INSTITUTIONAL REVIEW BOARD (IRB)

MANUAL

Table of Contents

1. Foundation of IRB …… Page 3
2. Jurisdiction of IRB …… Page 3
3. Membership of IRB …….. Page 3
4. Meetings of IRB …… Page 5
5. Record-keeping of IRB …… Page 5
6. Actions of IRB ……..…… Page 7
7. Criteria for Approval of Research ……. Page 10
8. Cooperative Research Projects Involving Other Institutions …… Page 13
9. Appendix 1: List of research activities that qualify for exempt status
10. Appendix 2: List of research activities that qualify for expedited review
11. Appendix 3: Applicable University Policy
12. Appendix 4: Code of Federal Regulations, Title 45 Part 46: Protection of Human Subjects

1. Foundation of IRB

Purpose Statement: Freed-Hardeman University is a private institution, associated with churches of Christ, dedicated to moral and spiritual values, academic excellence, and service in a friendly, supportive environment. The purpose of the University is to provide every student an education permeated with these Christian values.

One of the university's aims is to provide higher education with a Christian perspective by viewing each person as a special creation of God, possessing an everlasting soul, with ultimate accountability to God.

The Institutional Review Board (IRB) will seek to ensure that all research efforts facilitated by the constituents of Freed-Hardeman University are consistent with the moral and spiritual component of the university's stated purpose. The IRB will consider its primary goal to ensure that each person is treated as a special creation of God.

Specifically, the IRB will seek to protect each person participating in research by ensuring that each subject is treated fairly, with respect, and in accordance with all applicable laws and university policies.

The IRB is not an entity that acts of its own accord. This manual, whose contents are determined by federal law, state law, and our Biblical foundation, will be the governing document for the IRB.

2. Jurisdiction of the IRB

The IRB is an administrative body established by Freed-Hardeman University to protect the rights and welfare of human research subjects who are recruited to participate in any research activities conducted through any university program. In order to accomplish this purpose, Freed-Hardeman University has voluntarily adopted the applicable federal regulations regarding the protection of human subjects in research; these regulations can be found in Appendix 4 to this handbook.

The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction, as specified by applicable federal regulations and applicable university policy. Research that has been reviewed and approved by the IRB may be subject to additional review by other university officials; however, those officials may not approve research that has been disapproved by the IRB.

For purposes of this handbook, **human subjects** are defined as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (See Appendix 4 for definitions of "intervention" and "private information.")

For purposes of this handbook, **research** is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

In the event that research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research must be reviewed and approved by the IRB.

3. Membership of the IRB

A. Qualifications

1. General Qualifications

The membership requirements of the Freed-Hardeman University IRB are consistent with federal law and regulations.

In general, the IRB membership will reflect the following qualities:

a. **Experience and Expertise** in the area of research. Members must be able to rightly determine whether research follows legal, ethical, and professional standards.

b. **Diversity**, including consideration of race, gender, and cultural backgrounds. However, no one will be offered an invitation for membership solely on the basis of diversity.

c. **Sensitivity to Local Attitudes.** Members should be familiar with the Freed-Hardeman community and must be aware of issues and attitudes impacting the local community.

d. **Professionalism** in conduct and practice. Members must be able to ascertain the acceptability of proposed research in terms of University policy, applicable law, and standards of professional conduct and practice.

2. Specific Qualifications

The IRB must include individuals who meet the following criteria:

a. A person whose primary concerns are in scientific areas.

b. A person whose primary concerns are in nonscientific areas.

c. A person who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

3. Restrictions

a. There must be at least five active members.

b. There must be more than one profession represented in the membership.

c. The membership must not be exclusively male nor exclusively female.

d. There may be no more than three members from any school or department of the University.

e. **Conflict of Interest**: If a member has a role or other interest in research that is being reviewed by the IRB, that member must recuse himself or herself from any participation in IRB actions regarding the project.

All members of the Freed-Hardeman IRB must have completed required training offered by the National Institute of Health (NIH) before being appointed.

The IRB chairperson may, at his or her discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

B. Appointment and Duration of Membership

1. A member's term may be between one and three years. Members may be reappointed.

2. Member terms will be staggered. The duration of a member's term may be dependent upon the term lengths of those currently serving on the IRB.

3. If a member is unable to serve the full length of his or her term, a replacement may be appointed by the Vice President for Academics to complete the academic year.

4. New appointments will be made by the Vice President for Academics in the summer preceding each academic year.

5. The members of the IRB will appoint a chairperson in the summer preceding each academic year, but prior to the appointment(s) of new member(s) made by the Vice President for Academics.

4. Meetings of the IRB

A. Regularly Scheduled Meetings

1. Meetings of the IRB will be convened monthly.

2. Scheduled meetings may be cancelled when

a. no proposals have been submitted for review, or

b. the agenda for the scheduled meeting only includes expedited review of research (see Section 6.B.4).

B. Membership Requirements for Regularly Scheduled Meetings

1. A majority of the members of the IRB must be present to fully review any proposed research, including modified research for which full review is required.

2. At least one member of the majority present must satisfy Section 3.A.2b regarding non-scientific expertise.

3. In order for the research proposal to be approved, it must receive the approval of a majority of those members present at the meeting.

4. Telephone or audiovisual conferencing may be used for members unable to physically attend a regularly scheduled meeting.

5. Record-keeping of the IRB

A. Required Records

Adequate documentation of IRB activities will be prepared and maintained, including but not limited to the following:

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

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

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and the investigator(s).

5. Written procedures for which the IRB will follow:

(a) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator(s) and the institution;

(b) for determining which projects require review more often than annually and which projects need verification from sources other than the investigator(s) that no material changes have occurred since previous IRB review; and

(c) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject(s).

6. Statements of significant new findings developed during the course of a research project that may relate to a subject's willingness to continue participation.

7. A list of IRB members identified by:

(a) name,

(b) earned degrees,

(c) representative capacity,

(d) indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations,

(e) any employment or other relationship between each member and the institution; for example, full-time employee, part-time employee, member of governing panel or board, stockholder, and paid or unpaid consultant.

B. Length of Maintenance of Records

The records required by this policy will be retained for at least 3 years, and records relating to conducted research will be retained for at least 3 years after completion of the research.

All records will be kept secured and will be accessible for inspection and copying by authorized representatives of Freed-Hardeman University.

6. Actions of the IRB

A. Determination of Exempt Status

Unless otherwise required by the Vice President for Academics, research activities involving human subjects that fall under one of the categories listed in Appendix 1 are exempt from the jurisdiction of the IRB and from the requirements of this handbook.

The Vice President for Academics has the right to require a research project that falls under one of the categories listed in Appendix 1 to undergo a full research review by the IRB. The Vice President for Academics must provide written notification of such a decision to the IRB.

B. Determination of Expedited Review Status

1. Criteria

A research proposal or minor modifications to a research proposal may qualify for an expedited review if they meet one of the following two criteria:

(a) The research presents no more than minimal risk to human subjects, and falls under one of the types of research listed in Appendix 2, or

(b) The research was approved during the previous twelve months, but minor changes have been made since it was approved.

2. Exceptions to Qualified Research

(a) 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; be damaging to the subjects' financial standing, employability, insurability, reputation; or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

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

3. Application

The researcher(s) must complete and submit all required forms according to published deadlines.

4. Informed Consent

Research that qualifies for expedited review must still meet the requirements set forth in Section 7B regarding informed consent.

5. Expedited Review of Research

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewer(s) may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Section 6C.

6. Notification of Expedited Review Status

Any decision regarding expedited review status must be communicated in writing to the researcher(s) and must be communicated to all members of the IRB prior to the next regularly scheduled meeting.

7. Limitations

The Vice President for Academics may restrict, suspend, terminate, or choose not to authorize use of the expedited review procedure by the University or the IRB.

C. Research Review

1. Disapproval

If the research proposal does not meet the required criteria (see section 7), the IRB will disapprove the proposal. The IRB will prepare a written statement of the reasons for its decision, which will be provided to the researcher(s).

The researcher has an opportunity to appeal a decision of disapproval by the IRB in person or in writing. If the researcher intends to appeal, he or she must notify the IRB Administrator within 7 days of the receipt of the disapproval decision. If the researcher intends to submit written support for the appeal, all written documents must be submitted within 14 days of the receipt of the disapproval decision. The IRB will consider appeals at its next regularly scheduled meeting. A decision of the IRB regarding an appeal of an initial decision to disapprove a research proposal is final.

2. Decision to Require Modifications

If the IRB determines that modifications are necessary in order for the research proposal to comply with all required criteria for approval, the IRB may decide to require modifications to the research proposal. The IRB will prepare a written statement of the required modifications, which will be provided to the researcher.

When the required modifications have been made, the researcher must re-submit the research proposal to the IRB for a full review.

3. Approval

If the IRB determines that the research proposal complies with all applicable federal regulations and all applicable institutional requirements as described in Section 7, then the IRB will approve the proposal. The IRB will prepare a written statement of its decision, which will be provided to the researcher.

In order for the research proposal to be approved, it must receive the approval of a majority of those members present at the meeting.

Approved research is subject to continuing review by the IRB. Such review will occur at intervals appropriate to the degree of risk; these intervals will be determined by the IRB at the time the research proposal is approved. The IRB must provide written notification to the researcher of the required intervals of continued review.

Continued review of any approved research proposal will not occur less than once per year. If the researcher fails to initiate the continued review process prior to the expiration date for continued review, as defined by the IRB, the approved status of the research project may be removed resulting in immediate termination of the research (see section below on "Suspension or Termination of Approved Research").

The IRB has the authority to observe the informed consent process required in Section 7 and to observe the approved research itself. The IRB also has the authority to appoint a third party to conduct such observation.

D. Review of Proposed Changes to Approved Research

It is the responsibility of the researcher to report to the board in writing any proposed changes in the research as well as any unanticipated problems that arise involving risk to subjects. Proposed changes by the researcher may not be implemented until the proposed changes have been reviewed and approved by the board. If deemed necessary, the board may require that the previously approved research project, including its proposed changes, undergo a full board review for approval of the entire project as modified.

E. Suspension or Termination of Approved Research

If the board becomes aware of any reason a previously approved research project is not in compliance with the criteria for approval of research (see section 7) or is believed to pose a serious risk or possible harm to subjects, the board may request a meeting with the researcher and suspend the research until the problem can be evaluated.

If a previously approved research project is deemed to have failed to comply with the criteria for approval of research, the board may choose to terminate the research project. The board's decision to terminate a research project is final.

In the case that a research project is suspended or terminated, the board will take appropriate steps to confiscate or protect data from the researcher.

The board will notify the Vice President for Academics if previously approved research is suspended or terminated.

The board will prepare a written statement of the reasons for its decision to terminate or suspend, which will be provided to the researcher.

If a suspended research project has satisfied the board's concerns with regard to non-compliance and/or serious risk or possible harm to subjects, the research project may be reinstated to approved status.

7. Criteria for Approval of Research

A. Requirements for Approval

1. The researcher(s) must complete and submit all required forms according to published deadlines.

2. Risks to subjects are minimized:

(a) By using procedures that are consistent with sound research design and that 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.

3. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

4. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted 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.

5. 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 Section 7B pertaining to informed consent.

6. Informed consent will be appropriately documented in accordance with and to the extent required by Section 7B2.

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

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

9. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

B. Informed Consent

1. Criteria

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator will seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative will be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, or the institution or its agents from liability for negligence.

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

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(i) public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs; and

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

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

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

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

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

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

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

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

2. Documentation

a. Except as provided in paragraph (c) of this section, informed consent will be 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. A copy will be given to the person signing the form.

b. Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator will give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there must be a witness to the oral presentation. Also, the IRB will approve a written summary of what is to be said to the

subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness will sign both the short form and a copy of the summary, and the person actually obtaining consent will sign a copy of the summary. A copy of the summary will be given to the subject or the representative, in addition to a copy of the short form.

c. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) 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 subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) 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 subjects with a written statement regarding the research.

8. Cooperative Research Projects Involving Other Institutions

Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the Vice President for Academics, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Appendix 1: List of research activities that qualify for exempt status

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Appendix 2: List of research activities that qualify for expedited review

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

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

(b) Research on medical devices for which

(i) an investigational device exemption application (21 CFR Part 812) is not required; or

(ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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

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

(b) from other adults and children[2], 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.

Appendix 3: Applicable University Policy

§46.118 Applications and proposals lacking definite plans for involvement of human subjects.

- Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101(b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§46.119 Research undertaken without the intention of involving human subjects.

- In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

- (a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
- (b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§46.122 Use of Federal funds.

- Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§46.123 Early termination of research support: Evaluation of applications and proposals.

- (a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.
- (b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§46.124 Conditions.

- With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.