upon the other IRB subcommittee. If there is a member of the other IRB without a conflict of interest and the necessary expertise the project will be assigned to that member.

Consultants
If the IRB staff determines that there is not at least one person on either IRB subcommittee with the necessary expertise, they will invite individuals with competence in that area to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. Consultants are not allowed to have a conflict of interest to the study whether personal, professional, financial or other. IRB staff will ask the consultant about conflicts prior to review assignment. The consultant will review the project and provide their opinions and comments in a written report.

The consultant’s findings will be presented to the full board for consideration either in person by the consultant or by the vice-chair of the IRB. The written report will be included in the board packet and available to all members. If the consultant is unable to attend the meeting, the vice-chair will read the report and proceed with discussion as deemed appropriate. If in attendance, these individuals will provide consultation but will not participate in or observe the vote. Information provided by the consultant is documented in a written report included in the board packet and in the minutes of the meeting.

Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher’s confidentiality and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research protocol).

For expedited studies, if the required expertise is not available in a non-conflicted member, the project will be assigned to the IRB Chair, one of the Vice-chairs. (or other member if the Chair or vice-chair have a conflicting interest). Consultation will then be arranged as described above. Consultation will be documented in a written report and the consultant will be available to address any questions or concerns during the expedited review process.

When needed, General Counsel for the University will be consulted on legal issues, to include interpretation of state law.

Expedited Review
The expedited review process is conducted by a single IRB board member. A reviewer is assigned by the IRB staff.

A copy of the complete submission packet is sent to the selected reviewer, along with any additional clarifications. The primary reviewer will conduct an in-depth review of all pertinent documentation (see submission requirements above) to ensure compliance with the applicable regulations permitting expedited review (45 CFR 46.110).

The primary reviewer generally reviews requests for expedited review within two weeks of receipt of the materials, and will return the review recommendation to the IRB administrative office for final processing. If the primary reviewer requests any revisions or modifications, the
HS IRB office will notify the investigator of the revisions. Please see the section below on “Revisions and Modifications.” If the primary reviewer does not approve the study, it will be placed on the agenda of the next available board meeting.

Expedited review guidelines:

- The reviewer must determine that all applicability criteria are met and that all research activities fall into one or more categories of research allowing review by the expedited procedure.

- In conducting review, the reviewer is to complete the IRB New Expedited Project Reviewer Checklist and all other checklists that would be used for review by a convened IRB. This documentation should include any actions taken by the reviewer and any findings required under the regulations.

- In order to grant approval the reviewer must determine that the protocol meets all regulatory requirements for approval.

- When granting initial approval the reviewer must document the category allowing review by the expedited procedure.

- When granting initial review approval, the reviewer must document any determinations required by the regulations for waiver or alteration of consent, waiver of consent documentation, research involving prisoners, pregnant women, fetuses, neonates or children, and must document protocol specific findings that justify those determinations.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.
(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

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

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

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

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

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

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

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

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

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

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

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

See Continuing Review Report for expedited procedure categories (8) and (9).

1 An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).


For studies approved via expedited review the project number, title and principal investigator’s name will be included in the attachments to the agenda and minutes of the next board meeting. For expedited studies, members may request to review the study and its changes when they are notified of the expedited study through the attachments to the agenda.

Full Board Review

Once each submission packet is finished with IRB administrative review, it will be assigned to a specific board meeting based on the date of submission of the materials. Typically, most applications are reviewed by the IRB within approximately one month of receipt. Projects which are submitted between the 5th and 19th of the month will be reviewed at the next mid-month IRB
meeting. Projects submitted between the 20th and the 4th will be reviewed at the next end-month IRB meeting. If a project requires extensive follow-up and/or clarifications by the IRB office, it will be held over until the next available agenda after all clarifications have been received.

The applications for full-board review are conducted using a primary reviewer system of review. Both a primary and lay reviewer are assigned to studies reviewed by the full board. A copy of the complete submission packet (see submission requirements above) is available to the primary and lay reviewers, at least 5 working days prior to the scheduled IRB meeting.

The primary reviewer will conduct an in-depth review of all documentation of the assigned project to ensure compliance with the applicable regulations. The primary reviewer will document determinations required by the 45 CFR 46.111 and protocol-specific findings supporting these determinations on the reviewer sheet. Other board members receive all submission information for each study and are expected to have a working knowledge of each study so that they are able to engage in a meaningful discussion of the project. All members receive a copy of the minutes from the prior meeting.

The lay reviewer will present any concerns or questions noted from their review of the consent document, or other materials, focusing particular attention to documents that will be seen by the research subject. Also, any board member may indicate for discussion any issues they found during their review of all supplied documentation for review.

Once all discussion has ceased on a project, a vote on the motion on the table will be taken.

The following items will be included in the recommended action motion:

- Approval, approval with documented modifications, disapproval, or defer
- Level of risk - minimal risk or significant risk
- Type of consent - written consent, waiver of consent, or waiver of documentation of informed consent
- Parental consent and minor assent, if applicable
- Child risk category, if applicable
- Continuing review interval - The determination regarding the appropriate review intervals will be made based on considerations of the potential or actual risks of the research, the degree of novelty of the research intervention, the number of subjects to be enrolled, any specific vulnerability associated with the research population, and/or the magnitude or frequency of risk to subjects.

All motions, discussions and actions taking place during the convened Board meeting will be documented in the written minutes of the meeting.

Revisions and Modifications

Many times the IRB will request clarifications or revisions to projects. Any member may request changes to any project materials during the review of a study.

Studies initially reviewed by Full board:

1) Specific revisions stipulated by the convened IRB requiring simple concurrence by the investigator or minor modifications or clarifications* as defined below may be reviewed using the expedited procedure.

*Minor Modifications or clarifications:
- Those modifications or clarifications that do not involve potential for increased risk or decreased benefit to the human subjects.
• Protocol revisions that entail no more than minimal risk to participants are considered “minor” modifications.
• Changes to informed consent documents that do not affect the rights and welfare of study participants, or do not involve increased risk, or significant changes in the study procedures
• New or revised recruitment advertisements or scripts.

The IRB administrative office will request the clarifications or revisions from the investigator in writing. This request and the written response will be documented in the file. The IRB staff will review for completeness, the clarifications or documented changes when they are received. The clarifications are subsequently reviewed and approved by the IRB chair or another designee in a timely fashion.

2) When the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB for research under 45 CFR 46.111, the convened IRB must review the revisions. The board will try to contact the investigator by phone and ask the investigator to come to the meeting for discussion or have a discussion by speaker phone. If the investigator is not available the board will defer the study and the modifications will be requested of the investigator by the IRB office in writing. The request and response will be documented in the file. The project will be reviewed with the written documented modifications at the next convened board meeting to determine approval status. The investigator may request to attend the meeting to discuss the study under review and answer questions or provide explanation. In addition, the board may request that the investigator attend the meeting to address concerns of the study.

Studies initially reviewed by Expedited Procedure:
1) If the request for modifications or clarifications is of such magnitude that they are directly relevant to the determinations required by the reviewer under 45 CFR 46.11, the IRB staff will contact the investigator and request the modifications or clarifications in writing. The request and response will be documented in the file. The reviewer will re-review the study once the modifications have been made and determine approval status.

2) Otherwise, specific revisions stipulated by the primary reviewer requiring simple concurrence by the investigator or minor modifications or clarifications as defined in this policy. These revisions may be processed administratively and reviewed by the Chair or other designee.

Expedited review, if the investigator is unwilling to make requested modifications and/or the reviewer will not approve the study it will be placed on the agenda for the next full board meeting. The investigator will be made aware of this in writing and this will be documented in the file.

Approval Date
The actual approval date of the study will be the date the IRB convened and approved the study with or without modifications. For expedited review, the approval date is date the reviewer gave approval and signed the reviewer sheet with or without modifications.

If, however, the investigator makes additional changes other than what the IRB (reviewer for expedited studies) specifically requested, or for some reason (i.e. sponsor insistence) the investigator did not make certain revisions, justification, in writing or by attending the meeting, must be provided to the IRB (reviewer for expedited studies) and the revisions must be reviewed by the full board (reviewer for expedited studies).
If the board (reviewer for expedited studies) agrees with the additional changes or lack of changes the approval date will remain as the first time the board (reviewer for expedited studies) approved the study with modifications. If the board does not approve the additional changes or lack of changes, the board will attempt to contact the investigator. The investigator will be invited to address the board’s concerns by speaker phone or in person. The board will deliberate and decide to approve or disapprove. For expedited studies, the study will go to the next available full board meeting.

Additional Review Requirements
Several other reviews are necessary for studies involving prisoners, devices, drugs, accounting, conflict of interest, veterans, and radiation or biosafety. Several questions within the application itself serve as a guide to the IRB office in determining whether additional reviews are needed. Most of the additional reviews will be required prior to final IRB approval being granted. In many cases, the reviews take place prior to the study being reviewed by the full board; however, some reviews may take place after the IRB has conducted their review. Rarely is it necessary to prolong an approval for a study due to an additional review, however, it can occur. Investigators will be informed that research cannot commence until all approvals have been obtained if applicable. Documentation of each additional review will be entered into the eIRB database. Please review the individual SOPs for each type of review for additional information or requirements.

1. If the project includes prisoners as subjects, a copy of the complete submission packet (see submission requirements above) will be sent to the designated prisoner reviewer. Additionally, the project will be scheduled for review at the board that the prisoner reviewer is a primary member. Depending on the funding source and type of research proposed, the Office for Human Research Protection (OHRP) may need notification, review, and approval before prisoner research can begin.

2. Devices - If the project includes the use of an experimental device, a copy of the application, the protocol and the device information will be sent to the designated device consultant prior to review by the full board (per 45 CFR 46.107(f)). The device review and recommendation will be sent to the assigned reviewer as part of the review packet and is required prior to IRB approval being granted.

3. Radiation or Biosafety - If the project includes radiation safety or biosafety, a copy of the application, consent, and the protocol will be sent to the radiation or biosafety office prior to review by the full board. The review and recommendation will be sent to the assigned reviewer as part of the review packet and is required prior to IRB approval being granted. Depending on the level of research, it is possible that radiation safety or biosafety may require additional reviews by their respective boards. If further review is needed, IRB approval may be delayed until approval from radiation or biosafety is received.

4. Investigational Drug Services (IDS) – If the project includes the use of medication(s), the IRB office will forward a report to the Investigational Drug Pharmacist. Trials involving the dispensing of investigational medications must be reviewed and approved by the IDS before they may be granted IRB approval. All trials must receive IRB approval prior to Pharmacy’s dispensing any medications pursuant to that protocol. Pharmacy (IDS) controls the storage, dispensing, labeling, and distribution of investigational medications.

5. Accounting – If the project plans to provide compensation to subjects, it must receive approval from accounting prior to IRB approval being granted. Procedures for obtaining Accounting Services approval for research participant compensation are available at: http://www.missouri.edu/%7Emuacct/BPPM%20Research%20Participant%20Compensation.htm
6. **Conflict of Interest** – If a conflict of interest is identified with the investigator and/or study staff and the proposed research, review by the Conflict of Interest (COI) committee is required. The investigator will be notified, as well as, the Office of Research about the possible conflict. The investigator may be required to submit additional paperwork for review by the COI committee. Depending on the level of conflict and the degree to which it impacts the proposed study, IRB approval may be delayed until a resolution or management of the conflict has been developed.

7. **Veterans** – If the proposed research plans to recruit veterans and/or use VA resources and/or staff, review by the VA Research and Development Committee is required. VA R&D approval is not required prior to IRB approval. However, it will be required prior to conducting any portion of the proposed research at the VA Hospital.

**Approval Time Frames**

Exempt and Expedited studies are approved for a period of one year from the approval date. For expedited review the approval period starts on the date the reviewer approved the study and signed the reviewer sheet with or without modifications. For full board review, the approval period starts on the date of the IRB meeting in which the project was approved or approved with modifications. The expiration date is defined as the first day that the protocol is no longer approved without continuing review and approval by the IRB. The expiration date is calculated as the date the IRB approved the study or approved the study with modifications, plus the interval of approval (maximum one year). The approval period ends on the day before the expiration date. For example, if the study was approved by the convened IRB for one year on 4/15/2006, then the approval period is 4/15/2006 to 4/14/2007 and the expiration date is 4/15/2007. If the study was approved with modifications by the convened IRB for one year on 4/15/2006, then the approval period is the same, 4/15/2006 to 4/14/2007 and the expiration date is 4/15/2007.

**Project Approvals**

Prior to final approval being granted on any project, the IRB office will determine that the Principal Investigator and all key personnel have completed the required educational and/or HIPAA training. If the requirement has not been met, the Principal Investigator will be notified of the requirement and the process to meet the requirement. IRB approval will be held until the required training has been completed for all key personnel.

The Principal Investigator will be notified in writing of the approval of the project, the risk level assigned, the consent requirements, and the continuing review interval. Included with the final approval letter will be the approved consent and any other approved documents (such as recruitment materials, questionnaires, etc.). A copy of the approval letter and attached documents will be kept with the file in the IRB administrative office as proof of approval.

If the study is disapproved the Principal Investigator will be notified in writing. The letter will include the reason(s) for disapproval and recommendations, if any, on how to proceed in an attempt to have the study approved. The investigator will be given the opportunity to respond. (see appeals policy)