

POLICIES AND PROCEDURES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

LOYOLA COLLEGE IN MARYLAND

STATEMENT OF PRINCIPLES

Loyola College is dedicated to the protection of the rights and welfare of all human subjects participating in research sponsored by the College. The College is guided by the ethical principles regarding research involving human participants 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* (the "*Belmont Report*"). All research involving human participants will be conducted in accordance with federal, state, and local law utilizing the guidelines established in Title 45, Part 46 of the *Code of Federal Regulations*.

DEFINITIONS

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

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

For purposes of this policy, the terms human subject and human participant are used interchangeably. This acknowledges the terminology used by federal agencies in their regulations, the traditions of various academic disciplines, and the role of a potential participant in consenting to be a part of a research study.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Informed consent means the knowing, legally effective consent of an individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Assent means the affirmative agreement of a minor to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as consent.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the subject's participation in the research procedure(s).

Exempt project means a research project involving human participants that falls outside the oversight of the Institutional Review Board on Human Subjects Research (IRB). Determination of exempt status may only be designated by the Office of Research and Sponsored Programs (ORSP) or the IRB. However, exempt designation does not release an investigator from upholding the ethical standards required by this policy in the conduct of their research.

INSTITUTIONAL POLICY

Loyola College bears full responsibility for complying with the requirements set forth in Title 45, Part 46 of the *Code of Federal Regulations* (45 CFR 46) for all research involving human subjects, without regard to funding source, if

- the research is sponsored by this institution, or
- 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
- 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
- the research involves the use of this institution's nonpublic information to identify or contact human research participants or prospective participants.

This institution will comply with all federal, state, or local laws as they may relate to research covered by this policy.

In accord with 45 CFR 46, Loyola College has established and will maintain the Institutional Review Board on Human Subjects Research (IRB), which has the responsibility and authority to

review, approve, disapprove, or require changes in research activities involving human participants.

All research covered by this policy will be reviewed by the IRB. Research involving human participants will not be permitted until the IRB has reviewed and approved the research protocol. Furthermore, all non-exempt projects lasting longer than one year will be subject to annual review by the IRB.

Unless informed consent has been specifically waived by the IRB in accord with 45 CFR 46.116, no research investigator shall involve any human being as a participant in non-exempt research unless the research investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized representative. Furthermore, unless the requirement for documentation of informed consent has been waived by the IRB in accordance with 45 CFR 46.117, informed consent shall be documented by use of a written consent form signed by the participant or the participant's legally authorized representative.

This institution also accepts responsibility for safeguarding the rights and welfare of human participants participating in cooperative research projects. When research covered by this policy is conducted at or in cooperation with another entity, all provisions of this policy remain in effect for that research, however, this institution may accept, for the purpose of meeting the IRB review requirements, the review of an Institutional Review Board established at another institution.

This institution accepts responsibility for complying with human subjects education requirements as required by federal, state, and/or local funding agencies.

This institution encourages and promotes constructive communication among research administrators, department heads, research investigators, members of the IRB, other institutional officials and human participants as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the participants.

To help ensure awareness of this policy, all relevant approval documents will contain the webpage address for the *Policies and Procedures for Research Involving Human Participants*. A statement directing investigators to acquaint themselves with these policies and procedures will be included on the approval form. Investigators will be provided with alternative means of obtaining a copy of the human participants policy and procedures if internet access is not available to an investigator.

PROCEDURES

A. RESPONSIBILITIES OF RESEARCH INVESTIGATORS

Research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research participants and insure that all pertinent laws and regulations are observed. Additionally, investigators shall be responsible for complying with all IRB decisions, conditions and requirements. These requirements are applicable even in cases where the research is exempt under 45 CFR 46.101.

Research investigators are responsible for ensuring that all research involving human participants is submitted to the Office of Research and Sponsored Programs (ORSP) for review by the IRB. Investigators shall use the definitions of “research” and “human subject” provided on Page 1 of this document and in 45 CFR 46.102 to determine whether the project is subject to the policies and procedures herein outlined. In the case of research conducted by students, the determination shall be made by the faculty member sponsoring the research project. When it is not clear whether the research involves human subjects as defined in 45 CFR 46.102, research investigators should seek assistance from the ORSP and the IRB in making this determination.

If it is determined that the research does involve human participants, the investigator shall complete an Application for Approval of Investigation Involving the Use of Human Participants, giving a complete protocol of the proposed research.

The research investigator or faculty sponsor shall make the preliminary determination on the Application for Approval of Investigation Involving the Use of Human Participants of whether the research is exempt from coverage under 45 CFR 46.101. However, if the project involves human participants that are minors, pregnant women, fetuses, neo-nates, or prisoners, the project will not be deemed exempt.

When required, research investigators shall include samples of proposed informed consent and/or assent forms with the protocol.

If research requires use or disclosure of protected health information for which a participant’s authorization or a waiver is required under the Health Information Portability and Accountability Act (HIPAA), an investigator must provide a copy of such authorization or waiver request as an attachment to the Application for Approval of Investigation Involving the Use of Human Participants. Investigator requests for waivers or alterations of the patient authorization requirements under HIPAA will be reviewed by the IRB using these procedures, as modified to reflect the applicable HIPAA regulations.

Informed Consent: In accord with 45 CFR 46.116, no participant may be involved in non-exempt research without the legally effective informed consent of the participant or the participant's legally authorized representative. Research investigators are responsible for obtaining the participant's informed consent and for insuring that no human participant will be involved in the research prior to the obtaining of the consent. In all cases informed consent shall conform with the following:

- a) The information given to the participant, or to the participant's legally authorized representative, must be in a language understandable to the participant or the representative;
- b) It must be obtained under circumstances that offer sufficient opportunity for the participant to freely consider whether or not to participate;
- c) It must not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the research investigator, the sponsor, the College or its agents from liability for negligence.

Basic Elements of Informed Consent: Unless waived by the IRB, research investigators shall provide the following information to each participant:

- 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 (if the risk potential is currently unknown or immeasurable, a statement to that effect will be required);
- 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/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- g) Identification of the responsible investigator and the investigator's sponsoring institution, and 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;
- h) A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled;
- i) The following statement will be included in ALL written informed consents (including letters): THIS PROTOCOL HAS BEEN REVIEWED AND APPROVED BY THE LOYOLA COLLEGE INSTITUTIONAL REVIEW BOARD ON HUMAN SUBJECTS RESEARCH.

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:

- 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 that 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.

Documentation of Informed Consent: 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 participant or the participant's legally authorized representative, unless this requirement is specifically waived by the IRB. A copy of the consent form shall be supplied to each person signing the form.

Research investigators may use a consent form that is either:

- a) A written consent document that embodies the elements of informed consent required by 45 CFR 46.116. This form may be read to the participant or the participant's legally authorized representative, but in any event, the research investigator shall give either the participant or the representative adequate opportunity to read the form before signing it, or
- b) A "short form" written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the participant or the participant's legally authorized representative. When the "short form" is used, research investigators shall insure that:
 - the written summary of what is to be said to the participant or the representative receives the prior approval of the HSRC
 - a witness is present at the oral presentation;
 - the short form is signed by the participant or the representative; the witness signs both the short form and a copy of the written summary of the oral presentation;
 - the person obtaining consent signs a copy of the summary; and
 - a copy of both the short form and summary is given to the participant or the representative.

Consent for Anonymous Questionnaires: Certain types of survey research use anonymous surveys that are returned by mail or delivered through a means that ensures that the identity of the participants remains individually unknown to the investigator. With prior approval by the IRB, the researcher may fulfill the requirements of informed consent by providing the participant with a cover letter or set of instructions that includes the following items:

- a) An explanation of the research project, its purpose and duration of participation time;
- b) An offer to answer questions concerning the project and information on how to contact the investigator;
- c) A statement indicating anonymity; and
- d) Indication that the return of the questionnaire will constitute the participant's consent to participate. A statement that participation is voluntary must be included.

Assent: In accordance with 45 CFR 46.408 and in addition to procedures for obtaining informed consent, verbal or written assent shall be obtained from minors when, in the judgment of the IRB, the minor is capable of providing assent. As a guideline, minors age 12 and over generally are capable to give written assent, and minors between seven and age 12 generally are able to give verbal assent. Even where the IRB determines that the participants are capable of assenting, the IRB may waive the assent requirements in accordance with guidelines for the waiver of consent contained herein.

Retention of records: Research investigators shall retain copies of documents related to the use of human participants in any research project approved by the IRB including but not limited to all signed consent and assent documents and complete records of any adverse incidents that occurred during the research as well as any follow-up correspondence or actions taken in response to the adverse incident. Research investigators are responsible for maintenance and retention of such records for a minimum of three years after the completion of the research. If the principal investigator is a student and the application is submitted for an independent research project, thesis or dissertation, the faculty sponsor is responsible for maintenance of these records. If the project is a supervised classroom project, the informed consent documents do not need to be retained unless the project required expedited review. If the principal investigator leaves the institution within this period, all records must be provided to the department so that they can be retained for the required three-year period.

Reporting changes in the research: Research investigators are responsible for prompt reporting of proposed changes in a research activity to the ORSP. When research is ongoing, the research investigator may not institute changes until IRB review and approval has been obtained, except when necessary to eliminate apparent immediate hazards to the participant. If steps must be taken to eliminate a hazard after approval has been given, documentation of the hazard eliminated and the steps taken to eliminate the hazard must be forwarded to the ORSP.

Submission of supplementary protocols to the ORSP: Research investigators shall be responsible for submitting a supplement and the original protocol to the ORSP when:

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

Submission of injury reports and reports of unanticipated problems involving risks:

Research investigators are responsible for reporting promptly to their department heads and to the ORSP any injuries to human participants and any unanticipated problems that involve risks to the human research participants or others.

Reporting of noncompliance: Research investigators and department heads are responsible for reporting promptly to the ORSP and the IRB any protocol violations, or serious or continuing noncompliance with this policy and/or the determinations of the IRB.

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

Notifying the ORSP concerning investigational new drugs: Research investigators shall be responsible for notifying the Food and Drug Administration (FDA) and the ORSP whenever it is anticipated that an investigational new drug or device exemption will be required.

B. RESPONSIBILITIES OF THE OFFICE OF RESEARCH AND SPONSORED PROGRAMS

The ORSP shall provide administrative support to the IRB.

The ORSP shall receive all protocols and ensure that all applicable questions have been completed. For protocols submitted under the exempt category the ORSP shall verify exempt status. The ORSP shall forward all non-exempt research protocols to the IRB for review. The ORSP shall keep research investigators aware of decisions and administrative processing affecting their prospective protocols and shall return all disapproved protocols to the research investigators. As appropriate, the IRB or the ORSP may negotiate protocol modifications with the research investigator.

For cooperative projects already approved by an Institutional Review Board of another institution, the ORSP may approve the research upon receipt of evidence of approval signed by the appropriate officials at the cooperating institutions. Alternatively, the ORSP may require the completion of an Application for Approval of Investigation Involving the Use of Human Participants prior to considering the research protocol.

Requests for Reconsideration: The ORSP shall receive all requests for reconsideration of IRB decisions with attached protocols from the research investigators. Upon receipt of a written request for reconsideration, the ORSP shall convene a meeting of the IRB for full review of the protocol.

Investigational New Drug or Device Certification Requirements: When the proposal involves a test article (i.e., drug biologic or device) which requires certification to the HHS, the ORSP shall identify the test article in the certification to HHS and state whether the 30-day interval required for test articles has elapsed or was waived by the FDA.

- a) If the 30-day interval has expired, the ORSP shall state in the certification to HHS whether the FDA has requested that the sponsor continue to withhold or restrict the use of the test article for application in human participants.
- b) If the 30-day interval has not expired and a waiver has not been issued, the ORSP shall send a statement to HHS upon expiration of the interval.

Supplements to Research Protocols: When required by the funding agency, the ORSP is responsible for submitting a certification to the funding agency and a supplement to an original protocol when:

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

In addition, the IRB will takes steps to ensure that no human participants are involved in research projects for which the filing of a supplement is required by HHS, prior to review of the submitted supplement and approval by appropriate HHS officials.

Reporting Requirements: The ORSP shall be responsible for promptly reporting information, as appropriate, to the IRB, the appropriate institutional authorities, the federal Office for Human Research Protections (OHRP), research investigators and department heads. Information may flow from sources such as human participants, research investigators, the IRB or other institutional staff. Specifically, the ORSP shall:

- a) Report promptly to appropriate institutional authorities or to the OHRP any instances of injuries to participants and unanticipated problems involving risks to participants or others;
- b) Report to the IRB information received concerning noncompliance by research investigators, injuries to participants, 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, when required.

The ORSP will be responsible for maintaining documentation of human participants education completed by investigators and forwarding said documentation to granting agencies as required.

The ORSP will remain abreast of policy changes made by OHRP, federal, state and local agencies and make recommendations, as needed, to the IRB so as to ensure compliance with regulatory requirements. The ORSP will ensure that necessary educational and administrative activities are completed so as to be able to provide federal assurances regarding human subjects protections.

C. STRUCTURE OF THE INSTITUTIONAL REVIEW BOARD

The IRB shall be comprised of a minimum of five Loyola faculty members and one outside member, including an elected chair, from diverse backgrounds to promote complete and adequate review of research activities covered by this policy and shall have the professional competence necessary to review the specific research activities assigned to it. The IRB shall be sufficiently qualified through the experience and expertise 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.

IRB membership may not consist entirely of men or women, or entirely of members of one profession. The Loyola faculty members assigned to the IRB shall include at least one member from the Natural Sciences, one member from the Social Sciences, and one member from either the Humanities or Business. The outside member may not be affiliated with Loyola in any way or be a part of the immediate family of a person affiliated with Loyola. The chair of the IRB will be elected by the Loyola faculty members serving on the committee. Normally, the chair

will be elected to a two-year term during the spring in which the incumbent chair's term will expire.

When research is reviewed involving a category of vulnerable participants (e.g., prisoners, children, individuals institutionalized as mentally disabled), the IRB shall include in its reviewing body one or more persons who have as a primary concern the welfare of these participants.

With the exception of the outside member, all members of the IRB will be selected by the Faculty Affairs Committee and approved by the Academic Senate. Members will be appointed for three year terms except for the Grants Development Coordinator who serves *ex officio* on the IRB. The Grants Development Officer also may be assigned as an *ex officio* member of the IRB. The Office of Research and Sponsored Programs will provide administrative support to identify an unaffiliated member to serve on the IRB. Upon identification of suitable candidate(s), resumes will be forwarded to the IRB and the Faculty Affairs Committee. The IRB will vote to approve or disapprove appointment of the unaffiliated member. The unaffiliated member will serve a three year term.

Convened meetings of the IRB shall occur:

- a) Once each semester; and
- b) At the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous; or
- c) At the call of the chairperson upon the receipt of a joint written request of three or more members; or
- d) At the call of the ORSP for the review of requests for reconsideration.

D. AUTHORITIES AND RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW BOARD

The IRB shall have the responsibility to review and the authority to approve, require modification of or disapprove all research activities or proposed changes to previously approved research activities covered by this policy, however, no IRB member may participate in the IRB's initial or continuing review of any project in which that member has a conflicting interest, except to provide information requested by the IRB.

IRB approval shall be based on the determination that the following requirements are satisfied:

- a) Risks to participants are minimized, by using procedures consistent with sound research design that do not unnecessarily expose participants to risk and, whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- b) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research),

the IRB shall not consider long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

- c) Selection of participants 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 and/or economically or educationally disadvantaged persons.
- d) Unless otherwise provided for in this policy, informed consent shall be sought from each participant or the participant's legally authorized representative and documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative.

Waiver or alteration of informed consent: The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waives the requirement to obtain informed consent, provided the IRB finds and documents that:

- a) 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: 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs; and
- b) The research could not practicably be carried out without the waiver or alteration;

OR

- a) The research could not practicably be carried out without the waiver or alteration;
- b) The research involves no more than minimal risk to the subjects; and
- c) The waiver or alteration will not adversely affect the rights and welfare of subjects.

Whenever appropriate the IRB will ensure that participants are provided with additional pertinent information after participation.

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the participants if it finds either:

- a) That 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
- b) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.)

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.

Frequency of review: The IRB shall determine, in its review of research protocols, which projects will require IRB review more often than annually.

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.

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.

Authority to suspend or terminate approval of research: The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's decisions, conditions and requirements or that has been associated with unexpected serious harm to participants.

Information dissemination and reporting requirements: The IRB shall have the authority and be responsible for promptly reporting information to the ORSP and, when appropriate, the OHRP 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 participants, research investigators, the ORSP 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 of the IRB - This information shall be reported promptly to the ORSP and, when required, the ORSP will report it to the OHRP.
- b) Injuries to human participants - Information received by the IRB concerning injuries to participants shall be reported promptly to the ORSP. The ORSP is responsible for reporting to the appropriate institutional officials and, when required, to the OPRR.
- c) Unanticipated problems - Information received by the IRB concerning unanticipated problems involving the risks to participants or others shall be reported promptly to the ORSP. The ORSP is responsible for reporting to the appropriate institutional officials and, when required, to the OHRP.
- d) Suspension or termination of IRB approval - The suspension or termination of approval of research protocols shall be reported promptly to the research investigator, the ORSP, and, when required, to the OHRP. Such reports shall include a statement of the reasons for the IRB's action.

IRB Records: The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

- a) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by research investigators and reports of injuries to participants.

- b) Minutes of IRB meetings shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the IRB; the vote of these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports with opinions. If a member in attendance has a conflicting interest regarding any project and therefore did not participate in a review, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.
- c) Records of continuing review activities.
- d) Copies of all correspondence between the IRB and the research investigators.
- e) A list of IRB members as required by 45 CFR 46.103 (b)(3).
- f) Written procedures for the IRB as required by 45 CFR 46.103 (b)(4) and (b)(5).
- g) Statements of significant new findings provided to participants, as required by 45 CFR 46.116 (b) (5).

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.

IRB records of research funded by federal agencies or departments shall be accessible for inspection and copying by authorized federal representatives at reasonable times and in a reasonable manner, or shall be copied and forwarded to the appropriate federal agency or department when requested by authorized representatives.

E. INSTITUTIONAL REVIEW BOARD PROCEDURES

Exemptions: The ORSP receives all applications that are submitted to the IRB. The ORSP will review all projects that are submitted under the exempt category to determine whether they meet the requirements for exemption. The ORSP also will review student classroom projects that meet the criteria for exemption. At the discretion of the ORSP discretion, such projects also may be sent to other IRB members for review.

Projects that include human participants who are minors, pregnant women; fetuses; neo-nates; and/or prisoners will not be considered exempt. In all other cases, the following types of research will be considered exempt:

- a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special educational instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (2) 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.

- 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 paragraph (b) of this section, if (1) the human subjects are elected or appointed public officials or candidates for public office; or (2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 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 the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- e) Research and demonstration projects which are conducted by or subject to the approval of any federal department or agency heads and which are designed to study, evaluate, or otherwise examine: (1) Public benefit or service programs; (2) procedures for obtaining benefits or services under those programs; (3) possible changes in or alternatives to those programs or procedures; or (4) 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, (1) if wholesome foods without additives are consumed or (2) 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.

Expedited review: 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 45 CFR 46.

Expedited review shall be conducted by two IRB members with the exception, generally, of any *ex officio* members. The IRB members conducting the expedited review may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. The reviewers shall refer any research protocols that are not approved through the expedited process to the full IRB for a full review. The reviewers also may refer other research protocols to the entire IRB whenever either reviewer believes that full review is warranted.

Waiver of Parental Consent for Minors: If an investigator requests a waiver of parental consent for a project involving minors, the application must be reviewed by a minimum of three members of the IRB.

When the expedited review procedure is used, the IRB members conducting the review shall inform IRB members in writing of research protocols which have been approved under the procedure.

At a convened IRB meeting, any member may request that an activity that 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.

In accordance with the categories established by the Secretary of Health and Human Services as published in the Federal Register and attached to this document or as amended, the expedited review procedure may be used to review some or all of the research appearing on the list and found by the reviewers to involve no more than minimal risk as well as minor changes in previously approved research during the period of no more than a year for which approval is authorized.

Full review: Research protocols scheduled for review by the entire IRB shall be distributed to all members of the IRB prior to the meeting, along with all relevant correspondence pertaining to the application. Additionally, the Principal Investigator will be invited to appear before the IRB during the discussion of the application.

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.

All IRB initial review and continuing review shall be conducted at convened meetings and at timely intervals.

A majority of the membership of the IRB, including at least one member whose expertise is in non-scientific areas, constitutes a quorum and is required in order to convene a meeting for full review of research protocols.

For a research protocol to be approved, the protocol must receive the approval of a majority of those members present at the convened meeting.

No member of the IRB may participate 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.

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 supersede any decisions made through the expedited review.

IRB notification to research investigators and the ORSP:

The IRB shall notify the research investigators and the ORSP in writing of the IRB's decisions, conditions and requirements.

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 ORSP by the IRB.

Reconsideration:

When a research investigator chooses to question a decision made by the IRB, the investigator shall submit a request for reconsideration, complete with justification or revised research protocol, in

writing to the ORSP. The ORSP shall convene a meeting of the IRB within 15 days of receipt of the request for the purpose of reconsideration of the protocol. The research investigator shall have the right to be present at a meeting convened for the reconsideration of his/her proposal.

rev. 5/9/08

**CATEGORIES OF RESEARCH THAT MAY BE REVIEWED BY THE
INSTITUTIONAL REVIEW BOARD ON HUMAN SUBJECTS RESEARCH (IRB)
THROUGH AN EXPEDITED REVIEW PROCEDURE¹**

Applicability

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

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

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

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

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

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

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/ approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

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

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations

for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

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

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

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

1 An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

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