Policy on Human Subjects Research At New Mexico Tech

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of New Mexico Tech
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I. INTRODUCTION

A. PURPOSE

This policy establishes an administrative process for ensuring that researchers at New Mexico Tech comply with federal regulations governing the appropriate use of human subjects in research. This policy must be enacted in order for New Mexico Tech to attain its Federal Wide Assurance from the Office for Human Research Protections (OHRP). The Federal Wide Assurance document is, in effect, a permit to conduct federally-funded human research at New Mexico Tech.

B. SCOPE

Federal regulations require that any and all research involving human subjects be reviewed and approved by an Institutional Review Board (IRB) for the Protection of Human Subjects in Research **PRIOR** to initiation of such research. This requirement applies to all human subject research conducted by faculty, staff, or students, on- or off-campus, regardless of the source of funding for the project.

All research at New Mexico Tech that involves human subjects must be submitted to the IRB for review before such research can be performed. The IRB is responsible for ensuring that the rights, welfare, and well being of human participants in research are protected according to the regulations given in the Federal Policy for the Protection of Human Subjects [45 CFR Part 46, also referred to as "The Common Rule"]. These regulations were adopted on June 18, 1991 and govern human subjects research supported by the Departments of Agriculture, Energy, Commerce, HUD, Justice, Defense, Education, Veterans Affairs, Transportation, and HHS, as well as NSF, NIH, NASA, EPA, AID, Social Security Administration, CIA, and the Consumer Product Safety Commission.

Nothing in these regulations shall relieve New Mexico Tech, the IRB or any other person or entity subject to application of the Common Rule from compliance with the Common Rule, including, but not limited to, Tech's conflict-of-interest policy.

For purposes of this policy, New Mexico Tech's IRB will use the definition of "research" given in 45 CFR §46.102(d), as follows:

> ***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.

For purposes of this policy, New Mexico Tech's IRB will use the definition of "human subjects" given in 45 CFR §102.46(f), as follows:

> ***Human subject*** means a living individual 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.

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.

<u>In summary:</u> If the project meets the definition of research given above, and if human participants are involved, the research must be submitted for review by New Mexico Tech's IRB.

II. DEFINITIONS

The Common Rule – The regulations given in Title 45 CFR Part 46 and which were enacted on June 18, 1991 to protect the rights and welfare of human subjects in research.

Department of Health and Human Services (DHHS) – the federal agency which oversees the federal Office for Human Research Protections, and which is ultimately responsible for enforcing the Common Rule.

Federal Wide Assurance (FWA) – The Federal policy for the protection of human subjects requires that each institution engaged in federally-supported human subjects research file an Assurance of protection for human subjects with the DHHS. The Federal Wide Assurance is an agreement that formalizes the institution's commitment to protect human subjects.

Human Subject – A living individual 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. [45 CFR §46.102]

Identifiable Private Information – Addresses, numbers, and/or demographic information that may be used to link the information back to a specific individual.

Institutional Review Board (IRB) – a specially appointed ethics committee that reviews all research projects involving human subjects to ensure that the rights and welfare of such subjects are being protected in accordance with the Common Rule.

Minimal Risk – A research project involves "Minimal Risk" if the participant experiences no pain or physical danger; experiences no emotional arousal or psychological stress beyond the level normally expected in everyday life; the project neither includes nor attempts to induce long-term significant change in the participant's behaviors; the data gathered would not embarrass or socially disadvantage the participant if confidentiality were violated; and if there is no reason to believe that the subject would choose not to participate if he or she were not aware of the specific purpose of the project.

The Office for Human Research Protections (OHRP) – the federal office directly responsible for enforcing the federal regulations given in Title 45 CFR Part 46.

Research – A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge. [45 CFR §46.102(d)]

III. GENERAL POLICY AND PROCEDURES

A. THE ROLE AND RESPONSIBILITIES OF THE IRB

1. Function of the IRB

The IRB will review all research at New Mexico Tech that involves human subjects to make sure that the rights, welfare, and well being of such subjects are protected according to federal regulations. The IRB will be guided in its decisions by the regulations given in the Federal Policy for the Protection of Human Subjects (45 CFR Part 46, also referred to as "The Common Rule").

The IRB also seeks to protect the rights of the researcher and of the university; however, the rights and welfare of human research subjects must be the IRB's first consideration.

2. Organization of the IRB

According to 45 CFR §46.107, an IRB must be composed of at least five members of several professions, include both men and women, and have at least one member with a scientific background and one member who is NOT otherwise affiliated with the university.

New Mexico Tech's IRB will consist of at least five people of diverse backgrounds (including cultural and racial) who have sufficient maturity, experience, and competency to ensure that the IRB will be able to discharge its responsibilities and that its determinations will be accorded respect by faculty and staff researchers, as well as the community served by Tech.

The Vice President for Research and Economic Development will recommend certain persons to be appointed to the IRB. The President of New Mexico Tech will hold final responsibility for appointing members to the IRB.

In addition to the regular Board members, an IRB Administrator will be appointed by the Vice President for Research and Economic Development. The responsibilities of the IRB Administrator are described in more detail in Section B of this policy. For purposes of this policy, the IRB Administrator will be considered a member of the IRB Board.

The IRB itself will select and appoint one member to serve as IRB Chair at its inaugural meeting. The Chair will serve for a period of one year, at which time another Chair will be appointed, if so desired by the majority of the IRB Board members.

Any member of the IRB shall recuse himself or herself from voting or otherwise participating in decision-making regarding any matter in which he or she has a commercial or pecuniary interest or is an investigator or experimenter.

3. IRB Review of Research

Review by the IRB is the cornerstone of New Mexico Tech's program for the protection of human research subjects. The IRB reviews, and has the authority to approve, require modification in, or disapprove all research activities that involve human subjects.

(a) Criteria for Review of Research

The criteria that New Mexico Tech's IRB must use to review and approve research projects involving human subjects are given in 45 CFR §46.111(a) and (b), as follows.

> (a) In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:
>
> (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
>
> (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
>
> (3) Selection of subjects is equitable. In making this assessment the IRB 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.
>
> (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR §46.116.
>
> (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR §46.117.
>
> (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
>
> (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
>
> (b) 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) Continuing Review Requirements

In accordance with 45 CFR46.103(b)(4), New Mexico Tech's IRB will conduct continuing review of ongoing approved research at intervals appropriate to the degree of risk, but not less than once per year.

The IRB will determine, based on its initial review of the research protocol, how frequently the research project must be reviewed. Approved protocols that involve more than Minimal Risk may require continuing review more frequently than every twelve months; otherwise, previously approved protocols will be reviewed at least annually.

The IRB will also determine, based on its initial review of the research protocol, whether a research project will require verification from sources other than the Principal Investigator that no material changes have occurred since previous IRB review.

The Principal Investigator must submit progress reports, including available study-wide findings, to the IRB as requested to facilitate such continuing reviews. The IRB has the authority to suspend or terminate previously-approved research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to its human participants.

Institutional Officials may not authorize or approve the conduct of human subjects research that has not been approved by the IRB; however, research that has been approved by an IRB may be subject to further review and approval or disapproval by officials of the institution.

(c) Levels of IRB Review

There are three levels of IRB review for research projects involving human participants:

1. Exempt From IRB Review

Certain types of behavioral, education, and social research listed in 45 CFR §46.101(b) are exempt from mandatory review by an IRB. ***Please see Appendix A for this list.*** Tech's IRB Administrator will issue administrative approval to such projects after determining that the safeguards for confidentiality and the methodology of obtaining informed consent are adequate.

2. Expedited Review

Certain other highly specific areas of research listed in 45 CFR §46.110(a) are eligible for an expedited IRB review process***. Please see Appendix B for this list.*** In this case, the IRB Administrator and at least one other Board member will review the research protocol. If the protocol meets the appropriate criteria, they will recommend approval to the IRB Chair.

In the case of both exempt and expedited review procedures, all IRB Board members will be notified promptly of the actions taken by the IRB Administrator. Should any Board member disagree with an action, a full IRB review will be required.

3. Full IRB Review

All protocols that do not qualify for either administrative or expedited review will receive full Board review. The IRB Administrator will schedule a meeting of the full Board as soon as possible and forward the research protocol to all Board members. The Principal Investigator will be notified of the date of the IRB review meeting as well.

To hold a review, a quorum (a majority) of Board members MUST be present at the meeting. The Board may call consultants to advise on a complex protocol, or request that the Principal Investigator be present to provide information about the research protocol.

(d) Results of Full IRB Review

Following a full IRB review, the Board can vote in one of three ways:

- to approve a research protocol;
- to approve the research protocol contingent upon modification of certain elements of the protocol; or
- to reject the research protocol.

If the research protocol has been approved by full IRB review, the IRB Administrator will work with the Principal Investigator(s) to prepare the human subject research protocol documentation required in funding proposals to federal agencies and other sponsors, as necessary.

If the research protocol has been rejected after full IRB review, it will be returned to the Principal Investigator with an attached statement describing why it was deemed unacceptable, and recommendations for modifications, if any.

B. THE ROLE AND RESPONSIBILITIES OF THE IRB ADMINISTRATOR

The responsibilities assigned to the IRB Administrator fall into three general areas:

1. Education and Communication

The IRB Administrator is responsible for training the members of Tech's research community in order to establish and maintain a culture of compliance with federal regulations and institutional policies relevant to the protection of human subjects.

The IRB Administrator is responsible for ensuring constructive communication between researchers, department heads, human subjects, and institutional officials as a means of safeguarding the rights and welfare of human research subjects.

The IRB Administrator will arrange for ready access to New Mexico Tech's Federal Wide Assurance, as well as copies of pertinent federal regulations, policies, and guidelines related to the involvement of human subjects in research, and institutional policies and procedures.

2. Recordkeeping and Reporting

The IRB Administrator will handle all administrative details for the IRB, including receiving research protocols and reviewing them for completeness; logging the protocols into a database; reviewing the protocols to determine the appropriate level of review for each; and scheduling full Board reviews when necessary.

The IRB Administrator is responsible for ensuring that IRB records are maintained in accordance with 45 CFR §46.115. The Administrator is also responsible for transmitting copies of New

Mexico Tech's Federal Wide Assurance and Certification of IRB Approval of proposed research projects to the appropriate federal department or agency.

Finally, the IRB Administrator is responsible for ensuring that any of the following events is reported to the IRB, appropriate institutional officials, OHRP, and any sponsored Federal department or agency:

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

3. Monitoring and Oversight

The IRB Administrator must ensure that any human subjects research at New Mexico Tech complies with 45 CFR §46.103, which includes the following requirements:

- appropriate oversight mechanisms to ensure compliance with IRB requirements.
- all cooperating performance sites in federally-supported research have appropriate OHRP-approved assurances and provide Certifications of IRB review to the appropriate federal authorities.
- performance sites cooperating in non-federally supported research have and can document appropriate mechanisms to protect human subjects.
- cooperative IRB review arrangements are documented in writing, in accordance with OHRP guidelines.
- all independent investigators who rely on the institution's IRB have documented their commitment to the institution's human subjects protection requirements and to the IRB's determinations.

C. THE ROLE AND RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR (PI)

Principal Investigators (PIs) have five primary responsibilities in protecting the rights and welfare of human research subjects.

1. Obtaining training and certification for all research personnel on project

To ensure that PIs meet their responsibilities under federal regulations, New Mexico Tech will institute a formal education program for all PIs who use human subjects in their research. All PIs, research staff, and student researchers must attend the required training and obtain a certificate of completion before they will be permitted to submit an application to the IRB for approval to conduct human research at New Mexico Tech. Similarly, any student advisor listed on an IRB application must have completed training for the application to receive IRB review. Departments or individual researchers should contact the IRB Administrator to schedule a training session as needed.

2. Submitting initial research plan to the IRB for its review and approval

If a research project meets both criteria for IRB review (it is considered "research" as defined above, and it involves human participants), the Principal Investigator must complete an IRB Application Form and attach a copy of the research protocol to it. The Application Form and the protocol should be sent to the IRB Administrator in the R&ED Office. The Application Form can be downloaded from the R&ED web site at http://infohost.nmt.edu/~red/IRB/index.html or obtained from the IRB Administrator in the R&ED Office.

When it is not clear whether a research project will involve human subjects, PIs should seek assistance from the IRB Administrator in making this determination [45 CFR §101(b)(1)-(6), §118, and §119].

The PI shall prepare a complete written description of the proposed research project. The description must include provisions for the adequate protection of the rights and welfare of prospective subjects and ensure that pertinent laws and regulations are observed. Samples of all proposed informed consent documents must be included with written description.

3. Obtaining IRB permission prior to any changes in research project

The PI must seek review and approval from the IRB before making any changes to a previously-approved research project, except when necessary to eliminate apparent immediate hazards to the subject.

4. Reporting progress of research project to the IRB on a regular basis

Principal Investigators must report the progress of their research project to the IRB and/or appropriate institutional officials as often as and in the manner prescribed by the IRB but no less than once per year [45 CFR §109(e)].

5. Soliciting informed consent from each potential subject involved in the research project

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to decide whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence. [45 CFR §46.116]

D. INFORMED CONSENT FOR HUMAN PARTICIPANTS IN RESEARCH

Informed consent is not a single event, nor merely a form to be signed. It is the educational process that occurs between the PI and the research subject. The general requirements for informed consent are given in 45 CFR §46.116(a) and (b), as follows:

> (a) Basic elements of informed consent. Except as provided in paragraph (d) of this section, in seeking informed consent the following information shall be provided to each subject:
>
> (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
>
> (2) a description of any reasonably foreseeable risks or discomforts to the subject;
>
> (3) a description of any benefits to the subject or to others which may reasonably be expected from the research;
>
> (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
>
> (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
>
> (6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
>
> (7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
>
> (8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
>
> (b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
>
> (1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
>
> (2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
>
> (3) any additional costs to the subject that may result from participation in the research;
>
> (4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

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

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

E. WAIVERS OF INFORMED CONSENT

Under certain circumstances specified in 45 CFR §46.116(d), the IRB may approve a consent procedure that waives some or all of the elements of informed consent, as follows:

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

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

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

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

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

F. DOCUMENTATION OF INFORMED CONSENT

Informed consent must be documented according to 45 CFR§46.117, as follows:

(a) Except as provided in paragraph (c) of this section, informed consent shall 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 shall 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 shall 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 shall be a witness to the oral presentation. Also, the IRB shall 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 shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall 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.

IV. CONSEQUENCES OF NON-COMPLIANCE WITH THIS POLICY

It is in the best interests of all parties (New Mexico Tech, the researcher, and the research participant) to have all human subject research reviewed by the IRB. Such review helps to ensure that the ethical principles of beneficence, respect for persons, and justice have been honored. Participation in research should be protected as a matter of ethics, not merely as a matter of "compliance" with New Mexico Tech or federal rules.

In instances when a researcher intentionally or unintentionally avoids ethical review procedures, the researcher should be aware that serious consequences could result. The New Mexico Tech IRB or the federal government *may* require that the research data that was collected before IRB approval of the project (or collected after IRB approval has been rescinded) be destroyed. Federal agencies can and have required that all research at a given university be halted while individual research projects are re-reviewed. Failure to comply with human research participant rules can cause a researcher's right to conduct research to be withdrawn.

Other consequences that can result from performing human subjects research that has NOT been reviewed by New Mexico Tech's IRB could include revocation of all of New Mexico Tech's federal funding, regardless of whether the research in question is using federal funding or funding from a different, non-federal source. Additionally, if a human subject experiences unanticipated negative effects from the research, criminal and civil charges against the researcher and the university could be filed. Therefore, researchers who plan to perform research involving human subjects MUST obtain IRB approval.

Researchers who fail to comply with New Mexico Tech's IRB policies and procedures will be subject to appropriate disciplinary action which could range from suspension of the research project to termination of employment at New Mexico Tech, depending upon the severity of the problem.

V. REVIEW OF POLICY AND PROCEDURE

This policy and procedure will be reviewed as needed by New Mexico Tech's Institutional Review Board. Any proposed modifications to this policy shall be submitted to the Vice President for Research and Economic Development for consideration. Proposed changes will be forwarded to the Institute Senate for comments, to the President for his/her approval, and finally to the Board of Regents for final approval and adoption.

APPENDIX A – CATEGORIES OF RESEARCH THAT ARE EXEMPT FROM MANDATORY IRB REVIEW

[From: 45 CFR §46.101(b)]

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

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

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

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

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

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

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

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

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

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

(i) Public benefit or service programs;

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

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

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

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

(i) if wholesome foods without additives are consumed or

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

APPENDIX B – CATEGORIES OF RESEARCH THAT QUALIFY FOR AN EXPEDITED IRB REVIEW

[From: 45 CFR §46.110]

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) below pertain to both initial and continuing IRB review.

Research Categories

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

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

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

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

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

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

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

(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 include:

(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 non-research 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.