KENNESAW STATE UNIVERSITY
Assurance of Compliance with the
Department of Health and Human Services
Regulations for Protection of Human Research Participants
REVISED October 18, 1995, April 15, 2002, March 6, 2007, September 15, 2015

With this document, Kennesaw State University (KSU or the University) gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human participants (45 CFR Part 46, March 8, 1983, revised June 18, 1991, revised June 23, 2005, revised January 15, 2009). This assurance is closely patterned after the recommendations found within the DHHS Office for Human Research Protections' (OHRP) Guidance on Written IRB Procedures dated July 1, 2011 [http://www.hhs.gov/ohrp/policy/irbgd107.html].

The items outlined below incorporate the most current thinking of the OHRP (September 8, 2015), considered the authoritative source for the protection of human participants. The policies and procedures described in this document are the KSU specific applications of OHRP general principles.

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I. Basic Institutional Policy

A. Institutional Responsibility

Kennesaw State University (KSU or the University) recognizes and accepts the responsibility to protect the rights and welfare of human research participants. The University is guided by the ethical principles as published in the report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Ethical Principles and Guidelines for the Protection of Human Subjects of Research) as well as the 1981 revision of Ethical Principles of Psychologists as written by the American Psychological Association.

B. Scope and Applicability

This assurance applies to all research activities conducted under the auspices of KSU that to any degree involve using humans as research participants.

C. Prior Review and Approval Requirement

It is the policy of KSU that all research projects that involve human research participants will be conducted only after a complete research proposal has been submitted and approved by the University. The President of the University, as chief executive officer responsible for all college programs, has delegated the authority for research approval as well as the responsibility to ensure that all ethical principles are met to the KSU Institutional Review Board (IRB) for research with human participants. The Vice President for Research will serve as the liaison officer between the President of the University and the IRB. The following sections of this document detail the policies and procedures developed to oversee research projects in order to comply with the principles stated in this assurance.

II. Role, Structure, and Responsibilities of the IRB

A. Role of the IRB

The IRB at KSU serves in an advisory capacity to the President of the University. The Vice President for Research will serve as the liaison officer between the President of the University and the IRB. The policies in this assurance have been formulated in order that, while maintaining this position in the institutional context, the IRB may also satisfy as its primary role the mandate of 45 CFR 46.109 to review research involving human participants. Although it remains the prerogative of the institution to determine its own policies regarding all aspects of the research program, we acknowledge by this assurance that all research involving human participants will require the prior approval of the IRB, as described in Section V B.1., unless the project is eligible for expedited review or exemption as described in Sections V B.2. and V B.3.

B. Structure of the IRB

The IRB of KSU is structured to include the University authorized institutional official (responsibilities are described in Section III.A) for purposes of federal assurance, the Human Protections Administrator (responsibilities are described in Section III.B), and the IRB Chairperson (responsibilities are described in Section IV). The membership of the IRB will include the following:

1. The Vice President for Research (authorized institutional official).

2. Ten KSU faculty appointed by the Vice President for Research in consultation with College Deans. Faculty will have diverse backgrounds as required to promote complete

and adequate review of research activities covered by this assurance. Faculty will have the professional competence necessary to review the specific research activities that will be assigned to it.

3. At least one faculty member appointed by the Vice President for Research will have scientific research experience.

4. Two individuals from the medical community to be appointed by the Vice President for Research. Neither this person nor a member of his/her immediate family should be affiliated with KSU. These two community members will also have an alternate member with a similar skill-set who is able to attend as their designated representative.

5. The IRB will consist of 13 members.

   Each member of the IRB (except for the Vice President for Research, which is a permanent appointment to the IRB) will serve for a term of three years, with terms running August 1 – July 31**.** Based on the recommendation of the IRB Chairperson, this term can be renewed in one, two or three year increments. Should an IRB member resign or need to be replaced prior to the end of his/her term, a replacement will be appointed for the balance of the term. The Chairperson of the IRB is appointed by the Vice President for Research and serves a two-year term as Chairperson that can be renewed.

   Members of KSU's IRB need to maintain a current CITI certification in the IRB Members Basic Course as well as the Social & Behavioral Research Investigators Basic Course during their term of service. The IRB Chairperson also must successfully complete the IRB Chair Basic Course as well.

6. IRB Membership Requirements

   IRB members will be chosen from diverse backgrounds to promote complete and adequate review of research activities covered by this assurance, and will have the professional competence necessary to review the specific research activities that will be assigned to it. The IRB will be sufficiently qualified, through the expertise and experience of its members and the diversity of the members' backgrounds (including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes), to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. Its membership will specifically include:

   a. Both male and female members;
   b. Members representing a variety of academic disciplines;
   c. At least one member whose primary expertise is in a non-scientific area;
   d. At least one member who is not otherwise affiliated with the institution and who is not a part of the immediate family of a person affiliated with the institution.
   e. At least one person with scientific research experience

7. IRB Meetings

   The IRB will meet at least once each academic term, on the call of its Chairperson. Meetings will usually be scheduled monthly to evaluate submitted proposals in a timely fashion. Meetings will be open except in the circumstances of a full board review and will be conducted under Robert's Rules of Order.

   For the IRB to approve a research proposal in a meeting, at least 60% of members must be present at that meeting, including a member whose primary expertise lies in

non-scientific areas. If the proposal involves participants who are minors or members of other vulnerable categories, the IRB must either have a member present whose expertise deals with such participants or the IRB will have consulted in advance with someone having such expertise in order to approve the proposal. No IRB member will participate in any decision involving their own research or presenting other conflicts of interest.

Minutes of IRB meetings will be kept and will include the names of members attending, summaries of discussions, actions taken and the numerical vote on these actions, dissenting reports and opinions and the basis for any required change in or disapproval of a proposal. Records will be maintained for at least three years. Meetings of the IRB may also occur via conference phone calls, or via electronic media, as long as the following requirements are met:

a. Accurate attendance records are kept.
b. All materials for examination are available to all participating IRB members.
c. All participants have full and equal opportunity for interactive discussion.

C. Responsibilities of the IRB

1. Review and Approval Procedure

The IRB will have the responsibility to review and the authority to approve, require modification for purposes of approval, or disapprove all activities or proposed changes in previously approved activities covered by this assurance. Approval of a proposal may be granted by a majority vote of members present at an IRB meeting.

All proposals approved on an expedited basis, or without detailed review, will be reported to the IRB at its next regular meeting after that approval. With a majority vote of IRB members present, the IRB will have the authority to examine these proposals and, if judged appropriate, to suspend the previous approval and conduct an immediate full board review of the re-examined proposal. In such cases, IRB decision will supersede those of the previous review.

2. Continuing Oversight

The IRB will have the responsibility and the authority to maintain continuing oversight of all projects involving human participants. The IRB may have one or more of its members observe the consent process or the research itself, and verify that the project is being conducted according to the approved proposal. The IRB has the authority and the responsibility to suspend or terminate approval of research that is not being conducted in accordance with the approved proposal or that has been associated with unexpected serious harm or risk to participants.

3. Audit to Determine Compliance

a. The IRB will conduct audits at regular intervals to determine whether projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
    i. Depending on staffing and available resources, as well as volume of submissions, the IRB Chairperson and IRB Administrator will conduct an audit within each college on a revolving basis.
    ii. These audits will focus primarily on the masters and doctoral programs.
b. These audits will help to ensure prompt reporting to the IRB of proposed changes in a research activity, and to ensure that such changes during the period for which IRB approval has already been given, may not be initiated without IRB review and

approval except when necessary to eliminate apparent immediate hazards to the subject.

4. Research Conducted Without Prior Approval of the IRB

In the case where research with human participants is conducted without having obtained the prior approval of the IRB, the IRB Chairperson will initially send a memorandum to the researchers asking them to suspend the research project. If the researchers fail to respond to the initial suspension notification within 14 days, a second memorandum will be sent and copies of this memorandum will also be sent to the Vice President for Research and the researchers' College Dean and Department Head. No further work can be done on this research project until the IRB has provided a final determination regarding the status of the study.

The following examples defines the circumstances in which data are considered to have been obtained by researchers without IRB approval.

- With no prior review or approval by the IRB;
- With no informed consent from the subjects or their legally authorized representatives (and when the IRB had not approved a waiver of consent);
- Using procedures that were not described in the IRB-approved consent document (and when the IRB had not approved a waiver for excluding the procedure from the consent document);
- After the expiration of IRB approval;
- After suspension or termination of IRB approval.

The IRB does not, and cannot, grant retroactive approval for use of data that was collected without IRB approval. Federal regulations allow IRB approval to be granted only when it is prior to the initiation of the research activities.

The IRB can embargo the data upon suspension until such time as a final determination has been made about the appropriate use of the data. Embargo notifications can be appealed utilizing the process detailed under Section V.D. Final decisions may then require the researcher to destroy data or prevent the researcher from analyzing and publishing data collected without IRB approval.

The IRB will provide a final determination on the collection of data without prior IRB approval as described in the consequences below:

Non-compliance determination. The IRB determines whether the data collection is minor, serious, or continuing non-compliance. Non-compliance: A situation, event or process in human subjects research that is under the researcher's control and that is inconsistent with the following. This can include inquiries and complaints directed to the researcher that involve an allegation of non-compliance as defined here.

a. Serious Non-compliance: Non-compliance which could significantly:
    i. Increase risks to, or jeopardize the safety, welfare, and/ or rights of subjects or others, or
    ii. Decrease potential benefits (including the scientific integrity of the research).
    iii. Conducting a research study without any prospective IRB approval is always considered serious non-compliance.
b. Continuing Non-compliance: A pattern of non-compliance that:
    i. Suggests that non-compliance will continue if there is no intervention, or
    ii. Increases the risk of serious non-compliance.
c. Minor Non-compliance: Non-compliance that is neither serious nor continuing.

The regulatory basis for non-compliance determinations includes (but is not limited to) the following:

- Obtaining human subjects data without IRB approval is always considered to be non-compliance with human subjects regulations and KSU's Federal-wide Assurance (FWA).
- Accessing Protected Health Information (PHI) without IRB approval and Health Insurance Portability and Accountability Act (HIPAA) authorization is non-compliance with HIPAA regulations, http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf .
- Publications and presentations. Data collected without IRB approval cannot be described as being part of an IRB-approved study. This may have implications for the publications or presentations, as many journals and conferences require IRB approval as a condition of publication or presentation of research that involved human subjects.
- Reporting to funding agencies and federal regulators. The IRB reports serious or continuing non-compliance to appropriate federal regulators and/or funding agencies, as described in the OHRP Guidance on Reporting Incidents.
- Corrective and preventative action. The IRB may require corrective or preventative actions to address or prevent the collection of data without IRB approval as well as any consequences of the data collection activity. Possible examples include:
    - Modification. Some or all parts of the research are modified.
    - Re-collection of data. The data are collected again, but with IRB approval.
    - Re-consent. The subjects provide consent again, using appropriately revised procedures and documents.
    - Notification of subjects. Notification of subjects may be required in studies that obtained PHI without the prior consent or authorization from the subjects. The researcher's department is responsible for the notification costs, which can be considerable. The costs cannot be charged to grants or contracts.
    - Recommendation to impose sanctions on use of the data. Although the IRB cannot impose sanctions on the use of data, the IRB can recommend that the appropriate institutional official consider the following actions:
        - Require that data not be published or presented;
        - Require that data not be used for a thesis or dissertation;
        - Require that data be destroyed; and/or
        - Other actions for which the institutional office has authority.
        - Suspension of research activities. The IRB may temporarily withdraw IRB approval for some or all parts of an approved study.
        - Termination of research activities. The IRB may permanently withdraw IRB approval for some or all parts of an approved study.
    - Closure. If the entire research study was conducted without IRB approval, the IRB Administrator or designee will administratively close the study, after all review activity related to the matter has been concluded. The file is retained as an IRB record in accordance with 45 CFR 46.115(b).

D. Communications and External Relations

Members of the IRB provide substantive advice and judgment on issues of basic concern to the University. They may, if judged appropriate, contact researchers or other members of the University on any occasion regarding a proposal being reviewed or a more general concern over the conduct of research involving human participants. They are encouraged to help bring increased awareness throughout the University of the responsibility to protect the rights and welfare of human participants. In that capacity, they may meet with departments or other groups or individuals.

The responsibility for routine communication with researchers, maintenance of records and documentation of IRB activities and approvals rests with the IRB Chairperson. Communication with federal agencies will occur through the authorized institutional official (the Vice President for Research or designee).

III. Responsibilities of the AIO and HPA

Federal regulations describe specific responsibilities for both the "authorized institutional official" (AIO) and the Human Protections Administrator (HPA). These positions are related to the issuance of a federal assurance of IRB compliance. Before the OHRP can approve an Assurance, it must be satisfied that the Institutional Official (AIO), the Chair of the Institutional Review Board (IRB), and the HPA (Primary Contact) at the institution understand the responsibilities involved in an institutional program of human subject protection.

A. Authorized Institutional Official (AIO)

The AIO (Vice President for Research) has responsibility for oversight of research and IRB functions. The AIO has the legal authority to act and speak for the University. This individual may appoint the Chairperson of the IRB, but cannot serve as Chairperson of the IRB.

B. Human Protections Administrator (HPA)

The responsibilities of the HPA are described within the following text taken directly from the OHRP web site:

"Effective administration of a Human Protections Program requires the designation of a Human Protections Administrator who serves as OHRP's primary institutional contact person and has administrative responsibility for the program. Institutions with a very small human research program may be able to assign other duties to the Human Protections Administrator, but that person's primary responsibility should be the Human Protections Program. Depending on the volume of work, the administration of the program may fall to the Human Protections Administrator alone, or to an office staffed by many persons with differing areas of responsibility.

The administrative responsibilities for the HPA fall into three general areas:

1. *Communication & Education*
2. *Recordkeeping & Reporting*
3. *Monitoring & Oversight*

1. Communication & Education

- *The HPA is responsible for ensuring constructive communication among the research administrators, department heads, investigators, clinical care staff, human subjects, and institutional officials, as a means of maintaining*

a high level of awareness regarding the ethical conduct of research, and safeguarding the rights and welfare of subjects.

- *The HPA arranges for ready access to the institution's Assurance, copies of pertinent Federal regulations, policies and guidelines related to the involvement of human subjects in research, as well as institutional policies and procedures.*
- *The HPA is responsible for educating the members of its research community in order to establish and maintain a culture of compliance with Federal regulations and institutional policies relevant to the protection of human subjects.*

2. *Recordkeeping & Reporting*

   - *The HPA is responsible for ensuring that IRB records are being maintained appropriately and that the records are accessible, upon request, to authorized Federal officials. For institutions relying on another IRB, records may be retained at the IRB site.*
   - *For Federally supported research, the HPA is responsible for forwarding Certification of IRB approval of proposed research to the appropriate Federal department or agency.*

   The HPA is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval, except when necessary, to eliminate apparent, immediate hazards to the subject.

   The HPA is responsible for ensuring the prompt reporting to the IRB, appropriate institutional officials, OHRP, and any sponsoring Federal department or agency head:

   - *any unanticipated injuries or problems involving risks to subjects or others;*
   - *any serious or continuing noncompliance with the regulations or requirements of the IRB, and*
   - *any suspension or termination of IRB approval for research.*

3. *Monitoring & Oversight*

   - *The HPA is responsible for ensuring that appropriate oversight mechanisms to ensure compliance with the determinations of the IRB have been implemented.*
   - *The HPA ensures that all cooperating performance sites in Federally supported research have appropriate OHRP-approved assurances and provide Certifications of IRB review to the appropriate Federal authorities.*
   - *The HPA should ensure that performance sites cooperating in non-Federally supported research have, and can document, appropriate mechanisms to protect human subjects.*
   - *The HPA ensures that cooperative IRB review arrangements are documented in writing in accordance with OHRP guidance.*
   - *The HPA ensures that all independent investigators, who rely on the institution's IRB, have documented, in accordance with OHRP guidance, their commitment to the institution's human subjects protection requirements and to the IRB's determinations.*

Most of the administrative functions of the HPA are shared or assumed by the Chairperson of the IRB. HPA functions related to external funding and federal assurances are undertaken by the University Office of Research, that also coordinates IRB training and education functions.

IV. Role and Responsibilities Assigned to the IRB Chairperson

A. Review and Approval of Proposals

The IRB Chairperson will receive proposals submitted by researchers. The Chairperson will determine if human participants are involved, and whether the project qualifies for expedited review, or for exemption from detailed review. Proposals that are exempt from detailed review, or qualify for expedited review, may be approved by the IRB Chairperson or his/her designated representative from among the IRB membership as described in Section II.B. Proposals requiring full board review will be forwarded promptly to IRB members.

B. Staff Support to the IRB

The IRB Chairperson will ordinarily serve as the communications channel between researchers and the IRB, requesting further information when necessary, notifying researchers of IRB decisions, and generally serving as support for all review activities. The HPA or designee will arrange space and keep minutes for IRB meetings. The HPA or designee will maintain files of IRB activities and correspondence. When IRB members visit research projects in progress, as part of their continuing oversight responsibilities, those visits will be coordinated by the IRB Chairperson.

C. Official Correspondence with Researchers

The IRB Chairperson will notify researchers officially and in writing of all actions involving their submitted proposals, including approvals, requirements of modifications, extension of time, suspensions and disapprovals, and will provide all necessary certifications of these actions.

D. Official Correspondence with Federal Agencies

The AIO (Vice President for Research) is the institutional official authorized to sign and certify approval of human participant procedures in projects that involve federal funding. This responsibility may be delegated to the IRB Chairperson, or in some cases, the HPA. Correspondence may include any matter that involves human participants in federally-funded research projects. The Vice President for Research, the IRB Chairperson, or the HPA will be responsible for notifying the Office for Protection from Research Risks (OPRR) or other relevant federal agencies of any injuries to participants in federally funded research, for complying with Food and Drug Administration (FDA) investigational new drug or device certification requirements, and for informing OHRP of the membership, or of any changes in membership, of the IRB.

E. Official Correspondence with the University Office of Research

The HPA will maintain communication with the University Office of Research regarding approval of projects that are to be submitted for external funding, any changes in the approval status of ongoing projects, and changes in the IRB membership.

F. Recordkeeping

The IRB Chairperson in cooperation with the HPA will maintain appropriate records for three years following the completion of a research project, in accordance with 45 CFR 46.115(b), including, in particular, the following:

1. A file on each research proposal received that contains:

a. a copy of the original proposal and a separate copy that documents any modifications to it;
b. a record of the review procedure used, and copies of the written evaluations of the reviewer(s);
c. copies of correspondence and memoranda of discussions relevant to consideration of the proposal;
d. copies of all certifications relating to the proposal;
e. records of continuing IRB oversight activities;
f. reports from researchers on the progress of the project;
g. copies of statements of significant new findings provided to participants, as required by 45 CFR 46.116(b)(5).

2. Minutes of IRB meetings, as described in Section II.B.7.

3. A list of all IRB members and a written description of IRB procedures, as required by 45 CFR 46.103.

4. An annual report summarizing all activities covered by this assurance.

These records will be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner. Records will be archived in the University Office of Research.

V. Basis and Mechanism for Approval

A. Basis for Approval

The approval of a research proposal will be based upon the determination that all aspects of the research that involve human participants meet the principles and guidelines put forth in this assurance. Specifically, the proposed research should:

1. Minimize any potential risks to the participants by employing standard research methodological principles that do not expose human participants to any unnecessary risks.

2. Ensure that any potential risks are reasonable with respect to both the anticipated benefits to the participant and the expected importance of the knowledge to be gained from the research. The review should consider only the risks and benefits directly related to the research, and not those that would occur even if the participant were not participating in the research. Any long-range applications of the research may be considered as a benefit but not as a risk.

3. Demonstrate that the selection of the research participants is equitable considering the purpose of the research, the setting in which the research will take place and the population from which the participants will be taken.

4. Take appropriate steps to obtain and document informed consent from the participants (or their legally authorized representative) prior to their participation in the research.

5. Include acceptable provisions for the protection of the participant's safety and privacy by ensuring anonymity or confidentiality with respect to the data collected.

B. Basic Methods of Proposal Review

KSU has adopted three basic methods to review and approve research proposals that involve human participants, as described below. In all cases, written notice of the action of the IRB is delivered to the submitter of the IRB approval request and maintained for IRB records.

1. Board Review: The KSU Institutional Review Board is charged with the responsibility of reviewing research proposals involving the use of human participants. The IRB may approve, require modifications before approval, or disapprove any proposal as described in Section II. IRB meetings are scheduled regularly (August, September, October, November, January, February, March and April); proposals to be considered should be submitted to the IRB one month prior to the meeting. Minimally, the Primary Investigator is required to attend IRB meetings at which their proposals are being considered; however, the IRB recommends that Co-Investigators with specific subject matter expertise involved on the project attend.

2. Expedited Review: If the IRB Chairperson determines that a submitted research proposal meets the eligibility requirements for expedited review, the Chairperson, or an IRB member appointed by the Chairperson, may approve the proposal or require modifications before granting approval via an expedited review. The entire IRB will be notified of all proposals approved through the expedited review process, and (by majority vote) may reconsider the proposal at the next IRB meeting. Any subsequent disapproval of a proposal requires full IRB consideration at the next scheduled meeting. To be eligible for expedited review the research must involve only minimal risk to the participants and must be in one of the following categories (see 45 CFR 46.110):

    a. Collection of hair, nails, or teeth in a non-disfiguring manner.
    b. Collection of excreta and external secretions (e.g., saliva, sweat, placenta at birth).
    c. Non-invasive data recorded from participants over 18 years of age during routine clinical practice (e.g., weighing, visual tests, EEG, EMG, EKG).
    d. Collection of blood samples from healthy, non-pregnant participants over 18 years of age. The amount should not exceed 450 milliliters in an eight-week period.
    e. Collection of dental plaque and calculus during routine prophylactic scaling.
    f. Voice recording for research purposes.
    g. Moderate exercise by healthy volunteer participants.
    h. The study of existing records or medical specimens.
    i. Research on individual or group behavior or characteristics that do not involve manipulation of behavior or stress to the participant.
    j. Research on drugs or devices that do not require an investigational new drug or investigational device exemption.

3. Approval without Detailed Review [Exempt]: Research proposals involving human participants that are in exempted review categories may be approved by the IRB Chairperson, or an IRB member appointed by the Chairperson, without further review. Research in the following categories will be eligible for IRB approval without detailed review (see 45 CFR 46.101(b) (1-5) or 46.101 (e):

    a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The research is not FDA regulated and does not involve prisoners as participants.

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. If the research involves children as participants, the procedures are limited to educational tests and observation of public behavior where the investigators do not participate in the activities being observed. Research is not FDA regulated and does not involve prisoners as participants.

c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (2), if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Research is not FDA regulated and does not involve prisoners as participants.

d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. Research is not FDA regulated and does not involve prisoners as participants.

e. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

f. 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. The research does not involve prisoners as participants.

C. Length of Approval Period

A research project approved as expedited will be valid for a period of no longer than one year. Any project requiring an extension beyond a year, or involving any changes in the original procedures once started, must be resubmitted to the IRB for a continuing review and approval. If external funding is involved, please follow all applicable guidelines of the funding agency regarding IRB approvals. Exempt studies do not require continuing review; however, any changes to the original approved study requires submission of a progress report for review and approval. The Primary Investigator is expected to close out the study when completed by submitting a Progress Report, this will then start the 3 year record retention requirement. For studies with students as the Primary Investigator, please see Section VII.I.

All studies are administratively closed if not submitted for continuing review in a timely manner. The specific expiration date and process for renewal are described and provided in each approval letter issued by the IRB. There are no projects that require review more often than annually, unless part of the approved protocol has changed. Those changes must be submitted for approval via a Progress Report prior to implementation of the changes.

D. Appeal Procedure

Researchers whose proposals have not been approved after submission of all required documentation may submit to the IRB a written request for reconsideration of the full board. This must include reasons for disagreement with the IRB decision and must be submitted within 30 days after written notification of non-approval. The IRB will then meet within 14 days to consider the appeal. If the IRB still does not approve the proposal, the appeal decision rendered by the full board will be final.

Research that has been approved by the IRB may be reviewed by college administrators including the President of the University, the Provost and Vice President for Academic Affairs, or the Vice President for subject to further appropriate review and approval or disapproval by officials of the institution; however, as stated in the federal guidelines (see 45 CFR 46.112), those officials may not approve the research if it has not been approved by an IRB.

E. Suspension or Termination of IRB Approval of Research

As stated in the federal guidelines (45 CFR 46.113), an IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, including the department chair.

An incident notification report will be submitted to the OHRP within 2-4 weeks depending on the seriousness of the incident per their Guidance on Reporting Incidents.

VI. The Research Proposal

A. Basic Content of the Research Proposal

A complete research proposal submitted by the researcher using forms available from the IRB Administrator or on the web (http://www.kennesaw.edu/irb/) will be reviewed for approval. The research proposal form asks for the following information:

1. A description of the research procedures to be used

2. A description of the characteristics of the participants in the project, the total number of participants, and the selection procedure for the participants;

3. A description of any potential psychological, physiological, legal or societal harm to the participants, and the steps to be taken to prevent or minimize these risks;

4. A description of the potential benefits to the participant or to humankind as a result of the research;

5. A description of the methods by which informed consent will be obtained from the participants and an example of the consent form to be used;

6. A description of the methods by which the participant's anonymity and confidentiality of data will be maintained.

7. A description of the measures planned to ensure anonymity or confidentiality; methods for storing data while study is underway; list of dates and plans for storing and/or destroying data and media once study is completed.

B. Technology Considerations

1. Online surveys: When a participant is asked to complete an online survey, the IRB grants a waiver of signed consent due to the impracticality of obtaining the participant's signature. The consent document must appear as the first page of the online survey, contain a statement regarding collection of Internet Protocol addresses, and contain participation agreement statements at the bottom of the consent document.

2. Qualtrics Accounts: Qualtrics is a software tool that is available to all KSU faculty, staff, and students for use in creating online surveys. To begin creating a survey, faculty and staff may visit http://survey.kennesaw.edu, accept the End-User License Agreement, and then login using their NetID and password.

   To request the use of Qualtrics on behalf of a student researcher, faculty must submit the Qualtrics Student Account Request Form to the IRB at irb@kennesaw.edu for approval. Once the IRB verifies that the student has an approved human subjects protocol on file, University Information Technology Services (UITS) will be notified and a student account will then be activated.

   Go to the UITS site for instructions on how to create, distribute and report on surveys or you may contact the KSU Help Desk.

3. KSU's Email Usage Policy was created to comply with University System of Georgia (USG) information technology policies. Pursuant to the USG Information Technology Handbook, Section 5.1.2, KSU is required to establish and maintain "appropriate internal policies, processes, standards, and procedures for preserving the integrity and security of each automated, paper file, or database." Coverage of all email usage policies and procedures can be found at https://policy.kennesaw.edu/sites/web.kennesaw.edu.policy/files/emailusagepolicy_09012015.pdf

C. Additional Content Required in Special Cases

Additional information may be requested by the IRB in some cases and must be supplied by the researcher. For example, the following types of research will require the additional information indicated below.

1. In cases where deception or the manipulation of the participant's behavior will occur, the researcher must provide a justification for the procedures and a copy of the debriefing procedures to be used.

2. In research involving institutionalized people, minors, or other potentially vulnerable participants for whom additional safeguards are desirable, the researcher should provide a description of the manner by which their "assent" to participate is obtained as well as the procedures used in obtaining consent from the legally responsible individual.

3. If the data to be collected is concerned with illegal activities by the participants, a description of the manner in which this data is to be treated is required.

4. In cases where research is being conducted outside of the United States, a letter providing proof of authorization to conduct your study from the officials in that country (e.g., letter from an administrator, agency official, etc.). Review the International Compilation of Human Research Standards in order to determine if there are specific procedures that you must follow for the country in which you will be conducting your research.

D. Contents of Legally Informed Consent

Researchers planning projects with human participants must obtain their prior informed consent as required by 45 CFR 46.116. All research proposals must include a detailed description of how consent is to be obtained from the participant or their legally authorized representative. The informed consent process should provide the potential participant with a full understanding of the research and its consequences, and an opportunity to carefully consider whether or not to participate. Informed consent should be obtained using a written form containing the items listed below unless otherwise authorized by the IRB.

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 which 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 which 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; and

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.

9. Additional information may be required by the IRB in the informed consent in certain cases, such as:

    a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

c. Any additional costs to the subject that may result from participation in the research.

d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

f. The approximate number of subjects involved in the study

E. Alternate Consent Procedures or Forms

The IRB, when appropriate, may approve alternative consent procedures differing from those described in Section D above provided that these procedures are consistent with the requirements put forth in 45 CFR 46 and the principles upon which this assurance is based. For example, in the case of phone surveys, consent may be obtained verbally and recorded by the investigator without the participant's actual signature.

VII. Responsibilities of Researchers

A. Determination of Human Participant Involvement

KSU requires prior review and approval to be obtained from the IRB for all research involving human participants, including plans to gather data from participants for master's theses and other student projects. Any administration of a substance or stimulus, interview, test, use of records that identify living individuals, or observations of non-public behavior must be approved by the IRB. It is the responsibility of the researcher to contact the IRB for a determination on whether a project will involve human participants.

All researchers not affiliated with KSU must request permission to recruit research participants on the KSU campus. Click here to view information on how to apply for permission.

Student research involving human subjects cannot be conducted without supervision by a Faculty Advisor as well as IRB oversight.

Staff/Administrator's holding at least a Bachelor's degree are encouraged to submit materials for review. Based on the methodological and ethical issues of the study, you may be required by the IRB to include a faculty investigator on your protocol to receive approval. As with any other study, there is no guarantee that the study will be approved.

B. Determination of Institutional Responsibility

KSU has responsibility for a research project with respect to the applicability of this assurance. If the researcher has any doubts as to what the IRB considers under its purview, they should contact the Chairperson of the IRB for advice. Unless it is clearly determined by the IRB that no human participants are involved in the research project, a proposal will be prepared by the researcher and submitted to the IRB for review. The policies and procedures described in this assurance are applicable to all activities, regardless of funding source, which:

1. Are sponsored by KSU; or

2 Are conducted using any facility or property of KSU; or

3. Are conducted by or under the direction of any faculty member, student, or other employee of KSU in connection with his/her on-campus responsibilities; or

4. Are conducted by or under the direction of any faculty member, student, or other employee of KSU while at an off-campus location (e.g., faculty on sabbatical, students on internship) with the prior agreement that the project is part of his/her institutional or academic responsibilities; or

5. Involve the use of the college's non-public records to identify, contact, or recruit potential participants if appropriate permissions are obtained.

C. Preparation, Submission, and Approval of Proposals

Researchers are responsible for preparing and submitting the appropriate IRB forms that addresses the complete research proposal as described in Section VI to the IRB Chairperson. An approval must be obtained from the IRB prior to commencing any research project covered by this assurance, and in cases of potential external funding no funds can be spent without an IRB approval in place. If the project is part of a proposal or application for funding from external sources, at a minimum, prior to proposal or application submission to a funding agency there must be an IRB approval in process; however, some funding agencies do require IRB approval to be provided upon submission.

D. Conducting Research

Researchers will carry out their research as described in the approval proposal. Changes in research procedures cannot be implemented unless a new proposal or progress report describing proposed changes has been submitted to and approved by the IRB, except when such changes are necessary to eliminate immediate hazards to participants or others involved in the research [e.g., it has been discovered that a procedure places a minor in physical or mental discomfort]. Emergency changes will be submitted promptly for approval. The project cannot continue without IRB approval. The IRB Chairperson will determine if the proposed changes require full IRB review of the proposal, or can be approved without detailed review.

E. Research Non-Compliance

It is the researcher’s responsibility to understand any of the following instances of non-compliance and immediately notify the IRB of any irregularities that have been noted.

Non-compliance determination. The IRB upon notification will make the following determination as to the degree of non-compliance using the following categories: minor, serious, or continuing non-compliance. Non-compliance: A situation, event or process in human subjects research that is under the researcher’s control and that is inconsistent with the following. This can include inquiries and complaints directed to the researcher that involve an allegation of non-compliance as defined here.

1. Serious Non-compliance: Non-compliance which could significantly:
    a. Increase risks to, or jeopardize the safety, welfare, and/ or rights of subjects or others, or
    b. Decrease potential benefits (including the scientific integrity of the research).
    c. Conducting a research study without any prospective IRB approval is always considered serious non-compliance.

2. Continuing Non-compliance: A pattern of non-compliance that:
   a. Suggests that non-compliance will continue, if there is no intervention, or
   b. Increases the risk of serious non-compliance.
3. Minor Non-compliance: Non-compliance that is neither serious nor continuing.

The regulatory basis for non-compliance determinations includes (but is not limited to) the following:

- Obtaining human subjects data without IRB approval is always considered to be non-compliance with human subjects regulations and KSU's FWA.
- Accessing PHI without IRB approval and HIPAA authorization is non-compliance with HIPAA regulations, http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf .
- Publications and presentations. Data collected without IRB approval cannot be described as being part of an IRB-approved study. This may have implications for the publications or presentations, as many journals and conferences require IRB approval as a condition of publication or presentation of research that involved human subjects.
- Reporting to funding agencies and federal regulators. The IRB will report serious or continuing non-compliance within 2-4 weeks depending on the seriousness of the incident to appropriate federal regulators and/or funding agencies, as described in the OHRP Guidance on Reporting Incidents.
- Failure to follow the ethical procedures outlined in any of the CITI Training Modules as they relate to your specific type of research will result in immediate suspension. Other consequences may also apply.
- Corrective and preventative action. The IRB may require corrective or preventative actions to address or prevent the collection of data without IRB approval as well as any consequences of the data collection activity. Possible examples include:
  - Modification. Some or all parts of the research are modified.
  - Re-collection of data. The data are collected again, but with IRB approval.
  - Re-consent. The subjects provide consent again, using appropriately revised procedures and documents.
  - Notification of subjects. Notification of subjects may be required in studies that obtained Protected Health Information (PHI) without the prior consent or authorization from the subjects. The researcher's department is responsible for the notification costs, which can be considerable. The costs cannot be charged to grants or contracts.
  - Recommendation to impose sanctions on use of the data. Although the IRB cannot impose sanctions on the use of data, the IRB can recommend that the appropriate institutional official consider the following actions:
    - Require that data not be published or presented;
    - Require that data not be used for a thesis or dissertation;
    - Require that data be destroyed; and/or
    - Other actions for which the institutional office has authority.
    - Suspension of research activities. The IRB may temporarily withdraw IRB approval for some or all parts of an approved study.
    - Termination of research activities. The IRB may permanently withdraw IRB approval for some or all parts of an approved study.
  - Closure. If the entire research study was conducted without IRB approval, the IRB Administrator or designee will administratively close the study, after all review activity related to the matter has been concluded. The file is retained as an IRB record in accordance with 45 CFR 46.115(b).

F. Documentation of Informed Consent

Researchers will ensure that the informed consent of each participant is documented by a signed copy of the form included in the approved proposal. These consent forms will be kept locked in a repository under the control of the researcher for a specified time as

described in the approved proposal. In addition, each participant (or his/her authorized representative) will be given a copy of the consent form that has been signed by the researcher. In the case of an online consent form, these will be downloaded and maintained by the researcher.

G. Web-based Training

Researchers that submit a proposal for IRB approval will complete the web-based training offered by the Collaborative Institutional Training Initiative (CITI) online training program (www.citiprogram.org). The details on which course is required can be found on KSU's IRB website (www.kennesaw.edu/irb). Initial training is good for a three year period after which a refresher course is required. It is the researcher's responsibility to maintain a current certificate.

H. Other Responsibilities

Researchers are also responsible for:

1. Seeking the advice of the IRB as necessary concerning any aspect of research involving human participants not covered by this assurance;

2. Reporting immediately to the IRB any injuries to human participants, emergency changes in procedure or any unanticipated problems that involve risk to human participants or to others involved in the project; follow the instructions found on the KSU IRB website for Reporting of Unanticipated Problems Involving Risks to Participants and Others: http://www.kennesaw.edu/irb/reporting-unanticipated-problems.html

3. Reporting to the IRB at the conclusion of the project, or at the end of the period, for which the project was approved, on human participant aspects of the project and conformity with the original proposal.

I. Responsibilities of Students, Non-faculty Staff and their Advisors

Students or non-faculty staff at the college carrying out projects involving human participants must conform to the policies and procedures put forth in this assurance. Since students are in a learning role, however, the faculty advisor under whose direction they are working also bears the responsibility to ensure that measures have been taken to ensure the safety of the student as well as that the student's responsibilities are fulfilled. This is to include the submission of a Progress Report at the end of their study to close it out, which begins the 3 year records retention process.

Staff/Administrator's holding at least a Bachelor's degree are encouraged to submit materials for review. Based on the methodological and ethical issues of the study, you may be required by the IRB to include a faculty investigator on your protocol to receive approval. As with any other study, there is no guarantee that the study will be approved.

NOTE: We gratefully acknowledge the contributions of the University of Washington in the development of Sections II.C.4. and VII.E.: http://www.washington.edu/research/hsd/docs/1727

Appendix A

45 CFR Part 46 (applicable sections)
Revised January 15, 2009
Effective July 14, 2009
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in §46.102, must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in §46.102(e) must be reviewed and approved, in compliance with §46.101, §46.102, and §46.107 through §46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if

the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes or research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these

actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[1] Institutions with HHS-approved assurances on file will abide by provisions of Title 45 CFR part 46 subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at70 FR 36328, June 23, 2005]

§46.103 Assuring compliance with this policy – research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federal-wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to Federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101(b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) 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; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head 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.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101(b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no

condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.115 IRB records.

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(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 which 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 which 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; and

(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.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

Appendix B
OHRP Guidance on Written IRB Procedures

NOTE: THIS GUIDANCE REPLACES OHRP'S JANUARY 15, 2007 GUIDANCE ENTITLED "GUIDANCE ON WRITTEN IRB PROCEDURES." THIS GUIDANCE HAS BEEN UPDATED TO REMOVE THE CONTENT RELATED TO CONTINUING REVIEW AND THE APPROVAL OF RESEARCH WITH CONDITIONS AND REPLACES THIS CONTENT WITH CROSS-REFERENCES TO OHRP'S NOVEMBER 10, 2010 GUIDANCE ON IRB CONTINUING REVIEW OF RESEARCH" AND OHRP'S NOVEMBER 10, 2010 "GUIDANCE ON IRB APPROVAL OF RESEARCH WITH CONDITIONS." IN ADDITION, A CROSS-REFERENCE TO OHRP'S JANUARY 15, 2007 "GUIDANCE ON REVIEWING AND REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS AND ADVERSE EVENTS" HAS BEEN ADDED.

(For a more detailed description of the changes made to this May 16, 2011 document titled,*Guidance on Written IRB Procedures*, see OHRP's listserv announcement at: http://www.hhs.gov/ohrp/newsroom/index.html.)

Office for Human Research Protections
Department of Health and Human Services

Guidance on Written IRB Procedures

This guidance represents the Office for Human Research Protections' (OHRP's) current thinking on this topic. OHRP guidance should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word must in OHRP guidance means that something is required under the Department of Health and Human Services (HHS) regulations at 45 CFR part 46. The use of the word should in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of 45 CFR part 46. OHRP is available to discuss alternative approaches by telephone at 240-453-6900 or 866-447-4777, or by e-mail at ohrp@hhs.gov.

Date: July 1, 2011
Scope: This document outlines the required elements of written Institutional Review Board (IRB) procedures under Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR Part 46) and provides an overview of relevant OHRP guidance regarding each required element.
Target Audience: This document primarily is intended to assist IRB administrators, IRB chairpersons, and other relevant institutional officials who may be responsible for preparing and maintaining written IRB procedures.

BACKGROUND

OHRP frequently receives requests for guidance and clarification regarding the content of written IRB procedures. In order to assist institutions in developing adequate written IRB procedures, OHRP has compiled the following summary of the relevant regulatory requirements and guidance issued routinely by OHRP over the past several years. OHRP has not developed a model written IRB procedures document for institutions to adapt because procedures appropriately can vary significantly among institutions as the result of differences in institution size, the type of research activities, institutional administrative practices, number of IRBs, and local and state laws and regulations. For each required element, the written IRB procedures should provide sufficient step-by-step operational details so that an independent observer can understand how an IRB operates and conducts its major functions.

REGULATORY REQUIREMENTS

HHS regulations at 45 CFR 46.103(b)(4) and (5) require that institutions have written IRB procedures for each of the following:

1. The procedures which the IRB will follow for conducting its initial review of research;
2. The procedures which the IRB will follow for conducting its continuing review of research;
3. The procedures which the IRB will follow for reporting its findings and actions to investigators and the institution;
4. The procedures which the IRB will follow for determining which projects require review more often than annually;
5. The procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
6. The procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and
7. The procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of:
    a. Any unanticipated problems involving risks to subjects or others (hereinafter referred to as unanticipated problems);
    b. Any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and
    c. Any suspension or termination of IRB approval.

GUIDANCE ON OPERATIONAL DETAILS

Written IRB procedures should provide a step-by-step description with key operational details for each of the above procedures. Important operational details for the above procedures should include:

1. A description of any primary reviewer system used for initial review, continuing review, review of protocol changes, and/or review of reports of unanticipated problems or of serious or continuing noncompliance;

2. Lists of specific documents distributed to primary reviewers (if applicable) and to all other IRB members for initial review, continuing review, review of protocol changes, and review of reports of unanticipated problems or of serious or continuing noncompliance;
3. Details of any process (e.g., a subcommittee procedure) that may be used to supplement the IRB's initial review, continuing review, review of protocol changes, and/or review of reports of unanticipated problems or of serious or continuing noncompliance;
4. The timing of document distribution prior to IRB meetings;
5. (5) the range of possible actions taken by the IRB for protocols undergoing initial or continuing review and protocol changes undergoing review;
6. A description of how expedited review is conducted and how expedited approval actions are communicated to all IRB members;
7. A description of the procedures for:

    a. Communicating to investigators IRB action regarding proposed research and any modifications or clarifications required by the IRB as a condition for IRB approval of proposed research; and
    b. Reviewing and acting upon investigators' responses;

8. A description of which institutional office(s) and official(s) are notified of IRB findings and actions and how notification to each is accomplished;
9. A description, if applicable, of which institutional office(s) or official(s) is responsible for further review and approval or disapproval of research that is approved by the IRB; please note that, in accordance with HHS regulations at 45 CFR 46.112, no other institutional office or official may approve research that has not been approved by the IRB;
10. A specific procedure for how the IRB determines which protocols require review more often than annually, including specific criteria used to make these determinations (e.g., an IRB may set a shorter approval period for high-risk protocols or protocols with a high risk:potential benefit ratio);
11. A specific procedure for how the IRB determines which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review, including specific criteria used to make these determinations (e.g., such criteria could include some or all of the following:
    a. Randomly selected projects;
    b. Complex projects involving unusual levels or types of risk to subjects;
    c. Projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations or the requirements or determinations of the IRB; and
    d. Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources);
12. A description of what steps are taken to ensure that investigators do not implement any protocol changes without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects (e.g., this might be addressed through

training programs and materials for investigators, specific directives included in approval letters to investigators, and random audits of research records);

13. A description of which office(s) or institutional official(s) is responsible for promptly reporting to the IRB, appropriate institutional officials, any supporting Agency or Department heads, and OHRP any:
    a. Unanticipated problems;
    b. Any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and
    c. Any suspension or termination of IRB approval;
14. A description of the required time frame for accomplishing the reporting requirements in the preceding paragraph; and
15. A the range of possible actions taken by the IRB in response to reports of unanticipated problems or of serious or continuing noncompliance.

ADDITIONAL OHRP GUIDANCE RELEVANT TO WRITTEN IRB PROCEDURES

A. Guidance Relevant to Initial and Continuing Review

1. **Requirement for Review of Research by the IRB at Convened Meetings.** In accordance with HHS regulations at 45 CFR 46.108(b), initial and continuing reviews of research must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (i.e., a quorum), except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(1) for the categories of research listed in the Federal Register of November 9, 1998 (see 63 FR 60364-60367 at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998_register&docid=98-29749-filed). Approval of research is by a majority vote of this quorum. Should the quorum fail during a meeting (e.g., loss of a majority through recusal of members with conflicting interests or early departures, or absence of a nonscientist member), the IRB may not take further actions or votes unless the quorum can be restored.
2. **Research Review Materials**
    a. **Initial Review Materials.** HHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things, determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting the initial review of proposed research, IRBs must obtain information in sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111. Materials should include the full protocol, a proposed informed consent document, any relevant grant application(s), the investigator's brochure (if one exists), and any recruitment materials, including advertisements intended to be seen or heard by potential subjects. Furthermore, for HHS-supported multicenter clinical trials, the IRB should receive and review a copy of the HHS-approved sample informed consent document(s) and the complete HHS-approved protocol, if they exist. Unless a primary reviewer system is used, all members should receive a copy of the complete documentation. These materials should be received by members sufficiently in advance of the meeting date to allow review of this material.

If the IRB uses a primary reviewer system, the primary reviewer(s) should do an in-depth review of all pertinent documentation (see previous paragraph). All other IRB members should at least receive and review a protocol summary (of sufficient detail to make the determinations required under HHS regulations at 45 CFR 46.111), the proposed informed consent document, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects. In addition, the complete documentation should be available to all members for review.

b. **Continuing Review Materials.** Investigators are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out continuing review prior to the expiration date of the current IRB approval. In particular, investigators are responsible for submitting sufficient materials and information for the IRB to meet its regulatory obligations, and should follow the institutional policies and procedures for continuing IRB review of research that are required by 45 CFR 46.103(b)(4) and referenced in the institution's OHRP-approved Federalwide Assurance. For additional guidance on continuing review see OHRP's November 10, 2010 "Guidance on IRB Continuing Review of Research" at http://www.hhs.gov/ohrp/policy/continuingreview2010.html and http://www.hhs.gov/ohrp/policy/continuingreview2010.pdf.

3. **Review and Reporting of Unanticipated Problems and Adverse Events.** For guidance on the provisions of 45 CFR part 46 related to the review and reporting of unanticipated problems involving risks to subjects and others, see OHRP's "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events" at http://www.hhs.gov/ohrp/policy/advevntguid.html and http://www.hhs.gov/ohrp/policy/advevntguid.pdf.
4. **IRB Review in Emergency Situations.** HHS regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval (see 45 CFR 46.103(b) and 46.116(f) and OHRP guidance at http://www.hhs.gov/ohrp/policy/hsdc91-01.html). When emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject under 45 CFR Part 46. Such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a prospectively conceived research activity. When emergency care involves investigational drugs, devices, or biologics, U.S. Food and Drug Administration (FDA) requirements must be satisfied.
5. **Approval of Research with Conditions.** In the course of initial or continuing review of research or review of proposed changes to previously approved research, IRBs often request that investigators (a) make specified changes to research protocols or informed consent document(s); or (b) submit clarifications or additional documents. When doing this, depending on the circumstances, an IRB is either precluded from approving the research, or permitted to approve the research with conditions. For additional guidance on this issue, see OHRP's November 10, 2010 "Guidance on IRB Approval of Research with Conditions" at http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html and http://www.hhs.gov/ohrp/policy/conditionalapproval2010.pdf.

6. **Conflicting Interest.** HHS regulations at 45 CFR 46.107(e) stipulate that no IRB member may participate in the IRB's initial or continuing review of a project in which the member has a conflicting interest, except to provide information requested by the IRB. OHRP recommends that except when requested by the IRB to be present to provide information, IRB members absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest, and such should be noted in the IRB meeting minutes.
7. **Initial and Continuing Expedited Review.** OHRP recommends that documentation for initial and continuing reviews conducted under an expedited review procedure include: (a) the specific permissible categories (see 63 FR 60364-60367 at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1998_register&docid=98-29749-filed) justifying the expedited review; and (b) documentation of the review and action taken by the IRB chairperson or designated reviewer and any findings required under the HHS regulations.

B. Guidance Relevant to IRB Records and Documentation

1. **IRB Protocol Records.** IRB protocol records must include all the information stipulated by HHS regulations at 45 CFR 46.115(a)(1), (3), (4), and (7).
2. **Minutes of IRB Meetings**. The minutes of IRB meetings must include all the information stipulated by HHS regulations at 45 CFR 46.115(a)(2). The minutes of IRB meetings should document, among other things:
    a. Separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB.
    b. 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 = 15; Vote: For-14, Opposed-0, Abstained-1.
        - Total = 14 (1 member recused and did not vote); Vote: For-12, Opposed-2, Abstained-0.

3. **Documentation of Findings.** HHS regulations at 45 CFR 46.116(d) require that the IRB make and document four findings when approving a consent procedure which 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:

a. Approving a procedure which waives the requirement for obtaining a signed consent form [see 45 CFR 46.117(c)];
b. Approving research involving pregnant women, human fetuses, or neonates (see 45 CFR 46.204-207);
c. Approving research involving prisoners (see 45 CFR 46.305-306); or
d. Approving research involving children (see 45 CFR 46.404-407), the IRB should document such findings.

OHRP recommends that for research approved by the convened IRB, all required findings be fully documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding.

For research reviewed under an expedited review procedure, these findings should be documented by the IRB Chairperson or other designated reviewer elsewhere in the IRB record.

4. **Documentation of Risk and Approval Period.** IRBs must determine which protocols require continuing review more often than annually, as appropriate to the degree of risk [see 45 CFR 46.103(b)(4) and 46.109(e)]. OHRP recommends that the minutes of IRB meetings clearly reflect these determinations regarding risk and approval period (review interval).
5. **Retention of IRB Records.** HHS regulations at 45 CFR 46.115(b) require that IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner.

C. Guidance Relevant to Review of Protocol Changes

1. **Requirement for Review of Proposed Protocol Changes by the IRB at Convened Meetings.** In accordance with HHS regulations at 45 CFR 46.108(b), review of proposed protocol changes must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas, except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b)(2).
2. **Expedited Review of Minor Changes.** OHRP recommends that institutions adopt policies describing the types of minor changes in previously approved research which can be approved under an expedited review procedure in accordance with HHS regulations at 45 CFR 46.110(b)(2).
3. **Protocol Revisions.** OHRP recommends that each revision to a research protocol be incorporated into the written protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This procedure is consistent with the procedure used for revised and approved informed consent documents which then supersede the previous one(s).

D. Miscellaneous Guidance

1. **Procedures for Determining Exemptions.** OHRP recommends that institutions adopt clear procedures under which the IRB (or some authority other than the investigator) determines whether proposed research is exempt from the human subjects regulations [see 45 CFR 46.101(b)]. Documentation should include the specific category justifying the exemption.
2. **Informed Consent Documents: Approval and Expiration Dates.** OHRP recommends that IRBs affix the approval and expiration dates to all approved informed consent documents and stipulate that copies of these dated documents must be used in obtaining consent. This procedure helps ensure that only the current, IRB-approved informed consent documents are presented to subjects and serves as a reminder to the investigators of the need for continuing review.
3. **Applicability of State and Local Laws to HHS-Supported Research.** The HHS regulations do not affect any applicable State or local laws or regulations which provide additional protections for human subjects [see 45 CFR 46.101(f)]. OHRP recommends that written IRB procedures describe applicable State and local laws and regulations relevant to the conduct of human subject research.
4. **Additional Considerations.** Institutions may wish to consider including additional pertinent information in their written IRB procedures, such as the following:
    a. Important definitions (e.g., the definition of *research, human subject*, and *minimal risk)*;
    b. A description of procedures for implementing other relevant Federal regulations that apply to human subject research (e.g., FDA and Health Insurance Portability and Accountability Act regulations);
    c. Procedures for selecting and appointing the IRB chairperson and members in order to satisfy the requirements of HHS regulations at 45 CFR 46.107;
    d. Procedures for training and educating IRB members and staff and investigators;
    e. A description of the required elements of informed consent and criteria for waiving or altering these requirements; and
    f. Procedures for ensuring that the IRB possesses sufficient knowledge of the local research context.

If you have any specific questions about how to apply this guidance, please contact OHRP by phone at (866) 447-4777 (toll-free within the U.S.) or (240)-453-6900, or by e-mail at ohrp@hhs.gov.

Appendix C
OHRP Guidance on Reporting Incidents

NOTE: THIS GUIDANCE REPLACES OHRP'S MAY 27, 2005 GUIDANCE ENTITLED "GUIDANCE ON REPORTING INCIDENTS TO OHRP" (Click Here) This guidance has been updated to clarify what information regarding serious or continuing noncompliance by the institutional review board needs to be reported, to include an e-mail address to report incidents to OHRP, and to update OHRP's contact information.

This guidance represents OHRP's current thinking on this topic and should be viewed as recommendations unless specific regulatory requirements are cited. The use of the word *must* in OHRP guidance means that something is required under HHS regulations at 45 CFR part 46. The use of the word *should* in OHRP guidance means that something is recommended or suggested, but not required. An institution may use an alternative approach if the approach satisfies the requirements of the HHS regulations at 45 CFR part 46. OHRP is available to discuss alternative approaches at 240-453-6900 or 866-447-4777.

Date: June 20, 2011

Scope:

This document provides guidance about procedures institutions may use to file incident reports with OHRP. Incident reports include reports of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with Department of Health and Human Services (HHS) regulations at 45 CFR part 46 or the requirements or determinations of the institutional review board (IRB); and suspension or termination of IRB approval. In particular, OHRP offers guidance on the following topics:

I. Applicability of incident reporting requirements;
II. Information to be included in incident reports;
III. Time frame for reporting incidents;
IV. OHRP focus on corrective actions when reviewing incident reports;
V. OHRP's response to incident reports;
VI. Where to send incident reports; and
VII. Additional guidance.

Target Audience: IRBs, institutional officials and institutions that may be responsible for review, oversight, or conduct of human subjects research covered by an OHRP-approved assurance.

Regulatory Background:

HHS regulations at 45 CFR 46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents related to regulatory requirements pertaining to research conducted under an OHRP- approved assurance are promptly reported to OHRP:

a. Any unanticipated problems involving risks to subjects or others;
b. Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
c. Any suspension or termination of IRB approval.

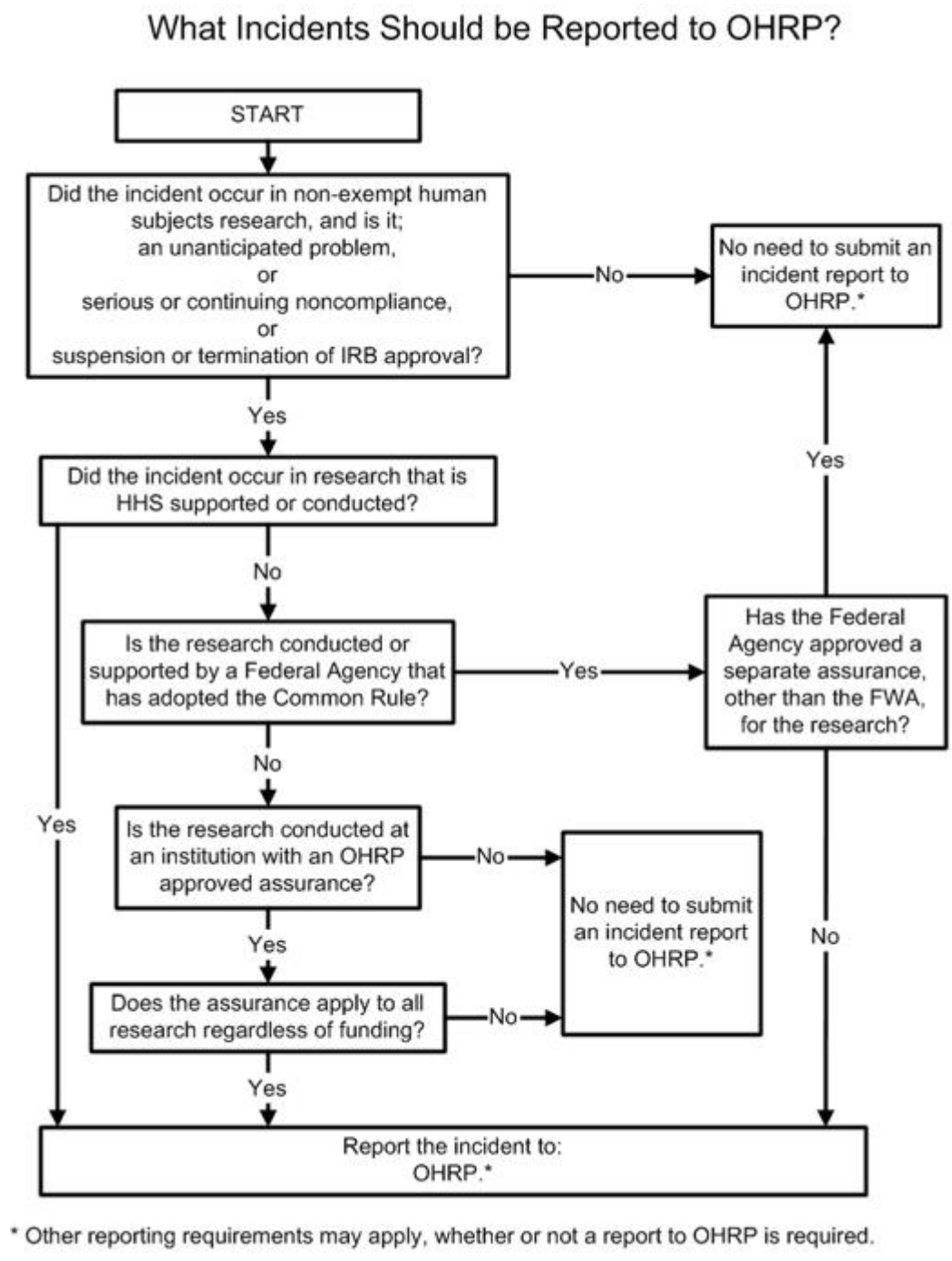
Guidance:

I. Applicability of incident reporting requirements

In general, these reporting requirements apply to all nonexempt human subjects research that is:

(a) conducted or supported by HHS;
(b) conducted or supported by any non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or
(c) covered by an FWA, regardless of funding source.

Federal departments or agencies other than HHS that have adopted the Common Rule may determine that the FWA is not appropriate for certain research that they conduct or support. OHRP notes that these incident reporting requirements are **not** applicable to such research. In such cases, the institution should contact the non-HHS department or agency that supports the research about reporting requirements. See the decision chart below.



* Other reporting requirements may apply, whether or not a report to OHRP is required.

II. Information to be included in incident reports

To fulfill the regulatory requirements for reporting incidents, OHRP would consider it acceptable for an institution to comply with written procedures specifying that the following information be included in an incident report submitted to OHRP:

A. For unanticipated problems involving risks to subjects or others:

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem; and
- Actions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.).

B. For serious or continuing noncompliance:

- Name of the institution (e.g., university, hospital, foundation, school, etc) conducting the research;
- Title of the research project and/or grant proposal in which the noncompliance occurred, or, for IRB or institutional noncompliance, the IRB or institution involved;
- Name of the principal investigator on the protocol, if applicable;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the noncompliance; and
- Actions the institution is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

C. For suspension or termination:

- Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;
- Title of the research project and/or grant proposal that was suspended or terminated;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the suspension or termination; and
- The actions the institution is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project, etc.)

III. Time frame for reporting incidents

The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting, except to say this must be done "promptly." For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow by the earlier of:

- a specific date; or
- when an investigation has been completed or a corrective action plan has been implemented.

IV. OHRP focus on corrective actions when reviewing incident reports

When reviewing a report of an unanticipated problem, OHRP assesses most closely the adequacy of the actions taken by the institution to address the problem. Likewise, when reviewing reports of non-compliance or suspension or termination of IRB approval, OHRP assesses most closely the adequacy of the corrective actions taken by the institution. In particular, OHRP assesses whether or not the corrective actions will help ensure that the incident will not happen again, with the investigator or protocol in question, with any other investigator or protocol, or with the IRB. Therefore, OHRP recommends that, when appropriate, corrective actions be applied institution-wide.

V. OHRP response to incident reports

After receiving and evaluating an incident report from an institution, OHRP will respond in writing and will either state that the report was adequate or request additional information. For questions on reporting, please contact the Director of the Division of Compliance Oversight, 240-453-6900 or 866- 447-4777.

VI. Where to send incident reports

Please send reports (PDF or Word documents preferred) to the following email address:

IRPT.OS@hhs.gov

VII. Additional guidance

Please see OHRP guidance on continuing review regarding the distinction between suspension and expiration of IRB approval by clicking here and OHRP guidance on unanticipated problems by clicking here.