

**UNIVERSITY OF WISCONSIN OSHKOSH
INSTITUTIONAL REVIEW BOARD
POLICY STATEMENT**

1.0 INTRODUCTION

The University of Wisconsin Oshkosh encourages and supports free investigation by faculty/academic staff members and by students into any general area of knowledge. When research is conducted using University facilities or otherwise under its sponsorship, the individuals conducting the inquiry act as University representatives. It is the University's policy that all research studies involving human participants shall be under the supervision of a qualified faculty/academic staff member and carried out so as to safeguard the rights and welfare of the participants in compliance with the Policies of the Office of Protection from Research Risks (OPRR), National Institutes of Health, as published in the Federal Register (June 18, 1991, Vol., 56, No. 117).

An Institutional Review Board for Protection of Human Participants (IRB) has been appointed by the Vice Chancellor to assist investigators in insuring that the rights and welfare of participants are adequately protected.

The IRB shall review all proposals prepared for extramural support that are determined by the Office of Grants and Faculty Development to involve human participants, including but not limited to grants, contracts, traineeships, and faculty fellowships, prior to signature by the appropriate university officials for submission to any funding agency. When such prior review is not feasible, it must be made before the acceptance of any award. Where requested, the University shall be prepared to certify its compliance with these procedures.

In addition, the IRB shall review all research activity involving human participants; that is, research proposed as part of master's theses, Faculty Development proposals, or class related activities, including undergraduate and graduate independent study courses.

2.0 STATEMENT OF PRINCIPLES

A balance between freedom of inquiry for scholars and recognition of the ethical concerns of peers, participants, sponsors, governments, and the public at large shall be maintained. The investigator must respect the individual's freedom to decline to participate in or withdraw from the research at any time. The members of the IRB concluded that numerous complex issues are involved which merit much further attention by the total academic community. The IRB strongly encourages faculty/academic staff members, student groups, departments, schools and colleges to stimulate further discussion of the ethical responsibilities of scholars. Further discussion of such issues will be continued in future meetings of the IRB.

The UW Oshkosh IRB has adopted Principle 9, "Research with Human Participants," of the "Ethical Standards of Psychologists" of the American Psychological Association as its standard for review of work with human participants. While written for a single professional group, this statement of principles appeared to be sufficiently broad and inclusive to serve as a general framework within which the IRB could function. A copy of this statement as reprinted in the American Psychologist, June 1981, is found in Section V.

3.0 DEFINITIONS AND DEFINITIONS APPLICABILITY

3.1 Research: Means a systematic investigation including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute "research" for purposes of this policy, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities [S_.102(d)].

3.2 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 of during the performance of routine physical or psychological examinations or tests [S_.102(i)].

3.3 Human Participant: 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 participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and participant. "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 participant is or may be readily ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants [S_.102(f)].

3.4 Exempt Research: Research activities in which the only involvement of human participants will be in one or more of the following categories and which do not involve sensitive or protected populations (see Section 4.0) are exempt from this policy. [Note: The IRB will make the final determination as to whether a research project may be classified as "exempt." Therefore, it is the responsibility of the Principal Investigator to file an IRB for Protection of Human Participants application form.

3.4.1 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 [S_.101(b)]. [Note: This exemption also applies to research involving minors].

3.4.2 Research involving educational tests (cognitive, diagnostic, aptitude, achievement)¹, survey procedures², interview procedures³, or observation of public behavior⁴, *unless*:

- i. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and
- ii. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability or reputation.

3.4.3 Research involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is **not** already exempt under #2, if:

- i. The human participants are elected or appointed public officials or candidates for public office; or

¹ Applies to minors

² Does **not** apply to research with minors

³ Does **not** apply to research with minors

⁴ Applies to research with minors **only** when the investigator(s) does **not** participate in the activities observed [S_.101(b)2].

- ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and hereafter [s_.101(b)3].

3.4.4 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 participants cannot be identified, directly or through identifiers linked to the participants. (Applies to research with minors) [S_.101(b)4].

3.4.5 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 these 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. [S_.101(b)5].

3.4.6 Taste and food quality evaluation and consumer studies,

- i. If wholesome foods without additives are consumed,
- 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 Services of the U.S. Department of Agriculture. [S_.101(6)].

3.5 Deception: Means that at the time of the data collection the participant is not fully informed of the nature and purpose of the research in order to prevent or minimize potentially biased reporting of data/information. The employment of deception by an investigator(s) for the purpose of securing participation and/or to prevent potentially biased reporting of data/information by the participant is permissible provided that all of the following conditions exist:

- i. Deception is necessary due to the lack of alternative procedures for data collection not involving deception;
- ii. The deceptive procedures will not place participants at significant financial, physical, psychological, or social risk;
- iii. The data collection/experiment will be followed by careful debriefing whereby the participants are fully informed of the nature and purpose of deception.

4.0 INFORMED CONSENT

The welfare of any human participant in research must be safeguarded. Such safeguarding is assured by fully informing potential participants about the nature of the research activity in which they are being asked to participate and then permitting each person to decide voluntarily whether they want to be a participant. A potential human participant is fully informed when all relevant elements of information, as listed below, have been effectively communicated in language that is comprehensible to that individual.

Research which is exempt from this policy (see Section 3.4), while not requiring documented (signed) informed consent, nonetheless should fully inform potential participants by providing them with the basic elements of informed consent as listed in this policy as described below. Permitting the participant, or parent/legal representative, to make a fully informed decision to participate in an activity averts potentially inequitable or coercive conditions of human participant use and assures the voluntary nature of participant involvement.

All research which is not exempt of which involves prisoners, fetuses, mentally retarded or mentally disabled person, pregnant women, legally incompetent persons, or human in vitro fertilization, requires documented (signed) informed consent. Obtaining the informed consent of a potential human participant is a safeguard for protecting his or her well-being. It is a safeguard of the basic ethical principle of voluntariness.

A full explanation of the procedures to be followed, their benefits, risks, and alternatives is a protective safeguard for the participant's well-being, and clearly stating the positive or beneficial aspects of the activity may also enhance participation. In studies involving participant deception, the reasons for deception must be fully justified to the IRB, and the participant must be given a complete explanation of the study upon completing his or her participation. (Refer to section 3.5 for definition of "deception.")

Federal policy [S_.116] (a) (1) through (8) has defined legally informed consent to include the following basic elements of information:

- i. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- ii. A description of any reasonably foreseeable risks or discomforts to the participant;
- iii. A description of any benefits to the participant or to others which may reasonably be expected from the research;
- iv. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- v. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- vi. 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;

- vii. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant; and
- viii. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Except as provided elsewhere in this or other sub-parts, no investigator may involve a human being as a participant in research covered by this policy unless the investigator has obtained the legally effective informed consent of the participant and/or the participant's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective participant 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 participant or the representative shall be in language understandable to the participant or the representative. (For help in interpreting the informed consent requirements when using minors as participants, contact the IRB for Protection of Human Participants).

No informed consent, written or oral, may include any exculpatory language through which the participant or the representative is made to waive or appears to waive, any of his or her legal rights, or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

When appropriate, additional elements of informed consent may be included as follows, and shall also be provided to each participant: a statement that a particular treatment or procedure may involve unforeseeable risk to the participant; anticipated circumstances under which the participation may be terminated by the investigator without regard to the participant's consent; any additional cost to the participant that may result from participation; consequences of a participant's decision to withdraw from the research and the procedures for orderly termination of participation by the participant; a statement that significant new findings may develop during the course of the research which may relate to the participant's willingness to continue participation; and the approximate number of participants involved in the study.

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

- i. The research/demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 - a. public benefit of service programs
 - b. procedures for obtaining benefits or services under those programs;
 - c. possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practically be carried out without the waiver or alteration [S_.116©1,2].
- ii. The research involves no more than minimal risk to the participants; the waiver or alteration will not adversely effect the rights and welfare of the participants; the research could not practically be carried out without the waiver or alterations; and whenever appropriate, the participants will be provided with additional pertinent information after participation. [S_.116(d)1,2,3,4]

Informed consent requirements 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.

Nothing in the regulations is intended to limit the authority of a physician to provide emergency medical care, or to the extent that the physician is permitted to do so under applicable federal, state or local laws.

4.1 Consent Procedures

4.1.1 Long Form Written Consent: When feasible and appropriate, the more desirable procedure for obtaining informed consent consists of having the participant sign a document that provides any and all appropriate elements of information about the project, as detailed above. Specific procedures for obtaining written consent are as follows:

- i. Prepare consent form (example provided in Section III).
- ii. Receive IRB approval of the consent form, as part of its approval of the project request.
- iii. Provide two copies of the consent form to each potential participant, legal representative of the participant or legal guardian of the participant.
- iv. The participant's copy must include the name, address and telephone number of the person to whom complaints may be addressed, please refer to the example below:

"If you have any complaints about your treatment as a participant in this study, please call or write:"

Chair, Institutional Review Board
For Protection of Human Participants
c/o Grants Office
UW Oshkosh
Oshkosh, WI 54901
920/424-3215

A statement regarding the confidentiality of the participants' complaints is needed:
"Although the chairperson may ask your name, all complaints are kept in confidence."

A CONSENT FORM MUST INCLUDE THE ABOVE REFERENCE.

AT THE END OF THE CONSENT FORM, A STATEMENT OF UW O IRB APPROVAL IS NECESSARY:

"This research project has been approved by the University of Wisconsin Oshkosh Institutional Review Board for Protection of Human Participants for a 1-year period, valid until (one year from the approval date)."

- v. Include as participants in the project only those individuals for whom legal signatures on both copies of the form have been obtained.
- vi. Keep one copy of the signed consent form in your records (but **not** in such a way that its existence constitutes an identifier of information that would otherwise be anonymous). Provide the other signed copy to the participant (or legal representative or legal guardian).

4.1.2 Short Form Written Consent: A short form consent may be signed by the participant or legal representative in instances where it is difficult or impossible for the participant to read or sign a long form informed consent. Specific procedures for obtaining short form consent are as follows:

- i. Prepare a written Information Sheet to be read to each potential human participant and/or to that person's legal representative or legal guardian (see Section III.C.). Include indication of how the short form consent, if obtained, will be explicitly recorded.
- ii. Receive IRB approval of a "short form" written consent document, as part of its approval of the project request (see Section III.B.). This short form consent document shall state that the elements of written consent, as stated above, have been presented orally and in writing to the participant or the participant's legally authorized representative.
- iii. Insure that every potential human participant (and/or representative or guardian) receives and understands all the information contained in the Information Sheet, and that explicit consent to participate is obtained before any other information is sought. There shall be a witness to the oral presentation of the Information Sheet.
- iv. Keep explicit record of short form consent being sought and obtained.
 - a. The short form itself shall be signed by the participant or the representative and by the witness.
 - b. The Information Sheet that is read shall be signed by the person actually obtaining consent and by the witness.
 - c. A copy of the Information Sheet and the short form written consent shall be given to the participant or the representative.

4.2 Waiver of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed informed consent for all or some participants if it finds: 1) that the only record linking the participant and research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In that case, each participant will be asked whether the participant wants documentation linking the participant to the research and the participant's wishes will govern; or 2) that the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context [S.117(c)1,2].

In cases where the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement explaining the research and/or provide information regarding complain procedures.

5.0 APPLICATION REVIEW

5.1 Timing of Review

All proposals involving human participants, including grants, contracts, traineeships and faculty fellowships, *which are seeking external funding*, should be reviewed by the IRB prior to signature by the appropriate University officials for submission to any funding agency whenever possible. When such prior review is not feasible, it must be completed and submitted to the agency within the time period specified by the funding agency.

The IRB will make every effort to process your application in a timely manner. **In order to do so, you must submit the required information on the Application Form (see page 1) and in the Project Outline format (see page 2).** Assuming that your research is appropriate for an Expedited Review (Refer to Section VI, 8.0) **and** that there is no need to request additional information from you, the review process typically is completed in approximately two weeks when school is in session during the academic year. An expedited review may take longer during vacation periods and the summer.

If the full IRB must review your application, either because it is not eligible for an expedited review or is not approvable through an expedited review, the process may take as long as 4-6 weeks.

5.2 Initial Review Process

Upon receiving a completed application, two IRB committee representatives will review the application to determine if the research can be classified as "exempt" (refer to section 3.4), or if an expedited review of the application is appropriate. If the research cannot be classified as exempt and if an expedited review of the application is not appropriate, the application must be reviewed by the IRB. The IRB committee members conducting reviews may request additional information from the Principal Investigator if clarification is needed. The Principal Investigator will be sent a written notification of the review results.

5.3 Continuing Review of Approved Projects

It is the Principal Investigator's responsibility to submit, in a timely manner, to the IRB Chairperson a written statement which identifies any emergent problems or proposed procedural changes which may affect the participants in a previously approved research protocol. No such changes, except those necessary to eliminate apparent immediate hazards, should be made without prior approval by the IRB.

In addition the IRB may carry out periodic reviews of all previously approved research involving human participants, taking into account apparent risks, existing administrative and supervisory organization, and other factors so as to assure that the research is being carried out as proposed and approved. Frequency of such reviews shall be at the discretion of the IRB chairperson, but not less than once a year.

6.0 CRITERIA FOR APPROVAL

6a In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

- 1) Risk to participants are minimized:
 - i. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and
 - ii. Whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposed;
- 2) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, 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 or therapies participants 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 (e.g., 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 participants 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 aware 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 properly sought from each participant (or legally authorized representative) in accordance with and to the extent required by section 4.0;
- 5) Informed consent will be appropriately documented in accordance with and to the extent required by section 4.0;
- 6) Where appropriate, the research plan makes adequate provision for monitoring data collected to insure the safety of participants; and
- 7) Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

6b When some or all of the participants are likely to be vulnerable to coercion or undue influence, such 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 participants [S_.111].

The IRB will not grant approval if the application appears inadequate regarding any of those criteria mentioned in 6.0 above. In this event, the IRB chairperson will communicate the Committee's concerns to the Principal Investigator, and if appropriate, request additional information that may enable the Committee to act favorably on the application. Any changes or additional information to an application which are made as a result of such communication, however, must be written and attached to the application form.

If the principal investigator fails to provide information which enables the Committee to approve the application, the IRB chairperson will return the application to the Office of Grants and Faculty Development with a signed statement which specifies the reason(s) for disapproval. This information will be sent to the Principal Investigator.

7.0 RETENTION OF RESEARCH RECORDS

All records relating to research that is **non-exempt** shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and in a reasonable manner [S_.115(b)].

8.0 RESEARCH ACTIVITIES WHICH MAY BE REVIEWED THROUGH EXPEDITED REVIEW PROCEDURES

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) 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 examination 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, non-pregnant 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: (a) hair and nail clippings in a non-disfiguring 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 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 e-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 of 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.