

# SOUTHERN ILLINOIS UNIVERSITY EDWARDSVILLE

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## Assurance of Compliance with Federal Regulations for the Protection for Human Subjects

Southern Illinois University Edwardsville (SIUE), hereinafter referred to as the “institution,” hereby gives assurance that it will comply with the Common Federal Policy for the Protection of Human Subjects, promulgated by 16 Federal departments and agencies of the U.S. Government on 18 June, 1991, hereinafter referred to as “the common rule,” as specified below. This common rule is based on and replaces Subpart A of the 1981 Department of Health and Human Services (HHS) regulations, Title 45 CFR Part 46.

### I. Statement of Applicability, Principles and General Policies.

#### A. Applicability

1. Except as noted in 2 below, this assurance is applicable to all activities which, in whole or in part involve research with human subjects if:
  - a. The research is sponsored by this institution, or
  - b. The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
  - c. The research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
  - d. The research involves the use of this institution’s nonpublic information to identify or contact human research subjects or prospective subjects, or

- e. The research involves institution students or personnel and is sponsored and/or conducted by outside agencies.
2. Only provisions II.A.1-6; II.B.1a, b, d, e; and III. Of this assurance are applicable to the activities listed above if the only involvement of human subjects will be in one or more of the categories exempted or waived under the common rule Section 101.

B. Ethical Principles.

1. This institution is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research.
2. In addition, the requirements set for the in the common rule will be met for all applicable federally-funded research and for all other research without regard to source of funding.

C. Institutional Policy.

1. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this assurance.
2. It is the policy of this institution that, except for those categories specifically exempted or waived under the common rule Section 104, all research covered by this assurance will be reviewed and approved by an institutional review board (IRB) which has been established under an assurance compliance negotiated with the Office for Human Research Protections (OHRP) in HHS. The involvement of human subjects in research covered by this policy will not be permitted until the IRB has reviewed and approved the research and protocol and informed consent has been obtained in accord with and to the extent required by the common rule Section 116. Certification of the IRB's review and approval for all human subjects will be submitted with the application or proposal for funding, or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Furthermore, the IRB's review of research on a continuing basis will be conducted at appropriate intervals but not less than every twelve months for all full board reviews and any expedited projects deemed by the IRB to require reports.

3. It is the policy of this institution that unless informed consent has been specifically waived by the IRB in accordance with the common rule Section 116, no research investigator shall involve any human being as a subject in research unless the research investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
4. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this assurance.
5. This institution bears full responsibility for complying with federal, state or local laws as they may relate to research covered by this assurance.
6. This institution has established and will maintain one IRB in accordance with the common rule. This IRB has the responsibility and authority to review, approve, disapprove or require changes in appropriate research activities involving human subjects.
7. This institution has provided and will continue to provide both meeting space for the IRB and sufficient staff to support the IRB's review and record keeping duties.
8. This institution encourages and promotes constructive communication among the research administrators, department heads, research investigators, clinical care staff, IRB, other institutional officials and human subjects as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.
9. This institution will maintain documentation of IRB activities as prescribed by the common rule Section 115.
10. This institution will exercise appropriate administrative overview carried out at least annually to ensure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are in compliance with the requirements of the common rule and this assurance.
11. This institution will comply with the policies set forth in Subpart B of Title 45 CFR Part 46, which provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization of human ova.

12. This institution will comply with the policies set forth in Subpart C of Title 45 CFR Part 46, which provide additional protections for prisoners involved in research.
13. This institution will comply with the policies set forth in Subpart D of Title 45 CFR Part 46, which provide additional protections for children involved in research.
14. This institution, in addition to complying with the requirements of the common rule, will consider additional safeguards in research when that research involves children, individuals institutionalized as mentally disabled, and other potentially vulnerable groups.
15. This institution will comply with the requirements set forth in the common rule Section 114 regarding cooperative research projects. When research covered by this assurance is conducted at or in cooperation with another entity, all provisions of this assurance will remain in effect for that research. With the approval of the federal department or agency head, this institution may, for the purpose of meeting the IRB review requirements, enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangement for avoiding duplication of effort. Such acceptance must be in writing, approved and signed by this institution's Office of Research and Projects, approved and signed by correlative officials of each of the other cooperating institutions. A copy of the signed agreement will be forwarded to the OHRP.
16. This institution shall provide each individual at the institution conducting or reviewing human subject research (e.g., PIs, department heads, clinical care staff, research administrators, IRB members) with a copy of this institutional assurance of compliance and copies of any future modifications that may be made to this assurance, with the exception of changes in IRB membership.
17. Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, these officials may not approve the research if it has not been approved by the IRB.
18. This institution shall provide Education through the CITI Program on-line training.

## II. Implementation

A. Responsibilities of Research Investigators and Department Heads.

1. Determination of human subject involvement.

- a. Research investigator shall make a determination as to whether research will involve human subjects as defined in the common rule Section 102.
- b. When it is not clear whether the research involves human subjects as defined in the common rule Section 102, research investigators should seek assistance from the ORP and the IRB in making this determination.

2. Preliminary determination of exemption eligibility.

Prior to submission to the IRB, research investigators and department heads shall make the preliminary determination of whether such research that involves human subjects is exempted from coverage under the common rule Section 104.

3. Preparation of protocol.

- a. Research investigators shall prepare a protocol giving a complete description of the proposed research. In the protocol, research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and insure that pertinent laws and regulations are observed. This requirement is applicable even in cases where the research is exempt under the common rule section 104.
- b. Research investigators shall include samples of proposed informed consent forms with the protocol, when they are appropriate.
- c. Research investigators and all supporting research staff shall include the institution's educational requirement certificate of completion. The certificate of completion provides proof that they have completed the CITI Program computer-based training on the Protection of Human Research Subjects. The certificate of completion will expire three years from the date listed on the certificate at which time the investigator must submit to the Office of Research and Projects a new certificate at the time in which the certificate expires or the next time they submit a protocol.

4. Scientific merit and ethical consideration review.

In addition to the IRB, department heads, through appropriate procedures established within their respective departments, are responsible for reviewing sponsored research protocols for ethical consideration and scientific merit.

5. Submission of protocol to the ORP.

Research investigators and department heads shall be responsible for insuring that all research involving human subjects is submitted to the ORP.

6. Submission of a supplement to an original protocol to the ORP.

- a. it is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects, or
- b. it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects, or
- c. it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

7. Complying with IRB decisions.

Research investigators shall be responsible for complying with all IRB decisions, conditions and requirements.

8. Obtaining informed consent.

- a. Research investigators are responsible for obtaining informed consent in accordance with the common rule Section 116, and for insuring that no human subject will be involved in the research prior to the obtaining of the consent.
- b. Unless otherwise authorized by the IRB, research investigators are responsible for insuring that legally effective informed consent shall:
  - (1) be obtained from the subject or the subject's legally authorized representative;
  - (2) be in language understandable to the subject or the representative;

- (3) be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
- (4) not include 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 research investigator, the sponsor, the institution or its agents from liability for negligence.

9. Providing basic elements of informed consent.

Unless otherwise authorized by the IRB, research investigators at a minimum shall provide the following information to each subject orally or in writing as directed by the IRB:

- a. 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;
- b. a description of any reasonably foreseeable risks or discomforts to the subject;
- c. a description of any benefits to the subject or to others which may reasonably be expected from the research;
- d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f. 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;
- g. 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

- h. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
- i. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens;
  - i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

10. Providing additional elements of informed consent.

When required by the IRB, the research investigator shall provide one or more of the following additional elements of information to each subject, either orally or in writing as directed by the IRB:

- 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 research 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.
- g. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
- h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- i. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

11. Documentation of informed consent.

- a. Research investigators shall be responsible for insuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB.
- b. Research investigators shall insure that each person signing the written consent form is given a copy of that form.
- c. Research investigators may use a consent form which is either:
  - (1) A written consent document that embodies the elements of informed consent required by the common rule Section 116. this form may be read to the subject or the subject's legally authorized representative, but in any even, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it; or
  - (2) A "short form" written consent document stating that the elements of informed consent required by the common rule Section 116 have been presented orally to the subject or the

Subject's legally authorized representative. When the "short form" is used, research investigators shall insure that:

- a) A witness is present at the oral presentation,
- b) The short form is signed by the subject or the representative
- c) The witness signs both the short form and a copy of the written summary of the oral presentation,
- d) The person obtaining consent signs a copy of the summary,
- e) A copy of both the short form and summary is given to the subject or the representative and,
- f) The written summary of what is to be said to the subject or the representative receives the prior approval of the IRB.

12. Retention of Signed Consent Documents.

Research investigators are responsible for placing the consent documents signed by human research subjects in a repository approved by the ORP.

13. Submission of progress reports on the research.

Research investigators are responsible for reporting the progress of the research to the ORP, as often as and in the manner prescribed by the IRB but no less than once per year.

14. Submission of injury reports and reports of unanticipated problems involving risks.

- a. Research investigators are responsible for reporting promptly through their department heads to the ORP any injuries to human subjects.
- b. Research investigators are responsible for reporting promptly through their department heads to the ORP any unanticipated problems which involve risks to the human research subjects or others.

15. Reporting changes in the research.

- a. Research investigators are responsible for reporting promptly through their department heads to the ORP proposed changes in a research activity.
- b. Changes in research during the period for which IRB approval has already been given, shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

16. Reporting of noncompliance

Research investigators and department heads are responsible for reporting promptly to the ORP and the IRB and serious or continuing noncompliance with the requirements of this assurance or the determinations of the IRB.

17. Attending the IRB meetings.

To facilitate the review of research and the protection of the rights and welfare of human subjects, research investigators and department heads are encouraged to attend IRB meetings when invited by the IRB.

18. Notifying the ORP concerning investigational new drugs.

The research investigator shall be responsible for notifying the Food and Drug Administration (FDA) and the ORP whenever it is anticipated that an investigational new drug or device exemption will be required.

B. Responsibilities of the Office of Research and Projects (ORP).

1. Institutional determinations concerning exemptions, sponsorship, and certification.

- a. The ORP shall receive from the research investigators through their department heads, or in the case of theses, through the chairperson of the thesis committee, all research protocols which involve human subjects.
- b. The ORP is responsible for reviewing the preliminary determinations of research investigators and department heads and for making final

institutional determination whether research protocols qualify for exemption from coverage under the common rule Section 104.

- c. The ORP shall forward all nonexempt research protocols to the IRB for review.
  - d. All exempted research protocols and all protocols approved by the IRB which are being submitted for funding by a federal department or agency shall be forwarded to this federal department or agency by the ORP 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. When the IRB approves a protocol on condition that the research investigator make modifications to the protocol, the ORP shall not forward the protocol to the federal department or agency until the ORP has determined that such modifications are made. As appropriated, the IRB or the ORP may negotiate protocol modifications with the research investigator. Each protocol submitted to a federal department or agency by the ORP must include:
    - (1) certification that the research was reviewed and approved by the IRB, established under this assurance the identification numbers of this assurance and the IRB must be included in the certification.); or
    - (2) certification that the research was reviewed and approved by an IRB established under another assurance (The identification numbers of the approving IRB and the assurance under which it was established along with a copy of the signed agreement stipulated at I.C.15. above must be included with the certification.); or
    - (3) notification that the research was determined to be exempt from coverage under the common rule Section 101 or that coverage was waived.
  - e. The ORP shall keep research investigators aware of decisions and administrative processing affecting their respective protocols and shall return all disapproved protocols to the research investigators.
2. Receive appeal requests.

The ORP shall receive all requested appeals of IRB decisions with attached protocols from the research investigators and forward those protocols to the IRB for reconsideration.

3. Comply with the Investigational New Drug or Device Certification Requirement.
  - a. The ORP shall identify the test article (i.e., drug biologic or device) in the certification to the federal department or agency when the proposal involves a test article and state whether the 30-day interval required for test articles has elapsed or was waived by the Food and Drug Administration (FDA).
  - b. If the 30-day interval has expired, the ORP shall state in the certification to the federal department or agency whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human subjects.
  - c. If the 30-day interval has not expired and a waiver has not been issued, the ORP shall send a statement to the federal department or agency upon expiration of the interval.
4. Certification requirement in cases of supplements to protocols funded by a federal department or agency.

The ORP is responsible for submitting a certification to the applicable federal department or agency, and when otherwise required by this department or agency, a supplement to an original protocol, when:

- a. it is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subjects, or
- b. it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects, or
- c. it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

In addition, the ORP shall insure that no human subjects are involved in research projects for which the filing of a supplement is required by a federal department or agency, prior to the IRB review of the submitted supplement and approval by appropriate department or agency officials.

5. Retention of signed consent documents.

The ORP shall designated procedures for the retention of the signed consent documents. These documents shall be retained for a t least three years after termination of the last IRB approval period.

6. Reporting requirements.

The ORP shall be responsible for promptly reporting information, as appropriate, to the IRB, the OHRP, and research investigators and department heads on a variety of issues. Information may flow from sources such as human subjects, research investigators, the IRB or other institutional staff. Specifically, the ORP shall:

- a. Report promptly to the OHRP any instances of injuries to subjects and unanticipated problems involving risks to subjects or others;
- b. Report to the IRB information received concerning noncompliance by research investigators, injuries to subjects, unanticipated problems involving risks, changes proposed in research activities and the progress of the research;
- c. Maintain information concerning the IRB's reasons for the termination or suspension of IRB approval; and
- d. Report promptly any changes in IRB membership to the OHRP.

C. IRB Structure.

1. Institutional establishment of the IRB.

The IRB is established within the Graduate School to review all research. The IRB membership is appointed by the Associate Provost for Research/Dean of the Graduate School and is subject to approval by the University Chancellor.

- a. The IRB is comprised of at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution, and has the professional competence necessary to review the specific research activities which will be assigned to it.
- b. The IRB is sufficiently qualified through the experience and expertise of its members, and the diversity of the members' backgrounds, including consideration of the racial, gender, 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 subjects.

- c. When research is regularly reviewed involving a category of vulnerable subjects (e.g., prisoner, children, individuals institutionalized as mentally disabled), the IRB shall include in its reviewing body one or more individuals who have as a primary concern the welfare of these subjects.
  - d. The IRB includes both male and female members.
  - e. The IRB includes members representing a variety of professions.
  - f. The IRB includes at least one member whose primary expertise is in a nonscientific area and at least one member whose primary expertise is in a scientific area.
  - g. The IRB includes 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.
3. IRB's membership lists and qualifications.

The names and qualifications of the members of the IRB are enclosed in accordance with the common rule Section 103(b)(3).

D. IRB authorities and responsibilities.

1. IRB review and approval of research.
  - a. The IRB shall have the responsibility to review and the authority to approve, require modification in (to secure approval), or disapprove all research activities or proposed changes in previously approved activities covered by this assurance.
  - b. The IRB shall approve research based on the IRB's determinations that the following requirements are satisfied:
    - (1) Risks to subjects are minimized:
      - (a) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(b) whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

- (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risk and benefits of therapies subjects would receive even if not participating in the research). The IRB shall not consider long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
  - (3) Selection of subjects is equitable. In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted, and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
  - (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by the common rule Section 116.
  - (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by the common rule Section 117.
  - (6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.
  - (7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- c. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons, the IRB will require that additional safeguards have been included in the study to protect the rights and welfare of the subjects.

2. Documentation of informed consent.

- a. In accord with the common rule Section 117, the IRB shall require documentations of informed consent by use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, or may waive the requirement for the research investigator to obtain a signed consent form for some or all subjects if the IRB determines that:
  - (1) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subjects wants documentation linking the subject with the research and the subject's wishes will govern; or
  - (2) The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research.
- b. When the documentation requirement is waived, the IRB may require the research investigator to provide subjects with a written statement regarding the research.

3. Waiver or alteration of informed consent.

- a. The 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 the common rule Section 116 (a & b), 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:
    - (a) public benefit or service programs,
    - (b) procedures for obtaining benefits or services under those programs,
    - (c) possible changes in or alternatives to those programs or procedures, or

- (d) possible changes in methods or levels of payment for benefits or services under those programs, and
    - (2) The research could not practicably be carried out without the waiver or alteration.
  - b. The 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 the common rule Section 116 (a & b), 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.

4. Non-preemption of other applicable laws.

- a. 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.
- b. This policy does not affect any state or local laws or regulations, or any foreign laws or regulations, which may otherwise be applicable and which provide additional protections to human subjects of research.
- c. When research covered by the common rule takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in the common rule. In these circumstances, if a department or agency head determines that the procedures prescribed by the foreign institution afford protections that are at least equivalent to those provided in the common rule, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in the common rule.

5. Emergency medical care.

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

6. Observation of the consent process and the research.

The IRB shall have the authority to observe or have a third party observe the consent process and the research.

7. Frequency of review.

a. the IRB shall determine, in its review of research protocols, which projects will require IRB review more often than annually.

b. Convened meetings of the IRB shall occur:

(1) quarterly; and

(2) at the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous; and

(3) at the call of the chairperson upon the receipt of a joint written request of three or more members.

8. Continuing review.

The IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

9. Verification of change.

The IRB shall determine which projects need verification from sources other than the research investigators that no material changes have occurred since previous IRB review.

10. Authority to suspend or terminate approval of research.

a. The 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.

- b. 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 institution officials, and the federal department or agency head.

#### 11. Information dissemination and reporting requirements.

The IRB shall have the authority and be responsible for promptly reporting information to the ORP, the OHRP or both on a variety of issues. In conjunction with this requirement, the IRB must be prepared to receive and act on information received from a variety of sources, such as human subjects, research investigators, the ORP or other institutional staff. For reporting purposes, the IRB will follow the procedures described below:

- a. Any serious or continuing noncompliance by research investigators with the requirements or determinations of the IRB. This information shall be reported promptly to the ORP and the OHRP.
- b. Injuries to human subjects – Information received by the IRB concerning injuries to subjects shall be reported promptly to the ORP. (The ORP is responsible for reporting to the OHRP)
- c. Unanticipated problems – Information received by the IRB concerning unanticipated problems involving risks to subjects or others shall be reported promptly to the ORP. (The ORP is responsible for reporting to the OHRP.)
- d. Suspensions or termination of IRB approval – The IRB suspending or terminating approval of research protocols shall include a statement of the reasons for the IRB's action and shall report the action promptly to the research investigator, the ORP, and the OHRP.

#### 12. Records.

- a. The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

- (1) Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by research investigators, and reports of injuries to subjects.
  - (2) Minutes of IRB meetings which shall be of sufficient detail to show the names of attendees at the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research and a written summary or the discussion of controverted issues and their resolution. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.
  - (3) Records of continuing review activities.
  - (4) Copies of all correspondence between the IRB and the research investigators.
  - (5) A list of IRB members as required by the common rule Section 103 (b) (3).
  - (6) Written procedures for the IRB as required by the common rule Section 103 (b) (4).
  - (7) Statements that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation and that must be provided to subjects, as required by the common rule Section 116 (b) (5).
- b. The IRB shall provide for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IRB approval period for the activity.
  - c. IRB records shall be accessible for inspection and copying by authorized representatives of the federal department or agency at reasonable times and in a reasonable manner, or shall be copied and forwarded to the department or agency when requested by authorized department or agency representatives.

E. IRB Procedures.

1. IRB receives protocols.

The IRB chairperson shall receive all nonexempt research protocols from the ORP.

2. Determination of review procedure.

- a. The IRB chairperson shall determine whether the research protocol meets the criteria necessary for an expedited review process.
- b. The IRB chairperson refers all research protocols to either full committee review or expedited review.

3. Expedited review.

- a. The eligibility of some research for review through the expedited procedure is in no way intended to negate or modify the policies of this institution or the other requirements of the common rule.
- b. The IRB may use the expedited review procedure to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized.
- c. The only other research for which the IRB may use an expedited review procedure is that which involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the following categories:
  - (1) Collection of: hair and nail clippings, in a non-disfiguring manner, deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
  - (2) Collection of excreta and external secretions including sweat, un-cannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
  - (3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are

applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

- (4) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant.
- (5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- (6) Voice recordings made for research purposes such as investigations of speech defects.
- (7) Moderate exercise by healthy volunteers.
- (8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- (9) Research on individuals or group behavior or characteristics of individuals, such as studies of perception cognition, game theory, or test development, where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- (10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
- (11) Any other category specifically added to this list by the Secretary, HHS, and published in the Federal Register.

- d. Expedited review shall be conducted by the IRB chairperson and by one or more of the experienced IRB members designated by the chairperson to conduct the review.
- e. The IRB member(s) conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove of the research. The reviewer(s) shall refer any research protocol that the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other research protocols to the full committee whenever the reviewer(s) believes that full committee review is warranted.
- f. When the expedited review procedure is used, the IRB chairperson or member(s) conducting the review shall inform IRB members of research protocols which have been approved under the procedure.
- g. At a convened IRB meeting, any member may request that an activity, which has been approved under the expedited procedure, be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue.

#### 4. Full committee review.

- a. Research protocols scheduled for review shall be distributed to all members of the IRB prior to the meeting.
- b. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.
- c. All IRB initial review and continuing review shall be conducted at convened meetings and at timely intervals.
- d. A majority of the membership of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols.
- e. An IRB member whose concerns are primarily in non-scientific areas must be present at the convened meeting before the IRB can conduct its review of research.

- f. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting.
  - g. The IRB may not have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
  - h. In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supercede any decisions made through the expedited review.
5. IRB notification to research investigators and the ORP of decision(s).
- a. The IRB shall notify the research investigators and the ORP in writing of the IRB's decisions, conditions, and requirements.
  - b. The IRB shall also provide to the research investigator reasons for the IRB's decision to disapprove a research protocol and an opportunity for the research investigator to respond. Reasons for disapproval shall also be transmitted to the ORP by the IRB.

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