

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 is made by the HSC Committee, HSC Chair, Director of HRPP, or the IRB Administrator. 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 HSC 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.

III. Guidance to Investigators

- A. The Human Research Protection Program is responsible for providing and updating guidance to investigators about activities that require prior HSC 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 below)
 - 5. Research on behavioral interventions
 - 6. Database queries 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. Quality improvement interventions
 - 13. Certain program evaluations (see below)

14. Pilot studies
 15. Student research projects
 16. Research conducted by KUMC personnel at other institutions
 17. Collaborative projects involving human data or specimens
 18. Use of human data or specimens transferred from a faculty member's former institution
 19. Feasibility studies that use the same or similar procedures that subjects will undergo in a future research study
 20. 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 become research if the KUMC faculty member keeps the evaluation data for presentations, further analysis or future grant proposals.
 2. 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 if:
 - 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.

3. Single case reports, if the report is compiled by persons already involved in patient's care, if the information is presented in de-identified form, and if 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 for presentation.
 4. Certain research activities, in which the investigator does not obtain individually identifiable information or specimens, may be considered not human subjects research. The HSC 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.
 5. Research using publicly accessed databases, if the databases contain no individual identifiers and if access is granted without requiring a data use agreement.
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- E. The HSC 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 activities.
 - H. If the activity is determined to be not human subjects research, the investigator will receive written confirmation from the HSC Office.
 - I. If the activity is determined to be human subjects research, the investigator will receive written instructions that outline steps for applying for human research 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 HSC'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 HSC'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 Committee 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 Committee 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 HSC 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 Committee 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 Committee 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 Committee will ensure that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. A data and safety monitoring plan is required for all studies that are greater than minimal risk. Plans for data monitoring will be assessed at the time of initial review. Monitoring reports will be reviewed on an ongoing basis and at the time of continuing review to ensure safety of subjects.
- F. The Committee 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.

- G. The HSC may require that a Certificate of Confidentiality be obtained when the participants are at risk for loss of privacy that could adversely affect financial standing, employability, insurability, or reputation.
- H. 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 Committee 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 human subjects research, the HSC 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 HSC applications. Scientific or scholarly review may be accomplished by one of several groups.
- B. Scientific review may be accomplished by an external peer review from NIH or other funding agencies.
- C. Departments or schools may designate an internal reviewer or review committee.
- D. The Kansas Masonic Cancer Research Institute's Protocol Review and Monitoring Committee (PRMC) performs the scientific review for all cancer or cancer-related proposals. PRMC approval must precede submission to the HSC.
- E. The GCRC Advisory Council (GAC) performs the scientific review for all investigator-initiated proposals that request the use of GCRC resources. HSC approval is contingent on GAC approval, for studies using the GCRC.
- F. At their discretion, the HSC and its Chairperson, or expert consultants may perform additional scientific or scholarly review.

IV. 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 HSC will rely on, when applicable, the determinations of other individuals or groups who have previously conducted a scientific or scholarly review of the proposed study, as described above.
- C. The HSC may use the expertise of its members when considering scientific or scholarly merit. In reviewing scientific or scholarly merit, the HSC review considers the presentation of all supporting background scientific information including, but not limited to, animal studies (whenever applicable) and sound study design.
- D. If the HSC believes it does not have the expertise required to understand the background, aims, and research methods proposed, the HSC will request outside scientific review by a consultant on a project consistent

with HSC SOP 2-8. HSC will request outside consultants prior to taking action on the protocol.

- E. HSC 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 Full-Committee Review Categories

I. Determination of Exempt Review

- A. Research proposals are initially screened by HSC staff for Exempt status by identifying which submissions include an Application for Exempt Status form.
- B. If a study includes an Application for Exempt Status form, the IRB Administrator will conduct an additional screening to determine if the proposed research fits into an exempt category of research.
- C. If the proposed research fits into an exempt category of research, it will be reviewed by HSC staff as described in section 2.5 below. Investigators do not determine Exempt status.
- 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 full-committee review procedures.

II. Determination of Expedited Review

- A. Research proposals not including an Application for Exempt Status form are screened by the IRB Administrator 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 HSC chairperson or other experienced HSC 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 full-committee review procedures. If the proposed research proposal is considered exempt, the investigator will be notified to submit an Application for Exempt Status.
- II. Determination of Full-Committee 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 Committee.
 - B. Research proposals needing full-committee review will be docketed 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 HSC Members and Consultants

I Identifying Conflicts of Interest

- A. Annually all HSC members complete a financial conflict of interest disclosure form that captures potential conflicts among members of compliance committees. Financial disclosure thresholds for HSC members are identical to the thresholds used for research personnel on the conflict of interest form mandated by the Kansas Board of Regents. The Associate Vice Chancellor for Compliance reviews disclosures of interest related to research that are made by HSC members.
- B. The Associate Vice Chancellor for Compliance informs the IRB Administrator if a conflict of interest is disclosed by an HSC member.
- C. HSC members are considered to have a protocol-specific conflict of interest if they, or their immediate family, have financial interests related to the study as described in the HSC application forms, i.e., payments, advisory relationships, licensing agreements, patents or royalty interests.
- D. HSC members are 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.

- E. The IRB Administrator will not assign a review to a member who has a known conflicting interest related to the proposal.
- F. As an additional confirmation, primary and secondary reviewers indicate on the reviewer checklist whether they have a conflicting interest related to the review. If reviewers have a conflict of interest, they are instructed to notify the IRB Administrator immediately so that the review can be re-assigned.
- G. 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 Director of the HRPP obtains the signed attestation prior to distribution of review materials.

II Assignment of Reviews

- A. Members are not engaged as a reviewer in the HSC's review of any aspect of the protocol, including initial review, review of amendments, unanticipated problems, continuing review or allegations of non-compliance if a conflict is known.
- B. Members who self-identify a conflict on a review assignment should promptly contact the IRB Administrator so that the review may be re-assigned to a reviewer with no conflict.

III Member Exclusion from Discussion and Voting

- A. Members who have a conflict of interest may provide information requested by the HSC 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. That member is not counted towards quorum.

References:

45 CFR 46.107

21 CFR 56.107

2.5 Review of Exempt Research

- I. All research conducted under exempt review is subject to all applicable KUMC institutional and HSC policies and procedures.
- 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 informed that their

participation is voluntary, and they should be given an opportunity to agree to participate without coercion. Subject selection must be equitable. Any associated risk to individuals or society must be low.

- 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 from the HSC.
- 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. All study personnel participating in exempt research must complete training in human subjects protection and have on file a current conflict of interest disclosure form.
- VI. Activities Eligible for Exempt Status.
 - A. Research activities involving human subjects that are exempt from the requirement that they receive HSC full or expedited review are identified in 45 CFR 46.101(b)(1)-(6), 45 CFR 406.301(a), 45 CFR 46.401(b) and 21 CFR 6.104(d). The HSC may not create new categories of this exempt research. Only the HSC 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 HSC 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 HSC.
 - C. Exempt determinations may be made by the HSC Chairperson, Vice Chair, Director of the HRPP, or IRB Administrator.
 - D. Research may be granted exempt status by the HSC 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.

VII. 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 HSC staff reviewers or HSC members, when applicable. Research activities may not commence until full approval for implementation is granted.
- B. Reviewers: Research qualifying for exempt review may be reviewed and approved by certain HSC staff members. Those staff members reviewing and approving exempt research must hold the current credential of "Certified IRB Professional (CIP)". In the course of the exempt review, staff members may consult with the HSC Chair or other experienced HSC 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 committee.
- C. HSC Actions on Exempt Studies: Exempt studies are placed in PENDING status when revisions or clarifications are necessary. After a complete review, an Exempt application may be APPROVED FOR IMPLEMENTATION or DENIED. Investigators will be notified, in writing, of the decision and maintain that decision in the HSC file. Reasons for DENIED research will be specified, in writing, to the investigator.
- D. Any changes to the approved exempt study shall be submitted to the HSC using the "Request for Amendment" form. Changes may not be implemented prior to HSC review and approval.
- E. Upon approval, the investigator receives written notification from the HSC, including the category allowing the exemption.
- F. 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).
- G. The HSC reserves the right to require studies that might be Exempt to undergo Expedited or Full-Committee review if, for example, vulnerable populations are involved or to address other ethical concerns or organizational standards.

References:
45 CFR 46.101

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 HSC to review certain applications on an expedited basis if they meet specified criteria. All expedited protocols are reviewed by the HSC at least once per year. Additionally, the standard requirements for informed consent (or its waiver, alteration, or exception) apply to all HSC approvals regardless of the type of review - expedited or full-committee - utilized by the HSC.
- B. HSC Actions on Expedited Research Protocols: An expedited review consists of a review of research involving human subjects by the appropriate HSC Committee Chairperson or an experienced HSC 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 full Committee except that the reviewer may not disapprove the research. Disapproval is only determined by the full Committee. Additionally, the reviewer may refer the application to the full Committee for a standard review as warranted.
- C. General Restrictions on Expedited Review
 - 1. Expedited review procedures may not be used for research involving prisoners.
 - 2. 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.
 - 3. 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.
 - 4. The research must not be classified research.
- D. The HSC 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 HSC Chair, or one or more experienced reviewer designated by the Chair, is required to review and approve research meeting expedited criteria. An experienced HSC member means a voting member or alternate voting member who has served on the HSC for at least one year, has received training relative to the expedited review categories, and possesses the scientific expertise needed to review the proposed research. The reviewer may, at their discretion, request a second reviewer or refer the research to the convened Committee 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 Committee.
- C. 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 HSC;
 - 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 HSC;
 - 6. When appropriate, the research plan makes adequate provisions for

7. 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.
- D. Submission Materials for Expedited Review: The following materials are submitted and provided to the reviewer for expedited review applications:
1. A completed HSC application page, List of Study Personnel, and IRSC form;
 2. Investigator's or sponsor's protocol;
 3. Proposed informed consent document(s) or script as appropriate;
 4. Copies of surveys, questionnaires, or videotapes;
 5. Copies of letters of assurance or cooperation with research sites;
 6. Relevant grant applications;
 7. Investigator's brochure (if one exists);
 8. Advertising intended to be seen or heard by potential subjects, including email solicitations.
 9. The DHHS-approved sample consent document (when one exists)
 10. The complete DHHS-approved protocol (when one exists)
- E. 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 HSC approval. The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of HSC approval. Therefore, continuing review and re-approval of the research occurs on or before the date when HSC approval expires. When continuing review occurs annually and the HSC performs continuing review within 30 days before the HSC approval period expires, the HSC may retain the anniversary date as the date by which the continuing review must occur.
- F. Standard requirements for informed consent or its waiver or alteration apply to all studies meeting criteria for approval under the expedited criteria.
- G. Any conditions that must be met prior to approval of expedited research are sent to the investigator by mail or email and documented in the HSC file. Final approval is withheld until all conditions are met.
- H. The full Committee is advised of research proposals/activities that have been approved under the expedited review procedure, through the meeting minutes. Committee minutes contain multiple addenda; one addenda lists the expedited approvals of new protocols. The list contains the study title, principal investigator, and one or more approvable categories justifying

the expedited review.

- I. Research cannot be disapproved by the Chair or his/her designee; it is forwarded to the full Committee for review.

References:

45 CFR 46.110, 111

21 CFR 56.110, 111

2.7 Review of Research by the Convened Human Subjects Committee (HSC)

I. Full-Committee Eligibility

- A. An Investigator may request a particular type of review, but the final determination is made by the HSC.
- B. The Committee 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 full HSC.

II. Review Materials

- A. Submission Requirements: The following materials are required for full-committee review:
 - 1. A completed Application for Full-Committee Review and IRSC form;
 - 2. Investigator's or sponsor's protocol;
 - 3. Sponsor's sample consent form (when one exists);
 - 4. Proposed informed consent document(s) or script as appropriate;
 - 5. Copies of surveys, questionnaires, or videotapes;
 - 6. Copies of letters of assurance or cooperation with non-KUMC research sites;
 - 7. Full grant application, if the study is grant-funded
 - 8. Investigator's brochure (when one exists);
 - 9. Advertising, referral letters and all other recruitment materials
 - 10. The DHHS-approved sample consent document (when one exists)
 - 11. The complete DHHS-approved protocol (when one exists)
- B. Primary and secondary reviewers are assigned, as described in SOP 16.5.
- C. Primary and secondary reviewers receive the complete packet of submission materials listed above. The remaining HSC members who are scheduled to attend the meeting receive the application form which contains the protocol summary, proposed informed consent document, recruitment materials and any other pertinent information as deemed necessary by the Committee Chair or IRB Administrator. All members

may request to review the information provided to the primary and secondary reviewers by contacting the HSC staff.

- D. Review packets are available to committee members four days before the meeting.

III. Quorum for Full-Committee Review

- A. The HSC Committee 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 Committee 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. HSC meetings are not convened if a nonscientist is not present.
- D. During the convened meeting, the IRB Administrator monitors the members present to ensure that the meeting is appropriately convened and remains so throughout the meeting.
- E. Should the Committee lose quorum during the meeting (e.g., those with conflicts being excused, early departures, loss of all non-scientists), the meeting is terminated from further votes until the quorum is restored.
- F. No HSC member may participate in the HSC's initial or continuing review of a project in which the member has conflict of interest. If a conflict exists, the Committee member can provide information requested by the HSC but must be excused during the discussion and the vote.

IV. Full-Committee Review Process

- A. Substantive review of protocols occurs at convened meetings. Applications are individually presented and discussed at the convened meeting.
- B. The primary and secondary reviewers must conduct an in-depth review of all submission materials. Remaining HSC members must review provided materials in sufficient depth to discuss and vote at the meeting.
- C. At the meeting, the primary reviewer presents a summary of the protocol, along with questions and substantive issues that the Committee 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.
- D. In conducting the full HSC review, the majority of the Committee 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 HSC 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 HSC;
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 HSC;
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 HSC 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.

V. Actions by the Full Committee

- A. The final action of the Committee 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 full Committee are listed below. Investigators should note that when a project falls under (3) or (4), a response to provisos must be received in the HSC office within 45 days of the meeting or the project will be administratively terminated. The response can include a request for extension which will be considered by the HSC or IRB Administrator on a case by case basis. Investigators may not initiate the study until all questions have been resolved 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 Committee identifies major ethical conflicts or safety issues in the project which cannot be remedied without major revision. Written notification from the HSC of a decision to disapprove a protocol is accompanied by the reasons for the decision.
 3. **Deferred-Additional Review by Committee Required.** Approval in this category is deferred when the HSC 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 section I.C). The investigator's responses to this category must be brought before the full Committee for action at a regularly convened meeting.
 4. **Conditional Approval -Additional Chair Review Required Before Implementation.** When the HSC's stipulations are minor in nature, (such as non-substantive issues require only simple concurrence by the investigator) the HSC may vote to authorize the Chair or another HSC member designated by the Chair, to review the investigator's responses under an expedited review procedure. If the responses are considered satisfactory, the deferred action will then be approved for implementation by the Chair or designee.
 5. **Tabled.** This action will be taken when the Committee determines that it is inappropriate to review the study because it does not have sufficient information for definitive action. If the project is tabled, the investigator will be given written notice, and no further action will be taken by the Committee until the investigator adequately addresses the deficiencies. When new information is submitted, the protocol may be reviewed at a regular convened meeting.
 6. **Restricted Approval.** This action will be taken when the Committee determines that the project will be conducted in phases and later phases have not been fully developed by the investigator.

VI. Approval Period

- A. The full HSC 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 HSC approval.
- B. The HSC 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 Administrative Holds or Suspensions of the research due to compliance, record-keeping or other concerns;
 - 7. Recommendations from other institutional committees (e.g., GCRC, PRMC, Conflict of Interest, Radiation Safety).

VII. Notifications

- A. The decisions and requirement for modifications by the HSC are conveyed by letter to the Investigator, within one week of the meeting. Results of reviews are also posted to an internal website that investigators may access.
- B. The KUMC Institutional Official (IO) is notified of HSC action(s) through the meeting minutes. Copies of the minutes are maintained in the IO's office.

References:

45 CFR 46.109, 111

2.8 Use of Consultants for Reviews

- I. As the agenda for an HSC meeting is being developed, the IRB Administrator makes an initial determination on whether the committee has the expertise to review the proposals. The IRB Administrator may consult with the HSC Chair or other HSC members in making the initial determination. Additional input on sufficient expertise is sought from the primary and secondary reviewers at the time of review. The primary and secondary reviewers use the reviewer checklist

- to indicate their assessment on whether the Committee has sufficient expertise to review the proposal.
- II. If the HSC determines that it does not have scientific, ethical, legal or other expertise to conduct a review of a proposed study, consultants from outside the Committee will assist with the review.
 - III. Consultants with sufficient expertise are identified by the IRB Administrator, in consultation with the HRPP Director, the HSC members or the Institutional Official. The HRPP Director or IRB Administrator manages the consultation process and ensures that appropriate documentation is obtained from the consultant and sufficient materials are provided for the review.
 - IV. When a consultant is identified and contacted about a potential review, he/she is given an 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 HSC member. Consultants complete the conflict of interest form that is used for HSC members. If a conflict of interest is disclosed, the consultant does not perform the review, and the HRPP Director or IRB Administrator must identify a different consultant.
 - V. KUMC consultants sign a Faculty/Staff Confidentiality Agreement. Non-KUMC consultants sign an HSC Consultant Confidentiality Agreement. When relevant, the sponsor is contacted about the need for a consultant review so that a confidentiality disclosure agreement can be obtained.
 - VI. Consultants may submit reviews by one of several methods. They may submit the review in writing or by telephone conference with HRPP and HSC 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 HSC members. When attending a convened meeting, consultants will present their review and HSC members may ask questions. Consultants are excused from the room during discussion and voting on the proposal.
 - VII. HSC members may obtain informal consultations by directly contacting colleagues for information, provided that proprietary information is not disclosed. HSC 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 changes needed to secure approval. If the protocol was reviewed under an expedited procedure, the investigator's responses will be reviewed by the HSC Chairperson or other experienced member. An experienced HSC member means a voting member or alternate voting member who has served on the HSC for at least one year, has received training relative to the expedited review categories, and possesses the scientific 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 conditionally approved with provisos, deferred with provisos, or tabled, the research may not proceed. All HSC actions and requirements for approval are detailed in a letter to the investigator.
- III. The investigator's response to provisos may be reviewed and accepted by the HSC Chairperson or an experienced member designated by the Chair, when the initial action by the Committee was conditional approval pending further chair review. If the reviewer determines that the Committee's requirements have been met, the investigator will be notified of approval. If the reviewer determines that the Committee's requirements have not been met, the reviewer has the option to request further clarification of the investigator by reiterating the Committee's requirements or to refer the investigator's responses to the convened Committee.
- IV. Investigator responses to conditions of deferred with provisos, tabled or disapproved with provisos, require full-committee review. If possible, the same primary and secondary reviewers will review the responses. Once the response is approved by the full Committee, the investigator will be notified by letter.

References:

45 CFR 46.109,111

2.10 Determination of Approval and Expiration Dates

- I. HSC Office staff place approval and expiration dates on all approved informed consent documents. Copies of the current, date-stamped approved documents are the only versions that may be used by investigators in obtaining consent for human research studies. This procedure helps assure that only the current, HSC-approved informed consent documents are presented to participants and serves as a reminder to investigators of the need for continuing review.

- II. Date of HSC Approval: The approval date is the date that the HSC application and informed consent documents were initially reviewed and granted final approval by the HSC, unless one of the following apply:
 - A. If the application has received a continuing review and approval of the research activities and informed consent documents, the date of the continuing review approval is used.
 - B. If the HSC approves an amendment to the informed consent documents at a convened meeting, the date of the convened meeting is the approval date for the amendment and the consent documents.
 - C. If the HSC has approved an amendment that does not involve a change to the informed consent, the informed consent approval date will not change.

- III. Calculating the date of HSC approval for informed consent documents
 - A. Approval at a convened HSC meeting: When the HSC approves the application at the convened meeting, the date of the meeting is the date of HSC approval that is stamped on the informed consent form.
 - B. When the HSC application is approved with provisos (i.e., conditional approval pending additional chair review prior to implementation), the date that the proviso responses are accepted by the HSC Chair or other experienced member is the date of HSC approval stamped on the informed consent document.
 - C. Expedited Review: When a new application or continuing review is approved through an expedited review process, the date that approval is extended by the HSC chair or other experienced member is the date of HSC approval stamped on the informed consent document.
 - D. Amendments: The date of HSC approval for amended informed consent documents is based on the type of review or determination as described above. For example, when an amendment is approved pending responses to proviso at a convened HSC meeting, the date that the proviso responses are accepted by the HSC chair or other experienced member is the date of HSC approval stamped on the informed consent documents.

- IV. Date of HSC Expiration. The expiration date is the date that signifies the end of the current HSC approval period. Projects may be approved for no longer than one year. Federal regulations make no provision for any grace period extending the conduct of research beyond the expiration date of HSC approval. Therefore, continuing review and re-approval of research must occur on or before the date when HSC approval expires. If this does not happen, research must be discontinued.

- V. Calculating the date of HSC expiration for informed consent documents
 - A. Approval at a convened HSC meeting: Based on the approval period granted, the date of expiration is calculated from the date of the convened

HSC meeting. For example, if the Committee meeting date is 12/11/05, then the date of HSC expiration is 12/10/2006 for a one-year review interval.

- B. When the HSC application is approved with provisos (i.e., conditional approval pending additional chair review prior to implementation), the date of expiration is calculated from the date of the convened HSC meeting. It is not calculated from the date that the proviso responses are verified by the HSC chair or other experienced member. For example, if the Committee approves an application *pending additional chair review prior to implementation* on 12/11/2005 and the “proviso responses” are verified by the chair on 3/1/2006, then the date of HSC expiration” is 12/10/2006 for a one year review interval and 6/11/2006 for a six month review interval.
 - C. Expedited review: Because there is no convened meeting in an expedited review, the date of HSC expiration will be calculated based on the review interval determined by the HSC chair or other experienced member. At maximum, expiration will be one year, less one day, from the date that the initial HSC application or most recent Continuing Review Form was approved by the HSC chair or other experienced member.
 - D. Amendments: The approval date of an amendment does not affect the calculation of the expiration date unless the HSC increases or decreases the review interval, within the one-year maximum.
- VI. Federal regulations recognizes the logistical advantages of keeping the HSC approval period constant from year to year throughout the life of each project. When continuing review occurs annually and the HSC performs continuing review within 30 days before the HSC approval period expires, the HSC may retain the anniversary date as the date by which the continuing review must occur. Investigators who submit continuing reviews with no intent to enroll additional participants do not need to submit a copy of the informed consent document for HSC re-approval and stamping. However, the research study cannot be re-opened to enrollment without an amendment including a current informed consent document.
- VII. It is the investigator’s responsibility to only use those informed consent documents bearing the correct approval and expiration dates when obtaining informed consent from research participants
- VIII. The HSC determines the appropriate review interval based on the federal regulations and Human Research Protections Program procedures. For continuing reviews that occur after initial approval, the HSC verifies that the currently approved and correctly date-stamped informed consent documents have been submitted for review.

References:

45 CFR 46.109