

## **2.0     Initial Review Procedures**

### **2.1     Determination of activities that constitute human subjects research**

- I.     The determination of whether or not a particular activity constitutes human subjects research may be made by the convened IRB, the IRB Chair, HRPP Director, or HRPP staff. The determination is based upon federal regulations found at 45 CFR 46 and 21 CFR 56. Research involving human subjects is any activity that either:
  - A.     Is “research” and involves “human subjects” as these two terms are defined by DHHS regulations; OR
  - B.     Is a “clinical investigation” and involves “human subjects” as these two terms are defined by FDA regulations.
- II.    KUMC investigators must obtain prior approval from IRB for all activities that qualify as human subjects research under HHS regulations or activities that qualify as a clinical investigation under FDA regulations.
- III.   Definitions
  - A.     “Research” as defined by DHHS regulations means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  - B.     “Human subject” as defined by DHHS regulations means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or Identifiable private information
  - C.     “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.
  - D.     “Interaction” includes communication or interpersonal contact between investigator and subject.
  - E.     “Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (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 for obtaining the information to constitute research involving human subjects
  - F.     “Research” or “clinical investigation” as defined by FDA regulations is any experiment that involves a test article and one or more human subjects and that either meets the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Food, Drugs, and Cosmetics Act or is not subject to requirements for prior submission to the

Food and Drug Administration under these sections of the act but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. An experiment includes any use of a drug except for the use of a marketed drug in the course of medical practice.

- G. “Human subject” as defined by FDA regulations means an individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research that involves medical devices a “human subject” is also an individual on whose specimen an investigational device is used.
- H. “Test article” means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation by the FDA.
- I. “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.
- J. “Generalizable knowledge” means that the intent of the project is to create information that is broadly applicable beyond the populations or settings that are being studied.

#### IV. Guidance to Investigators

- A. The Human Research Protection Program (HRPP) is responsible for providing and updating guidance to investigators about activities that require prior IRB review.
- B. The determination of “human subjects research” is made when the activity either:
  - 1. Is “research” and involves “human subjects” as these two terms are defined by DHHS regulations; OR
  - 2. Is a “clinical investigation” and involves “human subjects” as these two terms are defined by FDA regulations.
- C. Examples of human subjects research include, but are not limited to:
  - 1. Clinical trials of a drug, device or biologic product
  - 2. Research involving surveys, interviews or focus groups
  - 3. Collection of data obtained from clinical procedures
  - 4. Certain non-standard medical practices (see D. below)
  - 5. Research on behavioral interventions
  - 6. Queries of identifiable health records that are designed to answer a research question
  - 7. Banking of tissue, blood or other specimens for future research
  - 8. Research using non-invasive procedures, such as MRI, X-ray or ECG
  - 9. Research on educational practices
  - 10. Retrospective chart reviews
  - 11. Research on food, food supplements, vitamins or herbs

12. Certain quality improvement interventions (see D. below)
  13. Certain program evaluations (see D. below)
  14. Pilot studies
  15. Feasibility studies, when the participants in the feasibility study represent the population that will be included in the subsequent trial.
  16. Student research projects
  17. Research conducted by KUMC personnel at other institutions
  18. Collaborative projects involving identifiable human data or specimens
  19. Use of identifiable human data or specimens transferred from a faculty member's former institution
  20. Feasibility studies that use the same or similar procedures that subjects will undergo in a future research study
  21. Systematic modifications to surgical technique, not directly related to the patients' benefit.
- D. **Activities that typically do not constitute human subjects research include:**
1. Program evaluations are designed as a management tool to improve the provision of services to a specific population. Results of program evaluations are shared only with the program and entity in which the program operates; the activities are not intended to have any application beyond the specific organization in which they are conducted. Typically, program evaluations are performed under a contract for services, and the program being evaluated is the owner of the evaluation data, results and reports. Faculty should note that a program evaluation becomes human subjects research if it assesses a new, modified or previously untested intervention, service or program to determine effectiveness and potential for use in other settings. Assigning program participants into groups to compare outcomes also constitutes a research activity. Additionally, a systematic comparison of standard or non-standard interventions is considered to be research. Finally, program evaluations may be considered research if the KUMC faculty member keeps the evaluation data for presentations, further analysis or future grant proposals.
  2. Quality Improvement activities – projects designed to bring about immediate improvements to healthcare delivery in the local setting.
  3. Off-label use of a marketed drug or device, or non-standard medical or surgical practices, may be pursued with the sole intent of enhancing the well-being of an individual patient. Off-label use and non-standard medical practices are subject to hospital policy. Off-label use or non-standard practices may become human subjects research when one or more of the following is true:
    - a. there is a clear intent, before treating the patient, to systematically collect data on a series of patients receiving similar treatments;

- b. the physician keeps separate data sheets for reviewing patient outcomes or has other organized methods of gathering data;
    - c. extra tests are performed that are not directly related to the patient's benefit;
    - d. the care under consideration is delivered consistently across a series of patients according to an "unwritten" protocol in order to keep processes and procedures uniform.
  - 4. A descriptive report of a small number of cases (generally not more than three), provided the report is compiled by persons already involved in patient's care, the information is presented in de-identified form, and no changes were made in the patient's care or diagnostic testing for the sake of reportability. Case reports may become human subjects research if any of the previous three stipulations are not met, or if multiple cases are analyzed in a manner that tests a hypothesis.
  - 5. Certain research activities, in which the investigator does not obtain individually identifiable information or specimens, may be considered not human subjects research. The IRB will make the determination on a case-by-case basis, depending on the type of information/specimens being used, the source of the information/specimens, the coding system and the custodian of the code. Further information about research with coded information and specimens is found in SOP 10.0 – Research with Human Biologic Materials.
  - 6. Research using publicly accessed databases, if the databases contain no individual identifiers and if access is granted without requiring a data use agreement.
  - 7. Research involving de-identified cell-lines or tissues that are purchased from a commercial vendor.
- E. The IRB is the final arbiter on whether an activity constitutes human subjects research.
  - F. When questions arise, investigators are responsible for seeking a determination about their activities prior to initiation.
  - G. When seeking a determination of non-human subjects research, investigators should submit a summary that describes the sources of data or specimens, the identifiers or codes attached to the data or specimens, and the planned analyses.
  - H. If the activity is determined to be not human subjects research, the investigator will receive written confirmation from the IRB Office. Determinations are typically made within five business days.
  - I. If the activity is determined to be human subjects research, the investigator will be instructed to apply for IRB approval.

**References:**

45 CFR 46.102

21 CFR 50.3

21 CFR 312.3

21 CFR 812.3

**2.2 Criteria for Approval of Human Subjects Research****I. Regulatory Basis of Determination**

- A. The IRB's determination regarding approvability of new research is based on satisfaction of all of the conditions outlined in 45 CFR 46.111(a)(1-7).
- B. When applicable, the IRB's determination regarding approvability of new research is also based on satisfaction of all of the conditions outlined in 21 CFR 56.111(a)(1-7).

**II. Determinations**

- A. The board will confirm that risks have been 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. This includes consideration of whether the PI has adequate resources (in terms of time, assistance, equipment, support services) to protect and minimize harm to participants.
- B. The board will confirm that 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. Assessment of risks and benefits of the research will include consideration of immediate benefit to the individual subject as well as benefit to society.
- C. In order to ensure equitable selection of research participants, the IRB requires that the PI provide the characteristics of the subject population, anticipated accrual, age ranges, health status, gender and ethnic composition of the subject population, and criteria for inclusion or exclusion of any subpopulation.
- D. The board will ensure that 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 45 CFR 46.116 and 21 CFR 50. In addition, the board will ensure that informed consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117 and 21 CFR 50.27.
- E. For studies involving greater than minimal risk to subjects, the board will ensure that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. Planning for data and safety

monitoring is required for all studies that are greater than minimal risk. Plans may be included in the study protocol, in the project description or as a separate document, and will be assessed at the time of initial review. Safety monitoring reports will be reviewed as submitted and at the time of continuing review to ensure safety of subjects.

- F. The board will ensure that the research includes adequate provision to protect the privacy of subjects and confidentiality of data. When applicable, protocols must meet standards in the HIPAA Privacy Rule, 45 CFR part 160 and part 164, subparts A and E. The IRB may require that a Certificate of Confidentiality be requested when the participants are at risk for loss of privacy that could adversely affect financial standing, employability, insurability, or reputation.
- G. When some or all of the subjects in a research protocol are likely to be vulnerable to coercion or undue influence, including but not limited to children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the board will determine if additional safeguards have been included in the study to protect the rights and welfare of these subjects.

#### **References:**

45 CFR 46.111, 116, 117  
45 CFR Parts 160 and 164  
21 CFR 50  
21 CFR 56.111

### **2.3 Scientific or Scholarly Review**

All human subjects research protocols must employ sound research principles, minimize risks associated with participation and demonstrates an expectation to contribute to generalizable knowledge. Prior to approving prospective non-exempt human subjects research, the IRB will ensure that consideration of scientific or scholarly review has occurred.

- I. Investigators should be aware of the risks associated with study procedures and consider the following issues as they develop proposals:
  - A. Does the research use procedures consistent with sound research design?
  - B. Is the research design sound enough to reasonably expect the research to answer its proposed question?
  - C. What is the importance of the knowledge expected to result from this research?
  - D. Has the study been designed to minimize risk? Acceptable practices may include, for example:

1. Substituting less risky procedures for more risky procedures when adequate to answer the study question
  2. Use of the minimal number of procedures to answer the study question
  3. Enrollment of the minimum number of subjects needed to answer the study question
  4. Modification of inclusion/exclusion criteria to exclude participants who might be at increased risk if they undergo the research procedures, or include participants who might be at less risk if they undergo the research procedures
- E. Are risks reasonable in relation to potential benefits to the participants or to society at large?

## II. Persons or entities responsible for scientific or scholarly review

- A. Scientific or scholarly review is documented by the signature of the Department Head/Center Director (or designee) on new prospective non-exempt IRB applications. Scientific or scholarly review may be accomplished by one of several groups:
1. Scientific review may be accomplished by an external peer review from NIH or other funding agencies.
  2. Departments, schools, or centers may designate an internal reviewer or review committee.
  3. Dissertation or thesis committees will perform this review as the proposal is under development.
  4. The KU Cancer Center's Protocol Review and Monitoring Committee (PRMC) performs the scientific review for cancer or cancer-related proposals under their purview.
  5. The Scientific Advisory Research Committee of the Clinical and Translational Science Award (SARC) performs the scientific review for all investigator-initiated proposals that request the use of CTSU resources.
- B. The IRB, or expert consultants identified by the IRB, may provide additional scientific or scholarly review as part of the IRB review process.

## III. Determining Scientific or Scholarly Merit

- A. Individuals or groups who perform scientific or scholarly review should confirm that:
1. The research uses procedures consistent with sound research design, which do not unnecessarily expose subjects to risk.
  2. The research is likely to answer the proposed question.
  3. The knowledge reasonably expected to result from the research has scientific importance.
- B. The IRB makes the final determination about whether or not risks have been minimized through sound design. The IRB considers the feedback

- from the above-mentioned scientific merit review process as well as using the expertise of its own members.
- C. If the IRB believes it does not have the expertise required to understand the background, aims, and research methods proposed, the IRB will request outside scientific review by a consultant on a project consistent with IRB SOP 2.8.
  - D. IRB will disapprove an application if the research design does not adequately protect human subjects.

**References:**

45 CFR 46.111

21 CFR 56.111

## **2.4 Determination of Exempt, Expedited, and Convened Board Review Categories**

### **I. Pre-Review Procedures**

- A. IRB staff evaluates each submission to confirm that the submission is complete. Incomplete submissions are returned to the investigator before further review occurs.
- B. During the pre-review process, IRB staff determines the need for by ancillary reviewers, i.e. Radiation Safety, Nursing Impact, or Biosafety. IRB staff assigns ancillary reviews through the electronic system.
- C. IRB staff determines whether the review requires special representation, i.e. prisoner representative or other special consultation as described in SOP 2.8.
- D. Results of the pre-review are available to IRB members in the electronic system.

### **II. Determination of Exempt Review**

- A. Investigators can request exempt status by including the Exempt Project Description in their submission.
- B. IRB staff will evaluate the submission to determine if the proposed research fits into an exempt category of research. Investigators do not determine exempt status.
- C. If the proposed research fits into an exempt category of research, it will be reviewed by IRB staff as described in section 2.5 below.
- D. If the proposed activity has been determined to constitute human subjects research and is not found to be within the exempt categories, it will be reviewed under applicable expedited or convened-board review procedures. Investigators will be requested to complete the Expedited or Full Committee Project Description as applicable.
- E. If the proposed activity has been determined to constitute non-human subjects research, the investigator will be notified in writing.



## II. Determination of Expedited Review

- A. Investigators can request expedited review by including the Expedited Project Description in their submission. Research proposals are screened by the IRB staff to determine if they fit into an expedited category of research and represent minimal risk to subjects. 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.
- B. If the proposed research fits into an expedited category of research and represents minimal risk to subjects, it will be reviewed by IRB chairperson or other experienced IRB member as described in section 2.6 below.
- C. If the proposed activity has been determined to constitute human subjects research and is not found to be within the expedited categories, it will be reviewed using applicable exempt or convened board review procedures. Investigators will be requested to complete the Full Committee Project Description when applicable.

## III. Determination of Convened Board Review

- A. Research that has been determined to be human subjects research but is not within the exempt and expedited categories will be reviewed by the convened IRB.
- B. Research proposals needing convened board review will be placed on the agenda and individually presented, discussed, and voted on at a convened meeting.

### **References:**

45 CFR 46.101  
45 CFR 46.102  
45 CFR 46.110

### **2.4.1 Identification of Conflicts of Interest among IRB Members and Consultants**

#### **I Identifying Conflicts of Interest**

The HRPP staff monitors conflict of interest reports by IRB reviewers so that proposals are not assigned to a reviewer who has a known conflicting interest. The process to identify IRB members and consultants with a conflict of interest pertains to all types of review, such as: review by a convened IRB, review by the expedited procedure, review of unanticipated problems involving risks to participants or others, or review of non-compliance with regulations or laws or the requirements of the IRB.

- A. Annually all IRB members complete the financial conflict of interest disclosure form that is required for all KUMC faculty and unclassified staff. Financial disclosure thresholds for IRB members are identical to the thresholds used for research personnel on the conflict of interest form mandated by the Kansas Board of Regents.
- B. As required by all KUMC faculty and unclassified staff, IRB members must disclose the financial interests of themselves, their immediate family (spouse, dependent children, and other members of the personal household) and their extended family (siblings, parent, independent children, equivalents by marriage (in-laws) through the annual online conflict of interest disclosure form.
- C. The Conflict of Interest Manager reviews disclosures of interest related to research that are made by IRB members.
- D. The Conflict of Interest Manager informs the HRPP Director if a conflict of interest is disclosed by an IRB member. Conflicts of interests by IRB members are subject to management by the KUMC Conflict of Interest Committee which reviews all disclosures of faculty and unclassified staff.
- E. IRB members are also considered to have a protocol-specific conflict of interest if they, or their immediate family, are part of the study team for an individual protocol.
- F. The IRB staff will not assign a review to a member who has a known conflicting interest related to the proposal.
- G. If reviewers have a conflict of interest, they are instructed to notify the IRB staff immediately so that the review can be re-assigned.
- H. During the IRB meeting, members who have a conflict of interest with an agenda item leave the room during the discussion and voting on that item. Conflicts of interest may include financial relationships discussed above or participation on the study team. Members also may declare a conflict and leave the room if they have a personal relationship to the study or the study team that might bias their review of the proposal.
- I. Consultants who provide formal review of a protocol sign an attestation that they do not have a financial or non-financial conflict of interest related to the review. The HRPP Director obtains the signed attestation prior to distribution of review materials.

## II Member Exclusion from Discussion and Voting

- A. Members who have a conflict of interest may provide information or answer questions as requested by the IRB prior to discussion and voting. Members with conflicts leave the room during discussion and voting.
- B. The absence of a member with a conflict of interest during discussion and voting is noted in the meeting minutes, along with a note that a conflict of interest was the reason for the absence. The member is not counted towards quorum for that review.

**References:**

45 CFR 46.107

21 CFR 56.107

**2.5 Review of Exempt Research**

- I. Research conducted under exempt review is subject to all applicable KUMC institutional and IRB policies and procedures, including the requirements for human subjects training and conflict of interest disclosure for all study team members.
- II. Although some research activities are exempt from federal regulations, the research is not exempt from basic ethical standards. When the research involves direct interaction with subjects, subjects should be given a description of study activities and should be informed that their participation is voluntary. They should be given an opportunity to agree to participate without coercion or undue influence. Subject selection must be equitable. Any associated risk to individuals or society must be low. Subjects should be provided with contact information of the investigators to obtain answers to their questions.
- III. Exempt research must adequately protect the privacy interests of subjects. Research involving tests, surveys, interviews or observations will not be granted exempt status if it represents a possible intrusion on the privacy of subjects. Exempt research involving identifiable health information must meet the requirements in the HIPAA Privacy Rule. If the research involves access to identifiable health records prior to, or without, the patient's authorization, investigators must obtain a waiver of privacy authorization.
- IV. Exempt research must provide adequate provisions for confidentiality of study data. Confidentiality of data is ensured by good data practices, including but not limited to, locked file cabinets, storage of electronic data on the campus network that has firewall protection, strong passwords on computer files, and data access only for those involved in the study.
- V. Activities Eligible for Exempt Status
  - A. Research activities involving human subjects that may qualify as exempt are identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 46.401(b) and 21 CFR 56.104(d). The IRB may not create new categories of exempt research. Only the IRB may determine which activities qualify for an exempt review. Investigators do not have the authority to make an independent determination that research involving human subjects is exempt and must

contact the IRB concerning the status of proposed research or changes in ongoing research.

- B. An Investigator may request a particular category of exemption, but the final determination of applicability will be made by the IRB.
- C. Exempt determinations may be made by the IRB Chairperson, Vice Chair, Director of the HRPP, or qualified IRB staff as outlined in VI below.
- D. Research may be granted exempt status by the IRB if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b). ***NOTE: These categories do not apply to research involving prisoners, and categories 1-5 do not apply to FDA regulated research.*** They are:

1. **45 CFR 46.101(b)(1):** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - a. Research on regular and special education instructional strategies; or
  - b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. **45 CFR 46.101(b)(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 the human subjects' responses outside of 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.
  - c. If the research involves children as participants, the research must be limited to educational tests (cognitive, diagnostic, aptitude, achievement), and observation of public behavior when the investigator(s) do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the investigator(s) participate in the activities being observed cannot be granted an exemption.
3. **45 CFR 46.101(b)(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 45 CFR 46.101(b)(2) if:
  - a. The human subjects are elected or appointed public officials or candidates for public office; or

- b. Federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4. **45 CFR 46.101(b)(4)**: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
  - a. PLEASE NOTE: To qualify for this exemption, data, documents, records, or specimens must have been collected at the time the research project is proposed.
  - b. Under this exemption, an investigator (with proper institutional authorization) may inspect private, identifiable records, but may only record information in a non-identifiable manner. The data must be permanently and completely de-linked at the time of extraction. A code may be used to organize data as it is collected. However, the code may not be a means of re-linking the data set to the original data source.
- 5. **45 CFR 46.101(b)(5)**: Research and demonstration projects, which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
  - a. Public benefit or service programs; this exemption is for Federally supported projects and is most appropriately invoked with authorization or concurrence by the funding agency. The following criteria must be satisfied to invoke the exemption for research and demonstration projects examining “public benefit or service programs:”
    - i. The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services under the Older Americans Act);
    - ii. The research or demonstration project must be conducted pursuant to specific Federal statutory authority;
    - iii. There must be no statutory requirements that the project be reviewed by an IRB; or
    - iv. The project must not involve significant physical invasions or intrusions upon the privacy of participants.
  - 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.
  - e. This exemption is for projects conducted pursuant to specific federal statutory authority. Exemption may be approved if there are no statutory requirements for IRB review and the research does not involve significant physical invasions or intrusions upon the privacy interests of subjects. The exemption must have the concurrence by the funding agency.
6. **45 CFR 46.101(b)(6) and 21 CFR 56.104(d)**: Taste and food quality evaluation and consumer acceptance studies;
- a. If wholesome foods without additives are consumed; or
  - b. If 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

## VI. Review of Exempt Studies

- A. **Submission Materials**: Investigators may request exempt status at the time of filing an application. Prior to approval, the investigator must respond to all requests for revisions or clarifications requested by the IRB staff reviewers or IRB members, when applicable. Research activities may not commence until approval is granted. Submission materials include:
- 1. Exempt Project Description;
  - 2. Administrative Certification from the department chair or center director;
  - 3. Investigator's or sponsor's protocol
  - 4. Data collection form or list of variables (for retrospective chart reviews)
  - 5. Proposed fact sheet or letter of invitation (if applicable)
  - 6. Proposed interview questions or surveys (if applicable)
  - 7. Advertising intended to be seen or heard by potential subjects, including email solicitations
- B. **Reviewers**: In lieu of review by the IRB Chair, research qualifying for exempt review may be reviewed and approved by certain IRB staff members. Those staff members reviewing and approving exempt research must be qualified by training and experience. In the course of the exempt review, staff members may consult with the IRB Chair or other experienced IRB members with questions including, but not limited to, those relating to the scientific content or ethical issues that may impact an exempt determination. If exempt status cannot be granted, the research will be reviewed using an expedited review procedure or reviewed using the convened board.

- C. IRB Actions on Exempt Studies: Exempt studies are reviewed to determine whether revisions or clarifications are necessary. After a complete review, an Exempt application may be approved, or the investigator may be directed to make modifications in order to secure approval. Investigators will be notified, in writing, of the decision and maintain that decision in the IRB file. Reasons for modifications required will be specified, in writing, to the investigator.
- D. Any proposed changes to the approved exempt study shall be submitted as a modification in the electronic IRB system. Changes may not be implemented prior to IRB review and approval.
- E. Approval of exempt research is granted when IRB staff confirm that all conditions of approval are met. Exempt research projects do not have an expiration date.
- F. Upon approval, the investigator receives written notification from the IRB, including the category allowing the exemption.
- G. The investigator is responsible for assuring that the exempt research is carried out in an ethical manner that includes appropriate participant protections (i.e., confidentiality).
- H. The IRB reserves the right to require studies that might be Exempt to undergo Expedited or Convened Board review if, for example, vulnerable populations are involved or to address other ethical concerns or organizational standards.

**References:**

45 CFR 46.101  
45 CFR 46.401(b)  
21 CFR 56.104(d)

## **2.6 Review of Expedited Research**

- I. Activities Eligible for Expedited Status.
  - A. Federal regulations (45 CFR 46.110, 21 CFR 56.110) allow the IRB to review certain applications on an expedited basis if they meet specified criteria. During the pre-review process, IRB staff confirms that the project qualifies for expedited review. All expedited protocols are reviewed by the IRB at least once per year. Additionally, the standard requirements for informed consent (or its waiver or alteration) apply to all IRB approvals regardless of the type of review - expedited or convened board - utilized by the IRB.
  - B. IRB Actions on Expedited Research Protocols: An expedited review consists of a review of research involving human subjects by the appropriate IRB Chairperson or a qualified IRB member designated by the Chairperson, as described below in section II.A. In reviewing the research,

the reviewer may exercise all of the authorities of the convened board except that the reviewer may not disapprove the research. Disapproval is only determined by the convened board. Additionally, the reviewer may refer the application to the convened board for a standard review as warranted.

C. General Restrictions on Expedited Review

1. Expedited review procedures may not be used where identification of the subjects 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.
2. Only research categories described in 45 CFR 46.110 and 21 CFR 56.110 and published in the Federal Register are eligible for expedited review.
3. Research considered "classified" by the Federal Government cannot be reviewed under expedited procedures.

D. The IRB may use an expedited procedure to conduct initial review of research provided all research activities do not fall under any of the general restrictions, present no more than minimal risk to human subjects, and involve procedures listed in one or more of the following categories:

1. **45 CFR 46.110(F)(1)/21 CFR 56.110(F)(1)**: Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. **NOTE:** Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.
  - b. Research on medical devices for which;
    - 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. **45 CFR 46.110(F)(2)/21 CFR 56.110(F)(2)**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - a. From healthy, non-pregnant 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, when 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 are considered. For these participants, 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. Children are defined in the federal 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" (*See* 45 CFR 46.402(a)).

3. **45 CFR 46.110(F)(3)/21 CFR 56.110(F)(3)**: Prospective collection of biological specimens for research purposes by noninvasive means. For example:
  - a. Hair and nail clippings in a non-disfiguring manner;
  - b. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - c. Permanent teeth if routine patient care indicates a need for extraction;
  - d. Excreta and external secretions (including sweat);
  - e. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
  - f. Placenta removed at delivery;
  - g. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
  - h. Supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - i. Mucosal and skin cells collected by buccal scrapping or swab, skin swab, or mouth washings;
  - j. Sputum collected after saline mist nebulization.
4. **45 CFR 46.110(F)(4)/21 CFR 56.110(F)(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 include:
  - a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - b. Weighing or testing sensory acuity;
  - c. Magnetic resonance imaging;

- d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
  - e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual;
- 5. **45 CFR 46.110(F)(5)/21 CFR 56.110(F)(5)**: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). **NOTE**: Some research in this category may meet exemption under 45 CFR 46.101(b)(4); this listing refers only to research that is not exempt.
  - 6. **45 CFR 46.110(F)(6)/21 CFR 56.110(F)(6)**: Collection of data from voice, video, digital, or image recordings made for research purposes.
  - 7. **45 CFR 46.110(F)(7)/21 CFR 56.110(F)(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 meet exemption under 45 CFR 46.101(b)(2); this listing refers only to research that is not exempt.

## II. Review of Expedited Research Protocols

- A. The IRB Chair, or one or more qualified members designated by the Chair, is required to review and approve research meeting expedited criteria. A qualified IRB member is defined as a voting member or alternate voting member who has received training relative to the expedited review categories, and possesses the scientific or regulatory expertise needed to review the proposed research. At least annually, the chair reviews and approves the list of members who are qualified to perform expedited reviews. The reviewer may, at their discretion, request a second reviewer or refer the research to the convened IRB for further determination.
- B. The reviewer may also request review of the research by an expert consultant for issues which require expertise beyond, or in addition to, that available on the IRB.
- C. Expedited reviewers are required to declare whether or not they have a conflicting interest with the review. If a conflict exists, a different reviewer will be assigned.

- D. Research materials submitted include sufficient detail for the reviewer to determine the study meets criteria 45 CFR 46.111 and 21 CFR 56.111, if applicable for approval:
1. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
  2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the reviewer should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The reviewer should not consider possible long-range effects of applying knowledge gained in the research (e.g., 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 considering 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 and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
  4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal and state regulations and institutional policies and procedures including the IRB;
  5. Informed consent will be appropriately documented, in accordance with, and to the extent required by the federal regulations and institutional policies and procedures including the IRB;
  6. When appropriate, the research plan makes adequate provisions 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; and
  8. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons. The reviewer must determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- E. Submission Materials for Expedited Review: The following materials are submitted and provided to the reviewer for expedited applications:
1. Expedited Project Description;

2. Scientific Review;
  3. Administrative Certification from the department chair or center director;
  4. Investigator's or sponsor's protocol;
  5. Proposed informed consent document(s) or script as appropriate;
  6. Surveys, questionnaires, or videotapes;
  7. Data collection form or list of variables (for retrospective chart reviews);
  8. Letters of assurance or cooperation with research sites;
  9. Relevant grant applications;
  10. Investigator's brochure (if one exists);
  11. Advertising intended to be seen or heard by potential subjects, including email solicitations.
  12. The DHHS-approved sample consent document (when one exists)
  13. The complete DHHS-approved protocol (when one exists)
- F. The reviewer conducts a thorough review of all submission materials. The reviewer determines a review interval for the research as appropriate to the degree of risk, but not greater than one year from the last date of IRB approval.
- G. Standard requirements for informed consent or its waiver or alteration apply to all studies meeting criteria for approval under the expedited criteria.
- H. Where specific determinations are required under the laws or regulations, the investigator must provide protocol-specific rationale in their IRB application materials. Examples include a request for waiver of consent, alteration of consent, waiver of documentation, and inclusion of children and pregnant women. The expedited reviewer's approval of the project constitutes acceptance of the protocol-specific findings.
- I. Modifications required to secure approval of expedited research are communicated to the investigator through the electronic IRB system or email which is documented in the IRB file. Final approval is withheld until all conditions are met.
- J. The convened board is advised of research proposals/activities that have been approved under the expedited review procedure through a list in the electronic IRB software that is generated for each meeting. The list contains the study title, principal investigator, and one or more approvable categories justifying the expedited review. The electronic list contains a link to the complete submission. At each meeting, members are given an opportunity to ask questions about any of the expedited approvals.
- K. Research cannot be disapproved by the Chair or his/her designee; if disapproval may be warranted, the review is forwarded to the convened board for review.

## **References:**

45 CFR 46.110, 111

21 CFR 56.110, 111

## **2.7 Review of Research by the Convened IRB**

### **I. Convened-Board Eligibility**

- A. An Investigator may request a particular type of review, but the final determination is made by the IRB.
- B. The IRB must review human subjects research not qualifying for review under the exempt or expedited categories.
- C. Standard requirements for informed consent or its waiver or alteration apply to all studies meeting the criteria for review by the convened IRB.

### **II. Review Materials**

- A. Submission Requirements: The following materials are required for convened-board review:
  - 1. Electronic Application in eCompliance / eIRB
  - 2. Full Committee Project Description;
  - 3. Investigator's or sponsor's protocol;
  - 4. Sponsor's sample consent form (when one exists);
  - 5. Proposed informed consent document(s) or script as appropriate;
  - 6. Copies of surveys, questionnaires, or videotapes;
  - 7. Copies of letters of assurance or cooperation with non-KUMC research sites;
  - 8. Full grant application, if the study is grant-funded
  - 9. Investigator's brochure (when one exists);
  - 10. Advertising, referral letters and all other recruitment materials
  - 11. The DHHS-approved sample consent document (when one exists)
  - 12. The complete DHHS-approved protocol (when one exists)
- B. Primary and secondary reviewers are assigned, as described in SOP 16.5.
- C. All board members receive the meeting agenda with their review assignment(s) approximately five to seven calendar days before the meeting. All members have access to the complete submission in the eIRB system. All members are expected to be familiar with materials on the agenda in order to facilitate the discussion.

### **III. Quorum for Convened Board Review**

- A. The IRB may only review proposed research at a convened meeting at which a quorum is present. Quorum requires that more than half of the voting members of the board are present, including at least one member whose primary interests are in nonscientific areas.
- B. No official actions take place at a meeting if quorum is not established.
- C. IRB meetings are not convened if a nonscientist is not present.

- D. During the convened meeting, the IRB staff monitors attendance to confirm that the meeting is appropriately convened and remains so throughout the meeting.
- E. Should the board lose quorum during the meeting (e.g., those with conflicts being recused, early departures, loss of all non-scientists), the meeting is terminated from further votes until the quorum is restored.
- F. No IRB member may participate in the IRB's initial or continuing review of a project in which the member has conflict of interest. If a conflict exists, the member can provide information requested by the IRB but must be excused during the discussion and the vote and will not be counted for quorum for the conflicted proposal.

#### IV. Convened-Board Review Process

- A. All submission materials are housed in the KUMC electronic IRB system (eIRB). Prior to the meeting, members are notified about agenda items and their review assignments through an email that is generated by the system. Once notified, members have full access to all materials for all agenda items.
- B. Substantive review of protocols occurs at convened meetings. Applications are individually presented and discussed at the convened meeting.
- C. The primary and secondary reviewers must conduct an in-depth review of all submission materials. Remaining IRB members must review provided materials in sufficient depth to discuss and vote at the meeting.
- D. IRB members have access to materials and technology used to conduct meeting as detailed below:
  - 1. During the meeting, each agenda item is project on large screens that are visible to all members.
  - 2. Members have access to three university-owned laptop computers which they can use to bring up their reviews during their presentation. Members are also allowed to bring their own personal computers to use during the meeting.
  - 3. During the meeting, members are given a laminated document that summarizes key elements of the Common Rule, special considerations for Subparts B – D and selected FDA requirements for quick reference.
- E. At the meeting, the primary reviewer presents a summary of the protocol, along with questions and substantive issues that the board should consider in its deliberations. The secondary reviewer presents any additional questions and issues for consideration. After the primary and secondary reviewers give a preliminary recommendation on action, the discussion is opened for comments by all members.
- F. In conducting the convened board review, the majority of the board must agree that materials are in sufficient detail to determine the study meets criteria 45 CFR 46.111 and if applicable, 21 CFR 56.111, for approval:

1. Risks to subjects are minimized by (a) using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research);
3. Selection of subjects is equitable considering 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 and the potential need for additional protections, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by federal and state regulations and Institutional policies and procedures including the IRB;
5. Informed Consent will be appropriately documented, in accordance with, and to the extent required by the federal and state regulations and institutional policies and procedures including the IRB;
6. When appropriate, the research plan makes adequate provisions 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;
8. There are adequate provisions to protect the rights and welfare of vulnerable populations from coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. The IRB must determine if additional safeguards need to be included in the study to protect the rights and welfare of these subjects;
9. In addition to federal requirements, proposals must fulfill institutional requirements:
  - a. When appropriate, the need for ancillary care, additional monitoring, counseling, and social support are provided.
  - b. All research personnel must demonstrate current training in the protection of human subjects.
  - c. All research personnel must have on file a current disclosure regarding conflict of interest.
  - d. The proposal must comply with institutional policies on compliance with the HIPAA Privacy Rule and conditions

issued by other ancillary committees, such as Radiation Safety, Biosafety, and Nursing Impact as applicable.

10. The investigator and the institution must be able to provide adequate resources to protect the study participants. On a per protocol basis, these may include special equipment, training for personnel, and referral to additional services.

## V. Actions by the Convened Board

- A. The final action of the board will be decided upon after appropriate discussion and voting. In order for an action to be approved, it must be approved by a majority of those members present at the meeting.
- B. The types of action possible by the convened board are listed below. Investigators may not initiate the study until all conditions have been met and approval for implementation has been granted.
  1. **Approved.** This action indicates that the investigator may implement the project.
  2. **Disapproved.** This action indicates that the board identifies major ethical conflicts or safety issues in the project which cannot be remedied without major revision. Written notification from the IRB of a decision to disapprove a protocol is accompanied by the reasons for the decision.
  3. **Deferred.** Action on the proposal is deferred when the IRB requests substantive clarifications or modifications regarding the protocol or informed consent document(s) that are directly relevant to the federal criteria for human research approval (see above in section 2.2, II). The investigator's responses to this category must be brought before the board for re-consideration at a regularly convened meeting.
  4. **Modifications Required to Secure Approval.** When the required modifications are minor or prescriptive in nature, (such as non-substantive issues requiring only simple concurrence by the investigator) the IRB may vote to authorize the Chair or another IRB member designated by the Chair, to review the investigator's responses under an expedited review procedure. The initial approval date is the date that the Chair or designee confirms that all required modifications have been made.

## VI. Approval Period

- A. The IRB determines a review interval for the research as appropriate to the degree of risk, but not greater than one year from the date of the convened meeting.



- B. The IRB may require review more frequently than annually. Examples of research that may be reviewed more frequently than annually include, but are not limited to:
  - 1. Research that involves procedures having more than minimal risk that have never before been used in humans;
  - 2. Research involving more than minimal risk with adults who are unable to consent;
  - 3. Research involving serious risk and no direct benefit (e.g., Phase I studies);
  - 4. Research conducted internationally;
  - 5. Involvement of recombinant DNA or other types of gene transfer protocols;
  - 6. Previous suspensions of the research due to compliance, record-keeping or other concerns;
  - 7. Recommendations from other institutional committees (e.g., SARC, PRMC, Conflict of Interest, Radiation Safety, Biosafety).

## VII. Notifications

- A. The decisions and requirement for modifications by the IRB are conveyed by letter to the Investigator, within one week of the meeting.
- B. The KUMC Institutional Official (IO) is apprised of IRB action(s) through the meeting minutes. Copies of the minutes are maintained in a shared drive within the Office of Compliance.

## References:

45 CFR 46.109, 111

## 2.8 Use of Consultants for Reviews

- I. As the agenda for an IRB meeting is being developed, the IRB staff makes an initial determination on whether the board has the expertise to review the proposals. The IRB staff may consult with the IRB Chair or other IRB members in making the initial determination. Members are asked to contact the IRB office if they believe a consultant is needed for scientific, ethical, legal or other expertise.
- II. Consultants with sufficient expertise are identified by the IRB staff in consultation with the HRPP Director, the IRB members or the Institutional Official. The HRPP Director or IRB staff manages the consultation process and ensures that appropriate documentation is obtained from the consultant and sufficient materials are provided for the review.
- III. When a consultant is identified and contacted about a potential review, he/she is given an informal overview of the project and information about the sponsor and study personnel. A review may proceed if the consultant confirms relevant

expertise and does not identify any conflicts of interest. Criteria for determining conflicts of interest of a consultant are the same as the criteria for conflicts of interests for an IRB member. Consultants complete the conflict of interest form that is used for IRB members. If a conflict of interest is disclosed, the consultant does not perform the review, and the HRPP Director or IRB staff must identify a different consultant.

- IV. Non-KUMC consultants sign a Confidentiality Agreement. When relevant, the sponsor is contacted about the need for a consultant review so that a confidentiality disclosure agreement can be obtained.
- V. Consultants may submit reviews by one of several methods. They may submit the review in writing or by telephone conference with IRB representatives prior to the meeting; they may participate in a conference call during the meeting; or they may attend a convened meeting. If the review is obtained prior to the meeting, the written review or a written summary of the conference call will be provided to all IRB members. When attending a convened meeting, consultants will present their review and IRB members may ask questions. Consultants are excused from the room during discussion and voting on the proposal.
- VI. IRB members may obtain informal consultations by directly contacting colleagues for information, provided that proprietary or sensitive information is not disclosed. IRB members should disclose informal consultations in the course of their reviews. Depending on the relevance of the information, informal consultations may be noted in the meeting minutes.

**References:**

45 CFR 46.107

21 CFR 56.107

## **2.9 Review of Investigator Responses**

- I. Following review of a protocol, a letter is issued to the investigator that outlines any modifications required to secure approval. If the protocol was reviewed under an expedited procedure, the investigator's responses will be reviewed by the IRB Chairperson or other qualified member. A qualified IRB member is defined as a voting member or alternate voting member, designated by the Chair, who has received training relative to the expedited review categories and possesses the scientific or regulatory expertise needed to review the proposed research. If all required changes are made, the investigator is notified of the approval by letter.
- II. If the protocol was reviewed at a convened meeting and was deferred or had modifications required to secure approval, the research may not proceed. All IRB actions and modifications required to secure approval are detailed in a letter to the investigator.

- III. The investigator's response may be reviewed and accepted by the IRB Chairperson or a qualified member, when the initial action by the IRB was modifications required to secure approval. If the reviewer determines that the IRB's requirements have been met, the investigator will be notified of approval. If the reviewer determines that the IRB's requirements have not been met, the reviewer has the option to request further clarification or modifications from the investigator by reiterating the IRB's requirements or to refer the investigator's responses to the convened board.
- IV. Investigator responses to a deferral or disapproval require convened board review. If possible, the same primary and secondary reviewers will review the responses. Once the response is reviewed by the convened board, the investigator will be notified by letter.

**References:**

45 CFR 46.109,111

**2.10 Determination of the Approval Period**

- I. Approval dates (all studies) and expiration dates (non-exempt studies) are placed on all approved informed consent documents. The current, date-stamped consent forms, issued in the eIRB system, are the only versions that are to be used by investigators in obtaining consent for human research studies. This procedure helps assure that only the current, IRB-approved informed consent documents are presented to participants and serves as a reminder to investigators of the need for continuing review.
- II. For non-exempt studies, the approval period is calculated as follows:
  - A. Approved at a convened meeting:
    - 1. If the project is fully approved at a convened meeting, the date of the convened meeting is the date of IRB approval.
    - 2. The approval end date is based on the date of the convened meeting (minus one day).
    - 3. For example, if the IRB meeting date is 10/1/2013, the approval period is 10/1/2013 – 9/30/2014 for an annual approval or 10/1/2013 - 3/31/2014 for a six month approval.
  - B. Determination of Modifications Required to Secure Approval at a convened meeting:
    - 1. If the board determines that modifications are required to secure approval, approval is withheld until the IRB Chair or designee verifies that the required modifications have been made.

2. The initial approval is the date that all IRB requirements are verified.
  3. For the first approval period, the approval end date is based on initial approval date.
  4. For example, if modifications are required to secure approval at a meeting on 10/1/2013, and the requirements are verified on 10/15/2013, then the approval period is 10/15/2013 - 10/14/2014 for an annual approval or 10/15/2013 - 4/14/2014 for a six month approval.
- C. Reviewed through Expedited Process:
1. If a project is reviewed through an expedited review process, the date of approval is the date the IRB staff confirm that all requirements from the designated reviewers are satisfied.
  2. The approval end date is based on the date that the IRB staff verify that all requirements from the designated reviewers are satisfied (one year minus one day).
  3. For example, if the IRB staff verify that the designated reviewer's requirements are satisfied on 10/1/2013, then the approval period is 10/1/2013 – 9/30/2014.

- III. It is the investigator's responsibility to only use those informed consent documents bearing the correct approval dates when obtaining informed consent from research participants.

**References:**

45 CFR 46.109

OHRP Guidance on IRB Continuing Review of Research