Kentucky State University (KSU)
Human Research Protection Program (HRPP)
Policies and Procedures

Revised 09.01.2023

Issuing Office: Office of Sponsored Programs (OSP)

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PURPOSE

To provide a comprehensive outline of policies, procedures, and guidance for research by KSU faculty, staff, and students involving human subjects, including the composition and role of the Institutional Review Board (IRB) and the procedures the IRB will follow when reviewing and approving research, and to facilitate compliance with federal requirements regarding the protection of human subjects, including but not limited to 21 CFR § 56 and 45 CFR § 46. The policies and procedures outlined herein respond to and are aligned with the revisions made to 45 CFR § 46 in 2018.

I. OVERVIEW

1.1 The HRPP

The HRPP is a comprehensive and dynamic system of shared responsibility to ensure the protection of human subjects participating in research. The IRB is an important component of an HRPP, but it is only one part of an overall organizational effort to protect human subjects that involves administrators, faculty, staff, and students. The HRPP recognizes that individual researchers bear responsibility for following ethical principles, adhering to regulatory requirements, and avoiding conflicts of interest. The HRPP also recognizes that ongoing training, education, and communication regarding the protection of human subjects are vital to research integrity and compliance.

1.2 What is the IRB?

The IRB is an independent research review committee mandated by the U.S. Department of Health and Human Services (HHS). Federal regulations require each institution to implement human subject research regulations at its institution whenever its agents conduct research involving human subjects. The IRB and research activities by KSU faculty, staff, and students are subject to review by a variety of federal agencies; chief among them is the Office for Human Research Protections (OHRP).

1.3 The OSP's Role

OSP staff plays a crucial role in facilitating training, education, and communication regarding human subjects, and ensures that the HRPP responds to a changing research environment and remains relevant and effective. OSP staff is responsible for convening the IRB, reviewing and renewing the IRB's registration with OHRP and Federal Wide Assurance, and assisting the IRB with the review of research. One OSP staff member will serve as the designated HRPP specialist and IRB administrator, and up to two staff members will serve as alternate IRB members, as outlined in sections 3.6 and 4.2.

1.4 Federal Wide Assurance

KSU's IRB is registered with the OHRP and maintains a single Federal Wide Assurance (FWA) that commits the institution to complying with federal regulations related to human research protection, including maintaining written procedures for the review of research involving human subjects. This assurance is applicable to all funded and non-funded research conducted or led by KSU personnel. It stipulates that research by KSU personnel will be guided by ethical principles and the Federal Policy for the Protection of Human Subjects, known as the "Common Rule" (or 45 CFR § 46 Subpart A), as well as all other Subparts of 45 CFR § 46, which concern protections for pregnant women, fetuses, neonates, prisoners, and children in research.

1.5 Guiding Documents and Regulations

KSU's HRPP is rooted in and guided by the ethical principles outlined in two key historical documents, the *Nuremberg Code* and *Belmont Report*. These documents became the foundation for the "Common Rule" and 45 CFR § 46. These documents and the federal regulations founded on them are essential references for the IRB, OSP staff, and all KSU personnel conducting research involving human subjects.

Definitions

The policies and procedures herein adhere closely to 45 CFR § 46 and adopt the definitions of terms in 45 CFR § 46.102. These include the following definitions:

Human subject is defined as a living individual about whom an investigator (whether

professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Research does not include the following activities:

1) Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Required Written Procedures

The policies and procedures herein directly address the requirements of 45 CFR § 46.108, which require that institutions establish and follow written procedures for the IRB for each of the following:

- Procedures for the IRB to conduct an initial and continuing review of research and for reporting its findings and actions to the investigator and the institution.

- Procedures for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

- Procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

- Procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the OHRP, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

II. ROLE AND AUTHORITY OF THE IRB

The role of the IRB is to protect the rights and welfare of human subjects in research activities conducted by KSU faculty, staff, or students, as well as research conducted by non-KSU personnel on the campus of KSU. The IRB conducts initial reviews of proposed research and monitors continuing research in order to safeguard the rights and welfare of human subjects. The IRB's functions include:

a. To determine and certify that all projects approved by the IRB conform to the ethical guidelines, regulations, and policies regarding the protection of human research participants; and

b. To assist researchers in conducting ethical research that complies with federal regulations and is safe for the human subjects involved.

The IRB should not place undue burdens on researchers but should help to create a collaborative environment in which all faculty, staff, and students are following standard practices regarding research integrity and protection of human subjects.

The IRB has the authority to approve, require modifications in order to secure approval, or disapprove all research activities that fall within its jurisdiction in accordance with federal regulations and institutional policies. The IRB has the authority to observe or have a third party observe and monitor research activities in order to protect human subjects. In so doing, the IRB also has the authority to require periodic progress reports, oversee the conduct of studies, and to suspend or terminate approval of a study due to noncompliance. In cases where there is a dispute between researchers and the IRB specifically regarding the protocol review process, the researcher may pursue an appeal.

Research that has been reviewed and approved by the IRB may be subject to review and

disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB in accordance with federal regulations. Research that has been reviewed and approved by the IRB is subject to continuing IRB review and must be reevaluated at least annually or more frequently if needed.

III. COMPOSITION AND MANAGEMENT OF THE IRB

3.1 Appointment of Members

The IRB will be comprised of a minimum of five regular voting members qualified through experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Members will include faculty and staff of the University, as well as members from outside the University. The Provost or President will appoint members to the IRB and will appoint the Chair of the IRB in consultation with OSP staff. OSP staff will not serve as regular voting members of the IRB, but can serve as alternate members under circumstances where an alternate is needed. The Chair should not be an OSP staff member. Members are appointed for one or two-year renewable terms and for a maximum appointment of six consecutive years.

3.2 Affiliations of Members

The IRB must include at least one member with each of the following primary affiliations: nonscientific, scientific, and nonaffiliated with KSU. Members with scientific affiliations are generally those individuals with training, background, and occupations in STEM fields, behavioral sciences, and health-related disciplines, and/or who conduct scientific research on a regular basis. Members with nonscientific affiliations are individuals with training, background, and occupations in the humanities, interpretive social sciences, and arts and/or who do not regularly conduct scientific and quantitative research. Nonaffiliated members may not be affiliated with KSU or be a part of the immediate family of a person who is affiliated with KSU. It is possible for a member to fill two roles; for example, a member could be otherwise unaffiliated with the institution and have a primary concern in a non-scientific area. This individual would satisfy two of the membership requirements of the regulations.

The IRB will not consist entirely of members of one profession or discipline. The IRB shall be diverse in its composition and consideration will also be given to the race, gender, and cultural background of each member. In addition, the IRB composition will be sensitive to such issues as community attitudes, promoting respect for its advice and counsel.

3.3 Qualifications of Members

In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of regulations, applicable law and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas and who will continue to develop their knowledge of these areas through participation in

trainings and open and collaborative dialogue with OSP staff, other IRB members, and researchers. If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or persons with disabilities, then consideration will be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these populations.

The IRB will also invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These consultants will not be members of the IRB and may not vote on protocols. As non-voting consultants, these individuals do not affect the determination of a quorum.

3.4 OSP Staff as Alternate Members

Up to two members of OSP staff can serve as alternate members of IRB. Alternate IRB members replace regular IRB members who are unable to attend meetings of the IRB or conduct a protocol review. Alternate members must have qualifications comparable to the applicable regular members, including the completion of required training, and may be an alternate for more than one IRB member as needed. Alternates attending a meeting or conducting protocol review have all the authority of regular IRB members.

3.5 Meeting Attendance and Determination of Quorum

IRB members should be prepared to meet once monthly. If there are no protocols requiring review and discussion by the full Board in a given month, the Chair in consultation with OSP staff may postpone the meeting for that month.

A quorum will be constituted by more than half of the number of the regular voting active membership. When a quorum of regular members is not present, an OSP staff member may serve as an alternate member. No IRB action may be taken without a properly constituted quorum. If a quorum is lost during a meeting, then the Board may not take further action or vote until the quorum is restored.

3.6 Placing IRB Members on Inactive Status

Periodically, IRB members need to take an extended leave of absence from IRB service. In these cases, the IRB member may be placed on inactive status. Inactive status means that the member is still a member of the IRB, but their absence will not affect quorum. They will be noted on meeting minutes as inactive status, rather than merely absent.

Current active regular voting members of the IRB can petition the IRB Chair to be placed on inactive status if they anticipate an upcoming period of time lasting at least four months but no more than 12 months during which they will not be able to attend IRB meetings or complete regular duties of an active voting member. Current active voting members who wish to be placed on inactive status should make this request in writing to the IRB Chair. The request should be made as soon as possible, preferably at least six weeks before the placement on inactive status will begin. The request should include the start and end

date of the period that the member would like to be placed on inactive status. It should also include a brief description of the reason for the inactive status request.

The IRB Chair will decide whether or not to approve a request to place a member on inactive status in consultation with OSP staff and the immediate supervisor of the member making the request. The IRB Chair will inform the member of the decision in writing.

IV. TRAINING REQUIREMENTS

The foundation for the effective implementation of the HRPP and for efforts to promote compliance with HRPP requirements lies in a comprehensive, mandatory education program for all applicable personnel, including IRB members, OSP staff, and researchers seeking review and approval of research involving human subjects.

4.1 IRB Members

All IRB members are to be trained in the protection of human subjects. Members may meet this requirement by successful completion of Collaborative Institutional Training Initiative (CITI) online training. Members should provide OSP staff proof of the training received, such as certificates of completion of the CITI training, within the first three months of being appointed to the IRB. CITI certificates are valid for three years after the date of completion. In addition, OSP staff will provide an orientation to new IRB members every year, or as needed. IRB members are expected to be familiar with the policies and procedures herein, as well as relevant federal regulations.

4.2 OSP Staff and the HRPP Specialist

In order to serve as alternate IRB members, OSP staff members must also complete CITI training and provide the IRB with certificates of CITI training completion.

A member of OSP staff will serve as KSU's designated HRPP specialist. The HRPP specialist will complete the functions of an IRB administrator, as well as serve as an alternate IRB member. In addition to completing CITI training, the designated HRPP specialist will periodically participate in other training outside of the CITI training modules, to include conferences, webinars, and other programs. It is recommended that the HRPP specialist develop a training plan in consultation with their supervisor to ensure that the HRPP specialist is informed of any changes in regulations and best practices for HRPPs and can adequately support the IRB. The HRPP specialist will share with the IRB useful articles and other sources of information regarding regulations and best practices via email and in meetings. The HRPP specialist will also assist by providing the IRB clarifications on policies and procedures.

4.3 Researchers

Researchers seeking full or expedited review of research involving human subjects must complete CITI training and submit certificates of completion along with the other materials

being provided for IRB review. Researchers seeking a determination that their research is exempt are not required to complete CITI training; however, CITI training is strongly recommended for all researchers conducting exempt research.

V. PREPARING FOR RESEARCH REVIEW

Researchers should contact OSP staff prior to beginning any new research project involving human subjects, even if the researcher believes that their research is exempt. The IRB must review all non-exempt research protocols involving human subjects at a meeting of the full IRB, except in cases when the research qualifies for the expedited review process. The OSP staff member serving as the HRPP specialist/IRB administrator in consultation with the IRB Chair will assist with determining if the research should undergo full IRB review, qualifies for expedited review, or is exempt.

5.1 OSP as Main Point of Contact

OSP staff will be the main points of contact for researchers seeking IRB approval of their research or a determination as to whether or not their research is exempt. OSP staff will help determine if a project should undergo full review, expedited review, or consideration for exemption. OSP will provide the appropriate application forms to complete for the project, as well as guidance regarding the additional materials to submit.

Once researchers have completed the appropriate form, prepared additional materials that may be needed, and are ready to submit them for review, the researchers will send the materials to OSP staff. If an application requires full or expedited review, OSP staff will in turn provide the application materials to the IRB Chair and other IRB members. Once the IRB reaches a decision on an application, the HRPP specialist/IRB administrator will communicate that decision to the researchers. If the IRB requests revisions to a protocol, the HRPP specialist will communicate the requested revisions to the researchers. In some cases, researchers may communicate directly with the IRB regarding an application, but in general, the HRPP specialist will serve as the liaison between the researchers and the IRB. OSP staff will maintain complete files for each application containing the application materials and communications about the application involving the IRB and the researchers.

5.2 KSU Requirements Regarding Exempt Research

OHRP guidance indicates that determinations of exempt status should be made by individuals independent of the research who are well-acquainted with interpretation of regulations governing the conduct of human subjects research. For this reason, KSU will require that researchers conducting exempt research complete an application to determine that the research is in fact exempt. In most circumstances, the OSP staff member serving as alternate IRB members can determine if a project is exempt. In cases where it is unclear if a project is exempt, the HRPP specialist will ask for guidance from the IRB Chair and reach a decision with the IRB Chair.

5.3 Applications for Exempt Determination and IRB Review

Application Forms

Researchers seeking a determination of exempt status, an expedited initial review, an initial full review, or continuing review must complete the appropriate human research application form. The application form is intended to facilitate the review process by providing a complete and accurate representation of the project to reviewers and allowing researchers to reflect on and address directly questions about the protection of human subjects.

OSP staff will be responsible for developing, revising, and updating application forms and determining how applications should be completed and delivered to the OSP. This may include adoption of an online application system. In the development of application forms and submission procedures, staff will take into account suggestions from KSU researchers and IRB members, while also working to align application processes employed at other institutions of higher education. Applications will require signatures or endorsements by all researchers involved in the project. For students submitting an application, a signature by a faculty sponsor or advisor is required.

When completing human research application forms, researchers should thoroughly address all the questions and items on the applications. These will include questions regarding protecting the anonymity and confidentiality of human subjects and the security and retention of data.

Other Required Documents

All applicable supporting documents must be included with the application, which depending on the type of project, could include recruitment materials, such as flyers, the informed consent form, request for waiver of elements of informed consent, request for waiver of written informed consent, parental permission, any test or survey instruments to be used, child assent scripts, letters from school principals or district superintendents, and certificates of confidentiality. If the project is funded by an external grant, researchers may also be asked to provide a copy of the grant proposal. Application forms will have further instructions as to the additional documents that will be required for review.

Researchers seeking full or expedited review should complete training regarding the protection of human subjects through CITI. Documentation of completion of the CITI training must be submitted with the application. In those instances where a group of students are being used as research assistants for which human subjects are involved, a list of the students and the completion dates of their training must be included on the IRB application. CITI training is valid for three years after being completed.

5.4 Screenings of Protocols

The HRPP specialist or another OSP staff member with appropriate expertise or

qualification will conduct a preliminary screening of the human research applications and supporting documents submitted by researchers. OSP staff may make suggestions to researchers for revisions on the application form before forwarding the application to the IRB. Furthermore, if any of the required documents are missing upon submission, the OSP staff will ask the researchers for the missing documents and will not submit the application for review until all the relevant documents have been provided.

The type of review that a study receives is commensurate with the level and type of risk to participants involved. These risks include the probability and severity of possible harm to the participants' physical, psychological, social, or economic welfare.

5.5 Protocol Review Timeline

Applications that meet exemption criteria will be processed quickly and normally reviewed within a week following receipt. Applications meeting one or more expedited review categories will be processed quickly and normally be reviewed within two weeks following receipt. Applications that require full review by the IRB must be received approximately 30 days in advance of a scheduled IRB meeting.

5.6 Distribution of Materials to the IRB

In cases where a full review is needed, all active voting IRB members will receive all documents submitted by the researchers one week prior to the meeting date. Documents will be distributed electronically by email and/or a file sharing platform.

Additional materials included in the meeting packets will include a copy of the previous meeting's minutes, a list of all determinations of exempt status and expedited actions taken since the previous meeting and a copy of the meeting agenda.

All IRB members will have access to and may review files containing all the applications reviewed in the past year or that are under review. These files will include applications for exemption and expedited review, as well as applications for full review.

VI. DETERMINATION OF EXEMPT STATUS

6.1 Exempt Categories

According to 45 CFR § 46.104, as of 2023, research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one of eight categories. The eight exempt categories are as follows:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instruction strategies, and research on the

effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

This category does not apply to research regulated by the Food and Drug Administration (FDA).

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

   The first two criteria of this category (i and ii) may not be applied to research with minors when such research involves surveys and/or interviews. Those criteria may only be applied to research with minors that involves educational tests or the observation of public behavior and when the investigators do not participate in those activities. The third criterion (iii) may not be applied to research with minors in any capacity.

3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

   (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such

criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Research involving minors is not eligible for this exemption category. This category also does not apply to FDA-regulated research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for a nonrelated primary or initial activity, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

   This category may not be applied to research involving primary collection from subjects; collection must be performed for a non-related purpose. Collection may be either retrospective or prospective. This category also does not apply to FDA-related research.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate

agencies that have been delegated authority to conduct the research and demonstration projects), and that are designated to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies: (i) If wholesome foods without additives are consumed; or (ii) 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospeciments for secondary research use, if the following criteria are met: (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117; (iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

The list of exempt categories can also be found in 45 CFR § 46.104. Although research

in exempt categories do not need to be approved by the full IRB, the *Belmont Report* principles of respect for persons, beneficence and justice still apply.

Studies involving pregnant women, fetuses, and neonates are eligible for exempt status under all eight categories. The exemptions do not apply to research involving prisoners except "for research aimed at involving a broader subject population that only incidentally includes prisoners." All research involving prisoners requires obtaining a certification from OHRP and must be reviewed by the convened IRB. Research that involves children and falls into categories 1, 2, and 4–8 may be found to be exempt by the IRB. However, exemption category 2, pertaining to survey or interview procedures or observations of public behavior, does not apply to research involving children, except for research involving public behavior when the researcher does not participate in the activities being observed.

6.2 Procedures for Reviewing Exempt Research

Researchers seeking a determination of exempt status will complete an application for exemption and submit to the OSP. The HRPP specialist or another OSP staff member designated as alternate IRB member are the primary reviewers tasked with making exemption determinations. OSP staff may assign submissions to the IRB Chair or another IRB member to assist with or conduct the exemption review as needed or if specific expertise is required. OSP staff members who have a conflict of interest related to a specific application should assign the application to another reviewer.

Following review, the IRB reviewer will make one of the following recommendations, and OSP will notify the researchers of the IRB reviewer's decision by email:

APPROVED. IRB approval indicates that the IRB reviewer(s) concluded the research protocols meet the federal criteria for approval. OSP staff process the determination and the researcher is provided with an approval letter and, if applicable and practicable, stamped informed consent/assent documents.

REVISIONS and/or ADDITIONAL INFORMATION REQUIRED. The IRB reviewer(s) withhold approval pending submission of revisions or additional information. OSP provides the request for revisions to the researcher, and the researcher responds and re-submits the application within 90 days of receiving the requested revisions.

EXPEDITED or FULL REVIEW REQUIRED. The IRB reviewer may determine the protocol requires expedited or full review by the IRB.

When the IRB has certified a project as exempt, the IRB does not require continuation or annual administrative reviews. The exemption approval can be in effect for up to three years. After three years, if the research is still ongoing, researchers are required to submit a new application for determination of exempt status.

The IRB or OSP staff will not consider any research exempt that involves prisoners,

sensitive aspects of subject's behavior, sensitive surveys, or that takes place in settings where subjects have a reasonable expectation of privacy. The IRB or OSP staff will also not consider any research exempt that involves survey or interview procedures involving children or observations of public behavior of children, except for observations of public behavior when the principal investigator does not participate in the activities being observed. Furthermore, in most cases, the IRB or OSP staff will not consider any research exempt that involves a test article regulated by the FDA.

At the time the protocols are deemed to be exempt, researchers will be reminded of the responsibility to report all modifications to protocols and unanticipated problems involving risks to subjects or others in accordance with the policies and procedures herein regarding protocol modifications and unanticipated problems.

VII. IRB REVIEW CONSIDERATIONS

7.1 Criteria for IRB Approval

According to 45 CFR § 46.111, the IRB shall approve research after determining that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. 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). The IRB 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. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, 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, 45 CFR § 46.116.

5. Informed consent will be appropriately documented or appropriately waived in accordance with 45 CFR § 46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. For purposes of conducting the limited IRB review required by 45 CFR § 46.104(d)(7)), the IRB need not make the determinations on 1. through 7. of this section, and shall make the following determinations: (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of 45 CFR § 46.116(a)(1)–(4), (a)(6), and (d); (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with 45 CFR § 46.117; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Furthermore, when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

7.2 Informed Consent

The IRB will carefully review informed consent processes—and if children are involved, assent processes—to include when, where and how consent or assent is obtained, and any provisions for the on-going consent or assent of subjects. Informed consent shall be obtained only under circumstances that provide the prospective subjects or the subject's legally authorized representative with sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion and undue influence. Generally, the IRB will not dictate the procedure to be used to obtain informed consent or assent, but reserves the right to do so if deemed necessary.

General Requirements

According to 45 CFR § 46.116, general requirements for informed consent include:

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

5. Except for broad consent obtained in accordance with paragraph (d) of this section: (i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

6. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Basic Elements

45 CFR § 46.116 offers the following outline of the basic elements of informed consent:

> Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:
>
> 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
>
> 2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others that may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies

45 CFR § 46.116 provides further guidelines regarding broad consent, requests for waiver of informed consent, and clinical trial consent. The IRB should refer to the federal regulations when reviewing projects that involve these matters.

Documentation of Informed Consent

According to 45 CFR § 46.117, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

However, the IRB may waive the requirement for a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

45 CFR § 46 Subpart D addresses the process of obtaining assent for research involving children. IRB reviewers should refer to all relevant sections of the 45 CFR § 46 when making a determination regarding the adequacy and appropriateness of informed consent and assent processes.

7.3 Other Considerations

The following are other issues that the IRB may consider to meet its obligations under 45 CFR § 46.111 and University policies and procedures. This is not an exhaustive list, and the IRB may consider other issues not listed here.

Study Design

The IRB will examine the soundness of the study design insofar as it impacts the rights and welfare of the human subjects. The responsible conduct of research dictates that if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even inconvenience them through participation in such a study. The IRB may request an expert consultant review or defer to scientific review committees, in order to determine whether a study design places subjects at unnecessary risk. The IRB may approve a study design that involves deception or withholding of information, if the strategies are justified and the protocol provides for a post-study debriefing of the subjects.

Risks and Benefits

The IRB will assess whether the risks to subjects are reasonable in relation to the anticipated benefits, if any, to the subjects, and the importance of the knowledge reasonably expected to result from the research. The IRB will 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 federal regulations do not allow the IRB to evaluate the possible long-range effect of applying the knowledge gained through the research. The IRB is required to review any possible benefits a subject may derive from participation in research, or the benefits of new knowledge that may justify asking a person to undertake the risks of the study.

According to 45 CFR § 46, 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. For the prison population, minimal risk is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or the routine medical, dental, or psychological examination of healthy persons.

Selection of Subjects

The selection of subjects should be equitable and free of any coercion, both explicit and implied. The IRB will consider the purpose of the research and the setting of the research. The IRB will closely examine research involving vulnerable subject populations, such as children, prisoners, subjects with cognitive disorders, or economically or educationally disadvantaged subjects. Researchers should detail any extra precautions taken to safeguard the rights and welfare of subject populations.

Confidentiality

The IRB is required to review the method for prospective identification and recruitment of subjects, to include the means of identifying and contacting potential subjects and the methods for ensuring the subjects' privacy and confidentiality. Researchers will include plans for ensuring the privacy and confidentiality of subjects in their applications for IRB approval.

Subject Safety

Whenever appropriate, the IRB will require a research plan to make adequate provisions for monitoring the data collected to ensure the safety of subjects. The IRB will review who has been identified in the protocol as having the primary responsibility for analyzing and responding to subject safety issues and will determine whether the study should be modified to minimize risk to current or future research subjects.

Frequency of Review

The IRB may determine that a project requires more than annual review and may

require an appropriate monitoring procedure that could include monitoring of the consent process, observation of the research procedures, formulation of a data and safety monitoring plan, and review of research related records.

Reasons for requiring IRB review more frequently than annually may include but are not limited to: securing the confidentiality of sensitive information, monitoring the safety of subjects, and ensuring participants are free from undue influence or coercion.

Surveys and Other Instruments

Surveys, questionnaires, focus group and interview questions, and related materials should be reviewed to ensure that they adequately reflect the purpose and procedures in the study and handle sensitive issues appropriately. If the materials ask for information that, according to local law, would require reporting (e.g., elder, spouse, or child abuse), the consent form should explain this exception to the promise of subject confidentiality. There are, however, a variety of psychological and other measures which are considered "standard" and, while they cannot be modified, reviewers should still indicate if use of a given measure is appropriate for a particular study.

In particular, reviewers should consider if survey answers, if known, would impact a subject's reputation, liability, and insurability, or in other ways pose a risk for the subject.

According to the Protection for Pupil Rights Amendment, there are 8 categories of protected information for surveys involving K-12 students. These are: 1) political affiliations of student or student's parent; 2) mental or psychological problems of student or student's family; 3) sex behavior or attitudes; 4) illegal, anti-social, self-incriminating or demeaning behavior; 5) critical appraisals of others with whom students have close family relationships; 6) legally recognized privileged or analogous relationships, such as with lawyers, doctors or ministers, 7) religious practices, affiliations or beliefs of student or student's parent; and income. 8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program). Research involving any of the eight identified categories requires written parental informed consent prior to participation of a child.

Coercion and Undue Influence

Coercion occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, a researcher might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

Undue influence can occur through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, a faculty researcher might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the researcher is unduly influencing potential subjects. If, however, she offers comparable non-research alternatives for

earning extra credit, the possibility of undue influence is minimized.

In addition to undue influence that can arise with the offering of rewards, undue influence also can be subtle. For example, students might feel pressure to participate in research if everyone else in the class is doing so. Because influence is contextual, and undue influence is likely to depend on an individual's situation, it can be difficult for IRBs to distinguish undue influence. It is up to the IRB to use its discretion in determining which circumstances give rise to undue influence. For example, an IRB might consider whether the informed consent process will take place at an appropriate time and in an appropriate setting, and whether the prospective subject may feel pressured into acting quickly or be discouraged from seeking advice from others.

Because of their relative nature and lack of clear-cut standards on the boundaries of inappropriate and appropriate forms of influence, researchers and IRB members must be vigilant about minimizing the possibility for coercion and undue influence. Reasonable assessments can be made to minimize the likelihood of undue influence or coercion occurring. For example, the IRB may recommend restricting levels of financial or nonfinancial incentives for participation and should carefully review the information to be disclosed to potential subjects to ensure that the incentives and how they will be provided are clearly described. Known benefits should be stated accurately, and potential or uncertain benefits should be stated as such, with clear language indicating how much is known about the uncertainty or likelihood of these potential benefits.

The IRB should be especially attentive to reviewing research protocols when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. In these instances, additional safeguards are to be included in the study to protect the rights and welfare of these subjects. Thus, inducements that would ordinarily be acceptable in some populations may become undue influences for these vulnerable subject groups.

Payments to Subjects

It is not uncommon for subjects to be paid for their participation in research. Payments to research subjects for participation must not be considered a benefit. Researchers seeking IRB approval for a project involving payments to research subjects will present the amount and schedule of payments to the IRB at the time of the initial review. The IRB will review both the amount of the payments and the proposed method and timing of disbursement to assure that neither are coercive nor present undue influence.

In no case should remuneration for participation in research be viewed as a way of offsetting risks; that is, it should not be considered a benefit to be weighed against study risks. The level of remuneration should not be so high as to cause a prospective subject to accept risks that they would not accept in the absence of the remuneration.

Deception in Research

As a rule, deception of subjects is not considered ethical in human subject research, especially in relation to the principle of informed consent. In certain circumstances, the IRB may approve the use of deception when it is deemed absolutely necessary for the study and does not put the subjects at inappropriate risk. In such instances, researchers may be asked to debrief subjects upon completion of their participation, and this debriefing should disclose the deception used and why the use of deception was necessary.

Financial Conflicts of Interest

Financial conflict of interest in research is the existence of a significant financial interest on the part of researchers that an independent observer might reasonably determine could affect or compromise, or appears to affect or compromise, the design, conduct, reporting, or management of research. Financial conflicts of interest have the potential to skew or influence the collection, analysis, and interpretation of data, the hiring of staff, the procurement of materials, the sharing of results, the choice of protocol, the involvement or consenting of human participants, or the use of statistical methods.

The IRB must be concerned about potential for biased judgment or other abuse when IRB members and researchers have a financial obligation or interest that may pose a conflict of interest which competes with the obligation to protect the rights and welfare of human subjects. In cases where there may be a potential financial conflict of interest, the IRB will refer to KSU's policies regarding conflicts of interest. The IRB may request additional information and revisions of protocols to address conflicts of interest.

VIII. INITIAL FULL BOARD REVIEW

The IRB will review research protocols requiring full Board review at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concern is in a nonscientific area.

8.1 Procedures

Researchers seeking a full Board review of a project will submit an application package to the OSP at least one month before a scheduled meeting. In turn, OSP staff will conduct a preliminary screening of the application package, and once the screening has been completed and any issues with the screening have been addressed, OSP staff will provide the application package to the IRB at least one week before the meeting.

A primary/secondary reviewer system will be used for new applications reviewed by the convened IRB. However, all IRB members will review all information on the agenda in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the

regulatory criteria for approval.

The full review of research must be substantive and meaningful with a recorded vote for, against, abstentions, and recusals from each study. The minutes of IRB meetings should document with sufficient detail the deliberations, actions, and votes for each protocol undergoing review by the convened IRB, in addition to a written summary of the discussion of issues related to each application and their resolution.

Review by the full Board at a convened meeting is warranted in circumstances such as the following: the research protocol involves more than minimal risk of harm to subjects, which can include physical, emotional, social, psychological, or financial risks; a certificate of confidentiality is requested; the research involves recruitment of vulnerable populations; and/or a conflict of interest or potential conflict of interest exists.

OSP staff will be responsible for determining if the review of a protocol requires coordination with other University committees or consideration of additional federal regulations and requirements other than those contained in 45 CFR § 46. For example, the agency funding a project may have additional requirements that will have an impact on the review process. OSP staff will provide guidance to the IRB in cases where coordination is needed or where there are additional requirements.

8.2 Primary/Secondary Reviewers

The IRB Chair in consultation with the HRPP specialist assigns a primary and secondary reviewer for each protocol in advance of each full Board meeting. All members, including the IRB Chair, may serve as a primary or secondary reviewer. In selecting the primary reviewer, consideration is given to the individual's knowledge of the subject area embodied in the proposal. The primary and secondary reviewers conduct an in-depth review of all items required for IRB submission of a new application, including informed consent/assent documents and all supplemental materials.

The primary and secondary reviewers are encouraged to contact the IRB Chair and OSP staff in advance of the Board meeting to request any additional information or clarification. OSP staff may contact researchers to obtain any necessary additional information before the meeting. The primary reviewer will lead discussion of the project they were selected to review. The OSP staff member serving as the HRPP specialist will provide a checklist to primary and secondary reviewers to ensure that all criteria for approval of research have been fulfilled. The completed checklist will be returned to OSP staff so it can become part of the complete project file.

8.3 Assistance from Consultants

If none of the IRB member has adequate knowledge or experience to review a given protocol, a consultant with appropriate expertise and experience may be engaged to assist with conducting the review. Consultants may include ad hoc scientific consultants, with expertise in the relevant area of research, or cultural consultants, with specialized

knowledge of the populations that are the focus of the study. All ad hoc or cultural consultants will have access to the same information in the IRB review process as voting IRB members. However, consultants will not vote on protocols.

8.4 Avoiding Conflicts of Interest

No IRB member, including the primary and secondary reviewers, may participate in the review of any project in which the member has a conflict of interest or vote on any project in which the member has a conflict of interest. It is the responsibility of each IRB member to recuse themselves in cases of conflict of interest.

IRB members may consult with the IRB Chair and OSP staff to determine if a conflict of interest exists. OSP staff will ensure that ad hoc or cultural consultants do not have a conflict of interest related to the project under review.

8.5 Outcomes of Review

An IRB member makes a motion, another member seconds the motion, and then the convened IRB votes for, against, or abstains from one of the following five actions:

APPROVED. IRB approval indicates the IRB has concluded that the research and consent/assent forms meet the federal criteria for approval. IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described in the application. OSP staff process the approval, and the researcher is provided with an approval letter and, if applicable and practicable, stamped informed consent/assent documents.

MINOR REVISIONS and/or ADDITIONAL INFORMATION REQUIRED. This decision indicates that the IRB has approved the protocol pending submission of minor revisions and that the IRB has given the primary reviewer the authority to approve the minor revisions. OSP staff generates an email requesting revisions and returns the submission to the investigator. The investigator responds to the IRB's suggested revisions, making relevant changes in the application and re-submits to the OSP. OSP staff then provides the revised application to the primary reviewer. The reviewer may defer the response to a convened meeting for review by the full IRB, request additional information, or approve the protocol.

TABLED. This decision indicates that the IRB withholds approval pending submission of major revisions and additional information. OSP staff drafts a letter and returns the submission to the investigator, outlining the reasons for tabling the protocol, and includes a description of the revisions or clarifications requested. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator. In cases where the IRB decides to table discussion of an application, the IRB may also vote to invite the researcher requesting approval to a future meeting of the IRB in which the researcher will discuss or answer IRB concerns or question. OSP will be responsible for extending the invitation to the researcher to attend the meeting and providing a list of the

concerns or questions to be discussed.

DISAPPROVED. In the case of disapproval, OSP staff generates a letter describing the reasons for disapproving the protocol and provides it to the researcher. A study may be disapproved if the IRB has enough information to make the necessary determinations of approval in line with the federal criteria but believes the research protocol does not meet the criteria and is unable to provide suggested changes.

8.6 Approval Periods

During the convened meeting, the IRB determines the approval period, as appropriate to the degree of risk but not less frequently than once per year for research retaining full Board review status. The IRB may set a shorter approval period for high-risk protocols or protocols with high risk/low potential benefit ratios. The approval start date is the date on which the protocol receives final approval from the IRB. The beginning and end date of the approval period will be provided in the approval letter and any stamps placed on informed consent documents.

8.7 Appeal Process

If a researcher has concerns regarding an IRB decision, changes that the IRB has requested in a research protocol, or any other aspect of the submission and review process, the researcher may submit a formal appeal. The appeal will involve providing a letter to the OSP staff with a request for a change in the IRB's decision or processes and a justification for why the change is needed. The OSP staff will then submit the letter to the IRB and any additional materials needed for a full consideration of the appeal. The full IRB will consider and vote on a response to the appeal at the next scheduled meeting of the IRB. The IRB will provide the individual who submitted the appeal a letter notifying them of the IRB's response to the appeal and an explanation for the response. The IRB Chair should sign the letter.

However, the IRB may not vote to approve an ad hoc change in the submission and review processes that contravenes written policies and procedures. If a change in policies and procedures is needed, the IRB may vote to begin the process of revising policies and procedures, in consultation with OSP staff, and obtaining approvals for amended policies, as needed, from the Provost, President, and Board of Regents.

IX. INITIAL EXPEDITED REVIEW

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Federal regulations make provisions for certain categories of research to be reviewed through an expedited procedure if the research involves no more than minimal risk. Expedited review is intended to enable the institution to conserve administrative resources, provide timely reviews, and focus the convened meetings of the IRB on those research activities involving greater risks or ethical complexities. The IRB may also use the expedited review

procedure to review minor changes in previously approved research during the period covered by the original approval. Reviews are done on an ongoing basis, meaning that the review is accomplished independently of the IRB meeting schedule.

9.1 Procedures

Researchers seeking expedited review will submit an application package to the OSP. In turn, OSP staff will conduct a preliminary screening of the application package, and once the screening has been completed and any issues with the screening have been addressed, OSP staff will consult with the IRB Chair to determine who will be responsible for the expedited review. The expedited review may be carried out by the IRB Chair, an IRB member designated by the Chair, or the HRPP specialist serving as an alternate IRB member when an IRB member is unavailable to complete the review in a timely manner. It is preferable, however, that an IRB member complete the review.

If the IRB member selected for an expedited review has a conflict of interest with the project in question, it is the responsibility of the IRB member to notify the Chair and OSP staff and recuse themselves. If an IRB member is unable to complete a review because of conflict of interest, or for any other reason, the Chair will approach another IRB member to complete the review. Consultants may assist the IRB Chair and other IRB members in making decisions in expedited review, but expedited review cannot be performed solely by persons who are not voting members of the IRB.

Expedited reviewers only approve research that meets the federal criteria for approval. Also, expedited reviewers ensure that the study's informed consent process and documentation meet the requirements as specified in 45 CFR § 46.116 and 21 CFR § 50.25. Expedited reviewers exercise all the authority of the IRB in completing their review, except that the reviewers may not disapprove research. A research activity may be disapproved only after full Board review. Expedited reviewers should take into account any protective measures included in the research design as part of the process of determining if the proposed research involves no more than minimal risk. However, some social and behavioral studies involve more than minimal risk, even though they include such protective measures.

The expedited reviewer, with input from other IRB members and OSP staff as applicable, provides feedback for any clarification needed and documents the issues discussed on a reviewer checklist provided by OSP staff. The expedited reviewer records their determinations on the checklist and returns it to OSP staff.

OSP will provide an updated list of research protocols approved under the expedited review procedure to the IRB at each scheduled meeting, and all IRB members will have access to all files containing expedited review applications and decisions. Any IRB member may request additional information from the Chair or OSP staff regarding the expedited determination of any particular protocol.

9.2 HHS Guidelines for Expedited Review

In accordance with 45 CFR § 46.110, HHS has established guidelines regarding the applicability of expedited review and categories of research that are eligible for expedited review. These guidelines are posted on the HHS website and are as follows:

Applicability

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

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

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

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

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

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

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electro-encephalography, 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. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be

exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

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

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

8. Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

9.3 Outcomes of Review

Following review, the expedited reviewer will make one of the following recommendations, and OSP will notify the researchers of the reviewer's decision by email.

APPROVED. IRB approval indicates that the IRB reviewer(s) concluded the research and consent forms meet the federal criteria for approval. An approval determination verifies the IRB agrees with the assessment of the protocol and/or specific findings as described by the researcher in the application. OSP staff process the determination, and the research is provided with an approval letter and, when applicable and practicable, stamped informed consent/assent documents.

REVISIONS and/or ADDITIONAL INFORMATION REQUIRED. The IRB reviewer(s) withhold approval pending submission of revisions and/or additional information. OSP staff return the protocol to the researcher to address concerns and questions provided by the reviewer(s). The researcher responds and re-submits the application to the OSP within 90 days of receiving the requested revisions. OSP staff assign the response to the primary expedited reviewer who made the initial determination for further review and a

new determination. Barring extenuating circumstances, if a researcher does not respond to requested revisions in the 90-day time period, the application is withdrawn, and a new protocol submission is required.

FULL REVIEW REQUIRED. The primary expedited reviewer may determine the protocol requires full review by the IRB at a convened meeting.

The primary expedited reviewer may also determine that the project is eligible for exemption or the activities do not fall under the purview of the IRB. If the protocol is determined to be eligible for exemption, the researcher will withdraw their application and submit a new application for determination of exempt status.

9.4 Approval Periods

OSP staff will include in the approval letter the beginning and end date of approval. The date the primary expedited reviewer approves the study is the date the approval period starts. The approval period will last no more than one year. In some cases, the expedited reviewer may require continuing review of the project more frequently than once per year. In these cases, the reviewer must write a justification for this requirement and provide the explanation to OSP staff.

9.5 Urgent IRB Actions

An expedited review does not mean that the review will be concluded quickly, although it will usually be faster than a full Board review. An expedited review simply means that a review can occur without a convening of the IRB.

In cases where a full Board review is needed quickly, and the urgency is not a result of negligence or delay on the part of researchers to submit human subject applications in a timely fashion, researchers should contact the OSP, and the IRB Chair and OSP staff will determine if a quick turnaround is possible. If the IRB Chair agrees to the urgent full review of a protocol, and it is administratively feasible, the application materials will be distributed as soon as possible to IRB members to allow sufficient time for review prior to a meeting. In these cases, the researcher may also be asked to attend the meeting to answer any questions that arise.

X. CONTINUING REVIEW OF RESEARCH

Continuing review of research is for protocols that were previously approved by the IRB and must be completed before the current period of approval ends. The period of approval is usually one year but may be less, depending on the project.

In most cases, if a protocol was reviewed and approved by the full board, the IRB must review the continuation of research at a convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For certain categories of research, however, HHS guidelines

allow for continuing review through the expedited process of a protocol that was originally approved by the full Board. Projects originally approved through expedited review will, in most cases, be eligible for continuing review through the expedited process.

10.1 Procedures

Researchers requiring continuing review of their research should contact the OSP for the continuing review application form. Applications will require signatures or endorsements by all researchers involved in the project. For students submitting an application, a signature by a faculty sponsor or advisor is required.

Before submitting the application to the OSP, researchers should ensure that the application is complete and accurate, and they thoroughly address all items and questions on the application. In the application, the researcher will provide an updated summary of the protocol and provide justification for any proposed amendments to the protocol; a status report on the progress of the research, including the number of participants involved in the research and a description of participants; a summary of any adverse events that have occurred and/or any unanticipated problems involving risks to participants; and a summary of recent literature, findings, or other relevant information, if any, that may have an impact on the research and risks for human subjects.

As with the original application for IRB approval, all applicable supporting documents must be included with the application, such as recruitment materials, informed consent documents, and any test or survey instruments to be used. Application forms will have further instructions as to the additional documents required for review. In addition, researchers must ensure that the OSP staff has on file certificates demonstrating that the researcher and their assistants completed CITI training within the last three years.

After receiving the complete application package, OSP staff will conduct a preliminary screening of the application, and once the screening has been completed and any issues with the screening have been addressed, OSP staff will provide the application package to the IRB at least one week before the full Board meeting.

All procedures outlined for the initial review of research by the full Board will be followed in the continuing review of research by the full Board, including the use of a primary/ secondary reviewer system and a checklist for reviewers.

10.2 Review Timeline

Applications for full continuing review should be submitted to the OSP approximately two months before the approval end date to allow ample time for processing, review, and approval. Applications for expedited continuing reviews should be submitted at least 30 calendar days prior to the approval end date.

Applications that are not processed and approved before the approval expiration date will result in the expiration of the protocol's approval and will require that researchers delay

further research involving human subjects until approval is renewed.

10.3 Considerations for Continuing Review

For continuing review, the IRB must have the same considerations and use the same criteria to approve the continuation of a protocol as in the initial review of research.

At the same time, when conducting continuing review, the IRB needs to determine whether any new information has emerged either from the research itself or from other sources that could affect the IRB's approval of the continuation of research, particularly with respect to risk to subjects. In addition to the considerations outlined in section 7.2, the IRB at the time of continuing review will consider the following:

Risk Assessment and Monitoring

The IRB's continuing review should consider relevant information received from the investigator, any monitoring entity (such as the research sponsor, a coordinating or statistical center, a data and safety monitoring board, or a data monitoring committee), or any other source since the date of the last IRB approval of the project. Information regarding any unanticipated problems or irregular activities that have occurred since the previous IRB review in most cases will be pertinent to the IRB's determinations at the time of continuing review regarding determinations of risks and benefits.

It also may be appropriate for the IRB at the time of continuing review to confirm that any provisions under the previously approved protocol for monitoring the research data and ensuring safety of subjects have been implemented and are working as intended. This may include requesting that the investigator provide a report from any monitoring entity involved in the project and described in the protocol initially approved by the IRB.

Adequacy of Informed Consent

At the time of continuing review, the IRB should review the informed consent documents submitted by the investigator to verify that the investigator is using the most recently approved version and that the document contains the most accurate, up-to-date information. When reviewing an informed consent document, the IRB should also confirm that the currently approved or proposed consent document adequately addresses all the required elements of informed consent.

If the IRB waived the requirement for the investigator to obtain a signed consent form for some or all subjects, the IRB should reassess the accuracy of the content of the information that is being provided to subjects orally and of any written statement regarding the research that is being provided to subjects.

The IRB also may determine if there is any new information presented by the investigator or others (for example, subjects or other individuals who have observed the investigator obtaining subjects' informed consent) that raises concerns about the circumstances under

which informed consent is being obtained. The IRB may consider any new information indicating that the investigator may not be obtaining informed consent under circumstances that provide subjects with sufficient opportunity to consider whether or not to participate or that minimize the possibility of coercion or undue influence.

Continuing review also provides the IRB with an opportunity to determine whether there is any new information or any significant new finding that should be communicated to subjects who have already enrolled in the research. This could include, for example, important new toxicity information or new adverse event information related to the research interventions that are identified during analysis of the research data.

Investigator and Institutional Issues

When appropriate, the reviewing IRB should consider issues regarding the investigator and the institution(s) where the research is being conducted during its continuing review, such as the following: changes in the investigator's situation or qualifications; evaluation, investigation, and resolution of any complaints related to the investigator's conduct of the research; changes in the acceptability of the proposed research in terms of institutional commitments (such as adequacy of facilities); changes in applicable regulations, state and local laws, or standards of professional conduct or practice; and reports from any third party observations of the research.

Progress of Research Project

When evaluating research progress, the IRB should consider the consistency of information submitted at the time of continuing review with that of the IRB-approved protocol and, if relevant, the subject enrollment and subject withdrawal.

The IRB should confirm that the information provided by the investigator at the time of continuing review is consistent with the research protocol previously approved by the IRB. If this information suggests that the investigator is not conducting the research in accordance with either the IRB- approved protocol or the requirements or determinations of the IRB, the IRB should defer approving a continuation or research or approve the research for a limited period of time (such as two or three months) and seek an explanation from the investigator regarding the apparent discrepancies.

If relevant to the project, the IRB should pay special attention to the total number of subjects enrolled. If enrollment in a research project is occurring at a much slower rate than expected and there are concerns about enrolling enough subjects to provide sufficient data to answer the scientific question(s) being addressed, it may not be ethical to continue exposing subjects to the risks of the research. The IRB may request the PI to explore the reasons for low enrollment and take appropriate steps to remedy the situation. If no such remedy exists, the IRB should not approve continuation of the study because the risks to subjects are not reasonable in relation to the anticipated benefits to the subjects and the importance of the knowledge that may reasonably be expected. On the other hand, if the investigator has enrolled more subjects than the number indicated

on the IRB-approved protocol, this would represent a violation of the requirement that all changes in research not be initiated without IRB review and approval except when necessary to eliminate immediate risks or hazards to the subjects. If over enrollment occurs, the research must address why additional subjects were enrolled. The IRB will offer guidance on how data obtained from over enrollment may be used.

In addition, if relevant to the project, the IRB should receive and review information regarding the number of subjects who discontinued their participation and a summary of the reasons for the withdrawals, if known. IRB review of this information may shed light on problems related to the conduct of the research. For example, a high rate of subject withdrawal may indicate that the risks of the research are greater than expected and may lead the IRB to conclude that the research should not be approved for continuation. In addition, as with a lower-than-expected enrollment rate, if there is a higher-than-expected rate of subject withdrawal, it may not be ethical to continue exposing subjects to the risks of the research because the project may not provide sufficient data to answer the scientific question. An IRB may recommend that the reasons behind the high withdrawal rate be explored by the investigator and appropriate steps taken to remedy the situation. In the absence of an adequate plan to remediate a high withdrawal rate, the IRB may determine that the research should not be approved for continuation.

Verifications from Outside Sources

Investigators are expected to provide the IRB with all relevant information regarding the conduct of the research. In order to ensure that no material changes occurred during the IRB designated approval period, the IRB may require verification of information from sources other than the investigator. Such independent verification may be considered in the following:

- Complex protocols involving unusual levels or types of risks to subjects;
- Protocols conducted by PIs who previously have failed to comply with federal regulations or the requirements or determinations of the IRB;
- Protocols where concern about possible material changes occurring without IRB approval have been raised based on information provided in continuing review reports or from other sources.

The IRB will determine which projects need verification from sources other than the investigators regarding material changes on a case-by- case basis. When the IRB finds the need for independently verified information, it will notify the investigator in writing. The IRB will not give final approval for a protocol until it has received and reviewed the independently verified information and found it to be satisfactory.

Frequency of Continuing Review

In accordance with federal regulations, the IRB must conduct continuing review of

research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB should decide the frequency of continuing review for each study protocol necessary to ensure the continued protection of the rights and welfare of research subjects. The IRB may set a shorter approval period for protocols that they have determined are high-risk or have a high risk to potential benefit ratio. The IRB should consider the following factors in determining the frequency of review: the nature of the study; the degree of risk involved; and the vulnerability of the study subject population.

10.4 Lapses in IRB Approval

Continuing review of research must occur at intervals appropriate to the degree of risk but not less frequently than once per year. A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted continuing review and re-approved the research, with or without conditions, by the expiration date of IRB approval. The investigator and IRB should plan ahead to ensure that continuing review and approval of research occurs prior to the end of the approval period specified by the IRB. However, it is the responsibility of investigators to provide in a timely manner the information needed by the IRB to perform its continuing review functions, and any reminder notices regarding the need to do so from the OSP staff to investigators are a courtesy.

Limits on Research after a Lapse

If IRB approval lapses, all activities involving human subjects must stop after IRB approval expired, unless it is determined to be in the best interests of already enrolled subjects to continue participating in the research. The determination regarding whether it is in the best interests of already enrolled subjects to continue to participate in the research after IRB approval has expired may be made initially by the investigator, possibly in consultation with the subjects' treating physicians, psychologists or psychiatrist (if the investigator is not the subjects' treating physician, psychologists or psychiatrist). The investigator should also submit a request for confirmation that the IRB agrees with this determination. Confirmation may be provided by the IRB Chair in consultation with OSP staff or other IRB members.

Enrollment of new subjects cannot occur after the expiration of IRB approval. Continuing participation of already enrolled subjects in a research project during the period when IRB approval has lapsed may be appropriate, for example, when the research interventions hold out the prospect of direct benefit to the subjects or when withholding those interventions poses increased risk to the subjects. This determination may be made for all enrolled subjects as a group or for each individual subject. If the investigator or IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects and obtaining or analyzing identifiable private information about human subjects.

When IRB approval of an ongoing research project lapses and the investigator wants to

continue the project, the IRB should complete continuing review for the project as soon as possible. Investigators may resume the human subject research activity once continuing review and approval by the IRB has occurred. The IRB should document why the lapse in IRB approval occurred, and, if appropriate, any corrective actions that the investigator, institution, or IRB is taking to prevent any such lapse of approval of the project from occurring again in the future

When IRB approval of an ongoing research project lapses and the IRB subsequently approves continuation of the project, the IRB may approve the project for one year and establish a new anniversary date for the expiration date of subsequent approval periods, or the IRB may approve the project for a period of less than one year so as to retain the original anniversary date on which prior approval periods expired.

Lapse in IRB Approval vs. Suspension or Termination of Approval

When continuing review of a research project does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Such expiration of IRB approval is not considered to be a suspension or termination of IRB approval. Therefore, such expirations of IRB approval do not need to be reported. However, if the IRB notes a pattern of non-compliance with the requirements for continuing review (for example, an investigator repeatedly or deliberately neglects to submit materials for continuing review in a timely fashion), the IRB should determine whether such a pattern represents serious or continuing noncompliance that needs to be reported to appropriate institutional officials, agencies supporting the research, and/or OHRP.

10.5 Outcomes of Review

For a full continuing review, an IRB member makes a motion, another member seconds the motion, and then the convened IRB votes for, against, or abstains from one of the following five actions:

APPROVED. IRB approval indicates the IRB has concluded that the research meets the federal criteria for approval. OSP staff process the approval, and the researcher is provided with an approval letter and, if applicable and practicable, stamped informed consent/assent documents.

MINOR REVISIONS and/or ADDITIONAL INFORMATION REQUIRED. This decision indicates that the IRB has approved the protocol pending submission of minor revisions and that the IRB has given the primary reviewer the authority to approve the minor revisions. OSP staff generates an email requesting revisions and returns the submission to the investigator. The investigator responds to the IRB's suggested revisions, making relevant changes in the application and re-submits to the OSP. OSP staff then provides the revised application to the primary reviewer.

TABLED. This decision indicates that the IRB withholds approval pending submission of major revisions and additional information. OSP staff drafts a letter and returns the

submission to the investigator, outlining the reasons for tabling the protocol, and includes a description of the revisions or clarifications requested.

DISAPPROVED. OSP staff generates a letter describing the reasons for disapproving the protocol and provides it to the researcher. A study is not approved if the IRB has enough information to make the necessary determinations of approval but believes the continuation of research does meet the criteria for approval.

10.6 Approval Periods

OSP staff will include in the letter approving the continuation of a project the beginning and end date of approval. During the convened meeting, the IRB determines the approval period as appropriate to the degree of risk but not less frequently than once per year for research retaining full Board review status. The date when a protocol is approved by the full Board, or by the primary reviewer following the completion of requested minor revisions to a protocol, determines the latest permissible date of approval and, therefore, the latest permissible date for the next continuing review.

10.7 Expedited Review

In general, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. However, according to the HHS guidelines for expedited review, continuing review of a protocol that was originally approved by the full board may be eligible for expedited review if it falls within one of the following categories:

- Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

It is also possible that research activities that previously qualified for expedited review have changed or will change, such that expedited IRB review may not be appropriate for continuing review. Changes may include, for example, a modification to the protocol in which the previous risk to subjects was minimal but, as a result of the modification, now places them at more than minimal risk. Researchers may contact OSP staff for guidance as to whether they should apply for expedited or full continuing review.

Researchers seeking expedited review will submit an application package to the OSP. The application package will include a completed continuing review application form and all applicable supporting documents, such as recruitment materials, informed consent documents, and any test or survey instruments to be used. In the application, as with the application for continuing review by the full Board, the researcher will address any changes in the protocol or any developments affecting the research and risks for human subjects that have occurred since the initial approval of the research.

Once OSP has received the application package, OSP staff will conduct a preliminary screening of the application package, and once the screening has been completed, OSP staff will consult with the IRB Chair to determine who will be responsible for the expedited review. The expedited review may be carried out by the Chair, another IRB member, or the HRPP specialist serving as an alternate IRB member. All other procedures outlined for the initial review via the expedited process in section 9 apply for the expedited continuing review, including procedures regarding conflict of interest.

The expedited reviewer will make one of the following recommendations: APPROVED, REVISIONS and/or ADDITIONAL INFORMATION REQUIRED, or FULL REVIEW REQUIRED. OSP staff will then notify the researcher of the reviewer's decision by email. Once approved, OSP staff will provide an approval letter. OSP staff will include in the approval letter the beginning and end date of approval. The date the primary expedited reviewer approves the study is the date the approval period starts. The approval period will last no more than one year.

XI. REPORTING OF CHANGES IN RESEARCH ACTIVITY

Researchers for whom a protocol has been approved by the IRB should report any changes in the protocol and plans to make changes to the protocol to the IRB. Except in cases where modifications in a protocol are necessary to eliminate apparent immediate hazards to the subject, the IRB must review and approve all modifications to currently approved research protocols prior to implementation. Examples of modifications that researchers should report and seek approval for include, but are not limited to, changes in study personnel, recruitment materials and procedures, research procedures, subject populations, location where the research will be conducted, changes in consent or assent forms, and dates when the study will be completed.

11.1 Procedures

All modifications of a protocol approved by the full Board will be reviewed by the full Board, except where the modification is minor and qualifies for expedited review. The IRB Chair, in consultation with OSP staff, will make the final determination as to whether a modification is considered minor and qualifies for expedited review taking into account the totality of the circumstances. The IRB will follow the same procedures as described in section 8 when reviewing modifications at convened meetings.

Researchers seeking approval for a modification should provide a completed request for

modification approval form to the OSP. As applicable, researchers should also provide a revised protocol summary, revised recruitment materials, revised consent form documents, revised surveys or other instruments, and other materials that have changed as a result of the modification. In cases of changes in personnel, researchers should provide certificates of completion of CITI training for new personnel.

Researchers requesting approval of a modification by the full Board should submit their materials to OSP a month before the Board's meeting date. Expedited review of modifications can occur at any time and will be typically reviewed within two weeks, after which the investigator will receive feedback from the reviewers.

For modifications requiring full review, OSP staff will provide the modification request and supporting materials to the IRB one week before a meeting. In the IRB meeting, the primary reviewer assigned to review a modification will explain what the proposed modification is, and the Board as a whole will consider how the modification will affect the conduct of the study, the risk/benefit ratio, and whether or not it should be approved.

If an approved research protocol is changed to eliminate apparent immediate hazards to the subject, the principal investigator is required to notify the IRB of the change(s) within 48 hours. The IRB will review at the next convened meeting to determine if the change(s) instituted were consistent with the subject's continued welfare.

11.2 Minor Modifications

Regulations permit the use of expedited procedures for review of minor changes to previously approved research during the period for which the approval is authorized. Modifications that alter the risk/benefit ratio so that risks are increased or benefits are decreased shall be reviewed at a convened meeting. Investigators are encouraged to contact the IRB Chair and the OSP staff with any questions prior to submitting a modification request if uncertain about the review type required.

Minor changes have no substantive effect upon an approved protocol or present no change to or reduce the risk to the subject. Examples of minor changes are: changes in research personnel that do not alter the competence of the research team; scientific or therapeutic changes that leave the research population at the same or lower risk than risk(s) already approved; changes in research procedures that have a minor impact on risks to human subjects; an increase in the number of study visits for the purpose of increased safety monitoring; changes to improve the clarity of research statements, enhance comprehension, to correct typographical errors, or to update templates, without altering the content or intent of the statement; clarification of discrepancies within the IRB materials submitted for initial review, such as discrepancies regarding the numbers of subjects, number and identity of research sites, and timing, nature, and duration of research procedures.

11.3 Major Modifications

Major changes are changes that may increase the risk to human subjects or raise new questions concerning risks to human subjects. Examples of major changes that may increase the risk to subjects are: increasing the length of time a subject is exposed to experimental aspects of the study; changing the originally targeted population to include a more at-risk population (e.g., adding children or pregnant women to the study); adding procedures where the risk of the additional procedure is greater than a minimal risk; adding an element that may breech the confidentiality of the subject; or increasing the number of participants to be treated by more than 25%, which may affect the study's statistical analyses.

11.4 Change in Principal Investigators

When changing principal investigators, a protocol modification must be submitted to explain who the principal investigator was and who is being appointed the new principal investigator. The original principal investigator completes and submits the request for modification approval form. Changes in principal investigators may qualify for expedited review if no other modification is being pursued.

11.5 Outcomes of Review

The IRB may approve, request minor revisions, table or defer, or disapprove modification requests. The OSP staff will notify the researcher in writing of the decision of the IRB and of any changes required. Modification approval is not granted until all required changes have been made and submitted for review and approval. Once approved, the researcher is sent a modification approval letter by OSP staff. Upon receipt of the approval for the modification, the PI may initiate the modification.

11.6 No Change in Approval Periods

The IRB may only approve modifications through the current approval expiration period, unless considered at the time of continuation review. Approval of a modification outside of the continuing review does not extend or otherwise change the expiration date of the IRB's approval for the project. IRB review of a modification outside of a continuing review request does not constitute a continuing review. All researchers are still required to submit research projects for continuing review and approval on an annual basis.

XII. REPORTING OF UNANTICIPATED PROBLEMS

Federal regulations require the prompt reporting by researchers of unanticipated problems that occur in the course of a current IRB approved research project and involve risk to subjects or others. Unanticipated problems may include unexpected adverse events. Unanticipated problems must be reported, within 48 hours, in a written report with a detailed description of the problems by the principal investigator.

12.1 Clarification of Terms

OHRP provides guidance regarding the reporting of unanticipated problems or adverse events, including the following clarifications.

Unanticipated Problems

Unanticipated problems include any incident, experience, or outcome that meets all of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research;

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

OHRP recognizes that it may be difficult to determine whether a particular incident, experience, or outcome is unexpected and whether it is related or possibly related to participation in the research. OHRP notes that an incident, experience, or outcome that meets the three criteria above generally will warrant consideration of substantive changes in the research protocol or informed consent process/document or other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

Adverse Events

Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

The key question regarding a particular adverse event is whether it meets the three criteria described outlined above and therefore represents an unanticipated problem. To determine whether an adverse event is an unanticipated problem, the following questions should be asked: Is the adverse event unexpected? Is the adverse event related or possibly related to participation in the research? Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known

or recognized? If the answer to all three questions is yes, then the adverse event is an unanticipated problem and must be reported to appropriate entities.

For further clarifications as to whether or not a particular adverse event is an unanticipated problem that requires reporting, researchers should consult the OHRP guidance.

12.2 Types of Unanticipated Problems

The following are situations that may meet OHRP's definition of unanticipated problems involving risks to subjects or others and should be reported:

- Any serious accidental or unintentional change to the IRB-approved protocol that involves risk or has the potential to recur.
- Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject.
- Any publication, safety monitoring report, interim result or other finding that indicates an unexpected change to the risk/benefit ratio of the research.
- Any breach in confidentiality that may involve risk to the subject or others.
- Any complaint of a subject that indicates an unanticipated risk.

12.3 Procedures for Reporting and Responding to Reports

According to OHRP guidance, an investigator should include the following information when reporting an adverse event or any other incident, experience, or outcome as an unanticipated problem to the IRB:

1. appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number.
2. a detailed description of the adverse event, incident, experience, or outcome.
3. an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem.
4. a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

Once the report is ready, the investigator should submit it to the OSP, and OSP staff will in turn immediately provide the report to IRB members. After the IRB receives a report of an unanticipated problem involving risk to subjects or others, the IRB Chair in consultation with other IRB members and OSP staff will evaluate and make a decision on the reported event as quickly as possible. The IRB Chair may recommend that the problem be

reviewed by a convened meeting, depending on the nature of the problem.

OHRP guidance indicates that when reviewing a report of an unanticipated problem, the IRB should consider whether the affected research protocol still satisfies the requirements for IRB approval. In particular, the IRB should consider whether risks to subjects are still minimized and reasonable in relation to the anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result. At the conclusion of its review, the IRB may require that corrective actions be taken or that substantive changes be made to a protocol.

Examples of corrective actions or substantive changes that the IRB may consider in response to an unanticipated problem include: changes to the research protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects; modification of inclusion or exclusion criteria; implementation of additional procedures for monitoring subjects; suspension of enrollment of new subjects; suspension of research procedures in currently enrolled subjects; modification of informed consent documents to include a description of newly recognized risks; and provision of additional information about newly recognized risks to previously enrolled subjects.

When reviewing a report of an unanticipated problem, the IRB may also determine that the incident, experience, or outcome does not meet all three criteria for an unanticipated problem. In such cases, further reporting to appropriate institutional officials, funding agencies, and/or OHRP would not be required

Once the IRB has reached a decision in response to an unanticipated problem, OSP staff will provide the investigator with a summary of the IRB's evaluation and decision in writing. OSP staff will be responsible for providing a report about any adverse event that qualifies as unanticipated problem to KSU's Provost (or an another official designated as KSU's Institutional Official for the purposes of the FWA) in cases in which the event is related to research participation, presents greater risk to human subjects, and exceeds the frequency of occurrence initially anticipated in the research. If applicable, the OSP staff will also provide a report about the event to the funding agency and OHRP.

XIII. REPORTING OF NONCOMPLIANCE

The ethical conduct of research is a shared responsibility, requiring cooperation, collaboration, and trust among investigators, the participants who enroll in research, IRB members, and OSP staff. As the body responsible for ensuring the protection of the rights and welfare of research subjects at KSU, the IRB addresses allegations of noncompliance with IRB requirements and/or federal regulations.

Anyone, including research participants, may submit concerns or allegations having to do with noncompliance involving human subjects research to the OSP verbally or in writing. OSP staff and the IRB may also identify concerns regarding noncompliance during the continuing review process. The OSP and IRB will maintain confidentiality regarding the

identity of the person submitting an allegation to the extent possible.

13.1 Clarification of Terms

Noncompliance

Noncompliance consists of any action or activity associated with the conduct or oversight of research involving human subjects that fails to comply with either the research plan as approved by the IRB, federal regulations, or institutional policies.

Noncompliance may range from minor to serious, be unintentional or willful, and may occur once or several times. Noncompliance may result from the action of the participant, principal investigator, or staff and may involve a range of issues from relatively minor, administrative, or technical violations to more serious violations which pose risk to subjects and/or violations of their rights and welfare. Complaints or reports of noncompliance from someone other than the principal investigator are handled as allegations until such time that the report is validated or dismissed.

Serious Noncompliance

Serious noncompliance may include any behavior, action or omission in the conduct or oversight of human research that has been determined to: affect the rights and welfare of participants and others; increase risks to participants and others; reduce potential benefits or otherwise unfavorably alter the risk/benefit ratio; compromise the integrity or validity of the research; or result from the willful or knowing misconduct on the part of the principal investigators or study staff.

Serious noncompliance substantively comprises the effectiveness of the HRPP. The following are some examples of serious noncompliance:

- Conducting non-exempt research that requires direct interaction or interventions with human subjects without first obtaining IRB approval.

- Enrolling subjects who fail to meet the inclusion or exclusion criteria in a protocol that involves greater than minimal risk and potentially places the participants at greater risk.

- Failure to report unanticipated problems or substantive changes to the proposed protocol to the IRB.

Continuing Noncompliance

Continuing noncompliance is a persistent failure to adhere to the laws, regulations, or policies governing human research. Continuing noncompliance may result from a lack of understanding or disregard for the regulations or institutional requirements that protect the rights and welfare of participants and others. It may compromise the scientific integrity

of a study such that important conclusions can no longer be reached, and it may suggest a likelihood that noncompliance will continue without intervention. Continuing noncompliance may also include failure to respond to a request from the IRB to resolve an episode of noncompliance or a pattern of minor noncompliance.

13.2 Reporting and Screening of Allegations

After receiving an allegation, OSP staff will share it immediately with the IRB Chair. The IRB Chair in consultation with OSP staff will conduct an initial assessment of the allegation. If the IRB Chair and OSP staff determine that an allegation or concern is substantiated but it has to do with minor or administrative issues, the IRB Chair or the OSP staff member serving as the HRPP specialist may manage the concern through communications with the principal investigator and/or the complainant.

After an initial assessment, the IRB Chair and HRPP specialist may determine that the noncompliance is not serious or continuing and no additional action is needed, or determine further inquiry and a convening of the full IRB are necessary. If the IRB Chair and HRPP specialist determines that the allegation may be substantiated and may involve serious or continuing noncompliance, the full IRB will convene and decide if further investigation is needed before corrective action is considered. If the allegation is sufficiently substantiated after the initial assessment and further investigation is not needed, the Board will allow the principal investigator to respond to the allegation either by meeting with the IRB or in writing before deciding on and directing corrective action, which may include suspension or termination of IRB approval.

13.3 Investigations of Allegations

If the IRB decides to pursue an investigation, the IRB Chair in conjunction with OSP staff will appoint an ad hoc subcommittee to conduct the investigation. The ad hoc subcommittee will consist of a minimum of three voting IRB members. OSP staff will also provide a letter to the individual against whom the allegation was raised (if the individual is not the principal investigator, staff will also notify the principal investigator of the project in question) notifying them of the investigation.

The ad hoc committee will gather information pertaining to the nature of the allegation, the approved IRB protocol, and the procedures followed in conducting the study. An IRB representative will interview the complainant or, in cases where the complainant requests anonymity, the individual who received the original allegation will interview the complainant. The ad hoc committee will also interview the principal investigator and, if applicable, anyone else against whom the allegation has been raised. Depending on the nature of the allegation/concern and the information collected during the interviews, the ad hoc committee may interview other individuals. In addition, the committee may examine research data, both published and unpublished; informed consent/assent forms; medical records; inclusion/exclusion criteria; and any other pertinent information. The ad hoc committee, in cases of a credible allegation of serious or continuing noncompliance, will have authority to request an interview with anyone related to the project or request

any information about the project that is the subject of the allegation.

When the ad hoc committee determines that its investigation is done, it will prepare, with the assistance of the HRPP specialist, a summary report for the full IRB. The report may consist of a summary of the allegation, interview summaries, and copies of pertinent information or correspondence. The report may or may not include recommendations for IRB action.

13.4 Procedures for Reviewing Potential Serious or Continuing Noncompliance

The IRB will review the materials presented by the ad hoc committee at a convened meeting at which a quorum is present. The materials provided will include the summary report of the alleged noncompliance and any other relevant materials. The convened IRB determines whether to request additional information or whether to interview additional witnesses. The IRB may give the principal investigator of the project under review the opportunity to meet with the convened IRB before it takes final action.

The convened IRB will make the determination whether the allegation is substantiated, and if so, whether the noncompliance is serious or continuing based on the materials compiled by the ad hoc committee and any additional information that it may request. The IRB may also find that the allegation is unjustified or that noncompliance is a minor issue. If the issue is minor, then it may be resolved through communication involving the IRB Chair, the HRPP specialist, the principal investigator, and the complainant.

Once the IRB has made a determination about the allegation, the convened IRB may vote to approve a variety of actions, including but not limited to the following: approve continuation of research without changes; request formal educational intervention; request minor or major changes in the research procedures and/or consent documents; modify the continuing review schedule; require monitoring of research; require monitoring of the consent process; suspend or terminate IRB approval; require inspections of other active protocols of the investigator; disqualify the investigator from conducting research involving human subjects at KSU; determine that the investigator may not use the data collected for publication; require that the investigator contact subjects previously enrolled in the study and provide them with additional information and/or obtain consent from them again; request that the investigator inform publishers and editors if they have submitted or published manuscripts emanating from the research.

Once the IRB has reached a decision on the allegation and approved a course of action, the OSP will provide a letter to the following individuals notifying them of the allegation, the review process, the findings of the review: the principal investigator, the investigator's immediate supervisor, chair, or dean, and the complainant.

If the principal investigator is directed to take corrective action, the investigator must provide written documentation of the completion or implementation of any required actions to the IRB within 30 days. Once the IRB has evidence and agrees that the appropriate corrective actions have been completed or implemented, the matter will be

considered resolved, and the OSP staff in consultation with the IRB Chair will provide a letter to the principal investigator indicating that the matter is resolved.

The HRPP specialist will provide advice to the IRB regarding the applicable regulations during the review process, assist the IRB in documenting the review, answer questions about the review process, maintain records as required by state and federal laws or regulations, and serve as a liaison with the funding agency or agencies. In cases where the IRB determines that there is serious or continuing noncompliance, OSP will also provide a letter notifying KSU's Institutional Official of the noncompliance. If applicable, OSP will also notify the funding agency and OHRP of the noncompliance.

13.5 Noncompliance and Research Misconduct

Research misconduct includes but is not limited to fabrication, falsification and plagiarism. Research misconduct in human subjects research may occur in the proposal, conduct or reviewing of research, or reporting of research results. Examples of misconduct in human subjects research may include: substituting one subject's record for another's; altering eligibility dates and eligibility tests results; changing dates on patient screening logs; creating records of interviews that did not occur; and creating records of patient visits that did not occur and inserting false records into medical charts.

Research misconduct may constitute serious or continuing noncompliance and may need to be reported to regulatory agencies and the HHS Office of Research Integrity (ORI). ORI is the federal agency that is responsible for the administration and oversight of Public Health Service (PHS) policies and funds. A condition for PHS support is investigating research misconduct and reporting evidence of misconduct to OIR.

Not all instances of noncompliance fall within the definition of research misconduct. For example, in most cases, failure to report unanticipated problems, protocol deviations without IRB approval, failing to obtain or properly document informed consent, and breaching confidentiality of subject data should not be considered research misconduct. Similarly, not all instances of research misconduct constitute noncompliance with regulations and polices governing the protection of human subjects.

The IRB may respond to allegations of research misconduct that has implications for human subject protections and may be regarded as serious or continuing noncompliance by following the steps described in 13.2, 13.3, and 13.4. Examples of allegations that the IRB may respond to include: backdating enrollment forms to make subjects eligible for participation; falsifying a lab report required for admission to a clinical trial; and intentionally reversing or blending end point results between treatment and control subjects to improve the statistics in violation of IRB approved protocols.

In many instances, however, issues of research misconduct fall outside of the scope of the IRB. The reporting and response to allegations of research misconduct should follow KSU's policies and procedures for research misconduct, which do not involve the IRB. If there is an allegation of research misconduct that has implications for human subjects,

the IRB may defer responding to the allegation while a separate committee or disciplinary board completes an assessment and investigation of the allegation. A final report of the investigation will be provided to the IRB, and the IRB will determine if further action is needed to address issues of noncompliance. The IRB retains the authority to suspend approval of research while an investigation into research misconduct is ongoing when it believes suspension of approval is in the best interest of subjects.

XIV. SUSPENSION OR TERMINATION OF IRB APPROVAL

The convened IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with substantive harm to the rights and welfare of human subjects. Any suspension or termination of approval shall include a statement of the reason for the IRB action.

14.1 Suspension

The convened IRB may suspend approval of a protocol when it is believed to be in the best interest of participants to stop some or all protocol related activities temporarily. Studies may be suspended, put on hold during an investigation of noncompliance, or following a protocol deviation, adverse event, or unanticipated problem involving risks to participants or others. These protocols are still considered to be active studies and hence require continuing review by the IRB. OSP staff will provide the principal investigator a letter notifying them of the suspension and explaining the reasons for it.

14.2 Termination

The convened IRB may terminate approval of a protocol when it is believed to be in the best interest of participants to stop protocol related activities permanently. Studies may be terminated following an investigation of noncompliance, protocol deviation, or unanticipated problem involving risks to participants or others. OSP staff will provide the principal investigator a letter notifying them of the termination and the reasons for it.

14.3 Continuation of Research after Suspension or Termination

If approval of study is suspended or terminated, new participants may not be enrolled and no study procedures may take place, except when the IRB determines that continuation of study procedures is in the best interest of currently enrolled participants.

14.4 Reporting of Suspension or Termination

In addition to notifying the principal investigator of the suspension or termination of IRB approval, the OSP will report the suspension or termination to the principal investigator's immediate supervisor, chair, and/or dean, and KSU's designated Institutional Official. In cases of termination, if applicable, the OSP will also notify the funding agency, the OHRP, and the research integrity offices and/or IRBs of any institution that may be collaborating

with KSU on the study.

XV. RECORDS AND DOCUMENTATION

15.1 General Requirements

The OSP will be responsible for IRB records in accordance with 45 CFR § 46.115, which states that the University is required to prepare and maintain documentation of IRB activities including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

2. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

3. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review.

4. Copies of all correspondence between the IRB and the investigators.

5. A list of IRB members in the same detail as described in 45 CFR § 46.108(a)(2).

6. Written procedures for the IRB in the same detail as described in 45 CFR § 46.108(a)(3) and (4).

7. Statements of significant new findings provided to subjects, as required by 45 CFR § 46.116(c)(5).

8. The rationale for an expedited reviewer's determination under 45 CFR § 46.110(b)(1)(i) that research appearing on the expedited review list described in 45 CFR § 46.110(a) is more than minimal risk.

9. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in 45 CFR § 46.103(e).

15.2 Minutes of IRB Meetings

The minutes of IRB meetings should document, among other things: separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB; the vote on all IRB actions including the number of members voting

for, against, and abstaining; the basis for requiring changes in or disapproving the research; and a summary of the discussion of controverted issues and their resolution. OHRP recommends that the recusal of IRB members because of a conflicting interest also be documented when recording votes on IRB actions.

In order to document the continued existence of a quorum, the following examples demonstrate one acceptable format for documenting in the minutes the votes on actions taken by the IRB on research projects undergoing initial or continuing review:

- Total = 6; Vote: For – 5, Opposed – 0, Abstained – 1.

- Total = 5 (1 member recused and did not vote); Vote: For – 4, Opposed – 1, Abstained – 0.

OSP staff will develop IRB meeting minutes in draft form within three working days following an IRB meeting. Draft minutes will be sent to the IRB Chair for initial review. After initial review, the minutes will be distributed via email to all IRB members for review; minutes will be discussed and approved at the next scheduled meeting. IRB meetings may be recorded. Meeting recordings will be utilized for the primary purpose of developing the minutes. Once meeting minutes are approved, meeting recordings may be erased. The Chair or OSP staff may periodically utilize the OHRP self-assessment tool to evaluate the quality of meeting minutes.

15.3 Documentation of Findings

45 CFR § 46.116(d) requires that the IRB document findings when approving a consent procedure that does not include, or which alters, some or all of the required elements of informed consent, or when waiving the requirement to obtain informed consent. OHRP recommends that when approving such a waiver for research reviewed by the convened IRB, these findings be documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

Similarly, where HHS regulations require specific findings on the part of the IRB, such as approving a procedure that waives the requirement for obtaining a signed consent form, approving research involving pregnant women, human fetuses, or neonates, approving research involving prisoners, or approving research involving children, the IRB should ensure that findings are fully documented in the minutes of the IRB meeting, including protocol-specific information justifying each IRB finding.

15.4 Documentation of Approval Periods

The IRB must determine which protocols require continuing review more often than annually, as appropriate to the degree of risk. OHRP recommends that the minutes of IRB meetings clearly reflect these determinations regarding risk and approval period. OSP staff will be responsible for tracking the dates for continuing review and expiration of approval periods and periodically updating the IRB on the dates.

15.5 Copies of Revised Protocols

Following the approval of changes to a protocol either through the change in research activity approval process or continuing review, OHRP recommends that the investigator incorporate the revision into the written protocol and provide the OSP a copy of the revised protocol. This practice ensures that there is only one complete and up-to-date protocol. The revision dates should be noted on each revised page and the first page of the protocol itself. This procedure should also be used for revised and approved informed consent documents, which supersede previous one(s).

15.6 Retention of IRB Records

As stated in 45 CFR § 46.115(b), OSP will retain the IRB records described in section 15.1 for at least 3 years. Records relating to research reviewed by the IRB will be retained for at least 3 years after completion of the research. Records will be accessible to OSP staff, IRB members, and the designated Institutional Official. Investigators may request access to records relevant to their research projects. Furthermore, all records will be accessible for inspection and copying by authorized representatives of federal agencies at reasonable times and in a reasonable manner.

XVI. REVISING AND UPDATING HRPP POLICIES AND PROCEDURES

The following specifies the process of developing and initiating approval and implementation of changes to the current policies and procedures for KSU's HRPP and IRB.

When an HRPP policy or procedure requires modification, the IRB Chair in consultation with the HRPP specialist will draft a written proposal. Such proposal will include a statement of the need for the change, and a draft of the new policy or procedure. This proposal will be submitted to the IRB for consideration.

Minor procedural changes may not warrant this formal process and may be more appropriately termed IRB guidance or clarification. The IRB Chair will have discretion to determine what requires a formal policy or procedure change versus IRB guidance or clarification. Minor changes that the Chair determines fall into the IRB guidance or clarification category, and that do not contravene the policies and procedures herein, will be discussed and voted on at regularly scheduled IRB meetings.

Once the draft proposal of a revised policy or procedure has been reviewed by the HRPP specialist and/or the Director of Sponsored Programs (who may need to seek counsel from other staff/administrators to assure that the proposed policy and/or procedural change is consistent with KSU's policies and all relevant laws and regulations), it will be presented by email to the full Board for review and comments. The Board will be given one week ahead of a scheduled meeting to review the proposed change. IRB members should insert a comment into the document either indicating that they approve the

proposed change as written or suggest changes to the proposal.

After the review period, the Chair or the HRPP specialist will compile a final version of the policy or procedure. This version will be presented to the board at the IRB meeting. All active board members will be asked to vote to approve or disapprove or to abstain. A policy or procedure change will be recommended for adoption if more than 50 percent of active IRB members vote to approve the proposed change. The Chair and/or the HRPP specialist will then present the policy or procedure change to the Provost and/or President for guidance as to getting the change officially approved and adopted.

Once a policy or procedural change is officially approved by the Board of Regents, it will be added to an appendix to these policies and procedures. This entry will include the date the policy or procedure was adopted and include reference to the earlier sections of the policy and procedures that have been modified, clarified, or invalidated.

XVII. REFERENCING FEDERAL REGULATIONS AND GUIDANCE

For policies and procedures in matters not addressed in the policies and procedures herein, the IRB, OSP staff, and all KSU faculty, staff, and students should refer to and follow 45 CFR § 46, other relevant federal regulations, and OHRP guidance.