

UNIVERSITY OF MAINE

**POLICIES AND PROCEDURES FOR THE
PROTECTION OF HUMAN SUBJECTS
OF RESEARCH**

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I. Policies

A. Research with human subjects at the University of Maine shall be guided by three general ethical principles: respect for persons, beneficence, and justice. These principles and the rules that may be derived from them shall form the analytical framework for determining whether and how research with human subjects may be conducted. They are articulated in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research (See Appendix C: the [Belmont Report](#).)

B. The University shall maintain and support an Institutional Review Board for the Protection of Human Subjects, whose function it is to determine whether and how research with human subjects may be conducted, and to educate the community with regard to the protection of human subjects.

C. No research with human subjects shall be conducted until the Protection of Human Subjects Review Board has reviewed the research protocol and determined that the project is exempt from further review or has approved the research protocol. Before either action is taken, proper consideration shall be given to the risks to the subjects, the anticipated benefits to the subjects and others, the importance of the knowledge that may reasonably be expected to result, and the informed consent process to be employed.

D. The University of Maine shall acknowledge and accept responsibility for protecting the rights and welfare of human subjects of research. University Policies and Procedures for the Protection of Human Subjects of Research apply to all activities which include research with human subjects and:

1. are sponsored by the University; or
2. are conducted by or under the direction of any employee, student, or agent of the University in connection with his or her institutional responsibilities; or
3. are conducted by or under the direction of any employee, student, or agent of the University using any property or facility of the University; or
4. involve the use of the University's nonpublic information.

E. The University of Maine shall encourage and promote constructive communication among research administrators, department chairs, deans and directors, research investigators, research staff, human subjects, and University officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

F. The University of Maine shall comply with all federal, state, and local regulations pertaining to the protection of human subjects.

II. Definitions

A. "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 programs of "evaluation" or "instruction" may include research activities.

B. "Human Subject" means a living individual about whom an investigator conducting research obtains either

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. It also includes 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). If the private information is not individually identifiable (i.e., if the identity of the subject is not known and cannot readily be ascertained by the investigator or associated with the information), the research does not constitute research involving human subjects.

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

III. Procedures

A. Responsibilities of the Principal Investigator.

The individual employee, student, or agent of the University who conducts or directs research with human subjects exercises the following responsibilities:

1. The Principal investigator shall design and present to the Protection of Human Subjects Review Board a protocol of the research to be conducted.
2. The Principal Investigator shall make no alterations to the approved protocol without the prior approval of such alterations by the Protection of Human Subjects Review Board.
3. The Principal Investigator shall report at once to the Protection of Human Subjects Review Board any unanticipated harm to human subjects.

4. The Principal Investigator shall report to the Protection of Human Subjects Review Board on the conduct of the research and shall seek approval for continuation of the research at least annually, and more frequently if the Board so requires.

5. The Principal Investigator shall cooperate fully with the Protection of Human Subjects Review Board in monitoring the progress of the research.

B. The Protection of Human Subjects Review Board

1. Responsibilities. Responsibility for the protection of human subjects of research at the University of Maine is in large part vested in the Institutional Review Board. The Board is therefore responsible not only for reviewing, regulating, and monitoring such research, but also for educating the University community in the protection of human subjects. Specific responsibilities of the Board include the following:

a. Act on applications submitted to it by employees, students, or agents of the University.

b. Monitor the research it has approved.

c. Maintain records of its activities.

d. Report to the Director of Research and Sponsored Programs all actions pertaining to research supported by extramural funding or proposed for such support.

e. Report at once to the Vice President for Research any action to suspend or terminate approved research.

f. Assist the Vice President for Research as requested, in interpreting University research with human subjects for any of the University's constituencies or for the general public.

g. Devise and conduct programs of education in matters relevant to research with human subjects for the benefit of students and employees of the University.

i. Review annually the University's policies and procedures for the protection of human subjects and report any inadequacies or suggested improvements to the Vice President for Research

j. Report its activities to the Vice President for Research at least annually, or more frequently if so requested.

2. Authority. The Board is authorized to

a. Approve, disapprove, or require modifications in the research protocols submitted to it.

b. Monitor the research it has approved by any means it deems appropriate, including observation of the consent process and the research, and appointment of a third party to undertake such observation.

c. Suspend or terminate approved research, whenever the research is not being conducted in accordance with the Board's requirements or whenever it has been associated with unexpected harm to human subjects.

3. Membership. The President of the University appoints members of the Review Board to three-year terms. Members may be reappointed to further terms. Alternates may be appointed when desirable, and have the same voting privileges as the member for whom they substitute.

The President appoints one member of the Board to serve as Chair for a term of two years. At the beginning of the Chair's second year of service, the President appoints a Chair Elect to succeed the current Chair. The Chair is normally a member of the University's tenured faculty who engages in research with human subjects and who has substantial experience in the review of research with human subjects.

The Board shall have no more than nine and no fewer than five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. The Board shall be sufficiently qualified through the experience and expertise of its members, the diversity of the members, including consideration of race, gender, and cultural backgrounds, and their sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the Board shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The Board shall therefore include persons knowledgeable in these areas, or have access to the counsel of such persons.

Certain populations of human subjects require extra protection because of their diminished autonomy. Diminished autonomy may result, for example, from immaturity, illness, mental disability, or incarceration. The University regularly conducts research with one such population, children and youth. The Board shall therefore include one or more members who are primarily concerned with the welfare of children and youth. When the Board reviews research that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the Board must include at least one ad hoc member primarily concerned with the welfare of these research subjects. Persons qualified to serve in this capacity are identified by the Board and appointed by the President. Should the Board determine in the future that another vulnerable population of human subjects is regularly involved in University research, it shall amend its membership requirements to include one or more members who are primarily concerned with the welfare of such subjects.

The Board may not consist entirely of members of one sex or of one profession. The Board shall always include at least one member whose primary concerns are in nonscientific areas, such as lawyers, ethicists, or members of the clergy. The Board shall always include at least one community member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.

A single member of the Board may fill more than one representational role.

No member of the Board may participate in the Board's review of any project in which the member has a conflicting interest, except to provide information requested by the Board.

The Board may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues. These individuals may not vote with the Board.

4. Functions and operations. The Board convenes monthly meetings for the purpose of reviewing applications for approval of research. Except when an expedited review procedure is used, the Board reviews proposed research only at such meetings. Because members of the Board need to study research protocols before the convened meeting, the Board normally considers only applications that have been submitted at least two weeks prior to the meeting. In acting on applications for approval of research, the Board follows the written procedures outlined in this document.

A quorum consisting of the majority of the membership, including at least one member whose primary concerns are in nonscientific areas, is necessary for action on applications. Approval of an application requires the approval of a majority of the members present at the meeting.

The Board reports promptly to the Vice President for Research any serious or continuing noncompliance by investigators with the Board's requirements and determinations. It also reports such noncompliance to any extramural sponsors of the research in question.

5. Review of research. The Board reviews and acts to approve, require modifications in, or disapprove research activities with human subjects.

The Board requires that information given to subjects as part of informed consent meaningfully adds to the protection of the rights and welfare of subjects, and is in accordance with federal regulations. The Board either requires documentation of informed consent or, in circumstances described in these procedures, explicitly waives documentation.

The Board notifies investigators and the Vice President for Research in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure the Board's approval. If the Board decides to disapprove a research activity, it includes in its written notification a statement of the reasons for its decision and gives the investigator an opportunity to respond in person or in writing.

The Board conducts continuing review of research it has approved at intervals appropriate to the degree of risk, but not less often than once per year. It may also observe, or appoint a third party to observe, the consent process and the research.

5a. Expedited review. The Principal Investigator may request an expedited review of an application for approval of research in any of the following circumstances listed below. An expedited review procedure consists of a review of research by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in the [Code of Federal Regulations](#).

1) The PI and believes that the research activities proposed are limited to those in one or more of the categories of exemption (See Appendix A).

2) The PI proposes only minor changes in previously approved research during the period for which approval is authorized.

3) The PI believes that the research activities proposed involve no more

than minimal risk to human subjects and that they are limited to one or more of the categories eligible for expedited review established by the US Department of Health and Human Services and published periodically in the Federal Register (See Appendix B).

The Board attempts to act on a request for expedited review within ten business days. An expedited review is conducted by the Chair or by one or more experienced reviewers designated by the Chair from among the members of the Board.

In an expedited review, the reviewers may exercise all at the authorities of the Board except that the reviewers may not disapprove the research. If the reviewers find that the application does not meet the criteria of eligibility for expedited review outlined above, or if they fail to approve the application, the application shall be considered at the next regularly scheduled meeting of the full Board. If the reviewers approve the application, notice of their action shall be made promptly to the Chair and, at the next regularly scheduled meeting, to the full Board.

5b. Criteria of review. The Board approves research only when it has determined that all of the following requirements are satisfied:

1) Risks to subjects are minimized. Procedures used are consistent with sound research design and do not unnecessarily expose subjects to risk. Whenever appropriate, the research uses procedures already being performed on the subjects for other purposes, such as diagnosis or treatment.

2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result. The Board considers only those risks and benefits that may result from the research. The Board does not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.

3) The selection of subjects is equitable. In making this assessment, the Board takes into account the purposes of the research and the setting in which the research will be conducted and is 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 is sought from each prospective subject or the subject's legally authorized representative. The Board conforms to federal regulations of informed consent procedures and may impose additional requirements.

5) Informed consent is appropriately documented in accordance with, and to the extent required by, federal regulations. The Board may also impose documentation requirements in addition to those required by federal regulations.

6) Where appropriate, the research protocol makes adequate provision for monitoring the data collected to insure the safety of subjects.

7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8) Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included in the protocol to protect the rights and welfare of these subjects.

5c. Further administrative review. Research that has been approved by the Board may be subject to further review and approval or disapproval by the Vice President for Research, or by other University officers designated by the President. However, no officer of the University may approve research that has not been approved by the Board.

5d. Evaluation and disposition of applications. The Protection of Human Subjects Review Board evaluates applications for approval of research with human subjects according to its written procedures and review criteria. In doing so, it may call upon the Principal Investigator or appropriate third parties for information and assistance.

It is important for the University community to understand that the Board may not limit its concerns to specific research activities or procedures. In weighing risks and benefits, the Board is of necessity making judgments about the merits of the proposed research plan. In considering the ethical principles that guide the conduct of research with human subjects, the Board must of necessity resolve conflicts posed by the demands of the principles themselves.

For example, it is within the purview of the Board's responsibilities to determine that a research plan does not promise to generate the desired knowledge; or that the knowledge to be gained does not promise to outweigh the risks undergone; or that community attitudes and mores will find certain aspects of the research unacceptable.

The Board communicates its decision to approve, disapprove, or require modifications in the research protocol in writing to the Principal Investigator and to the Vice President for Research, who is authorized to inform other interested parties, including extramural sponsors, cooperating organizations, or other University officers, of the Board's decisions.

When the Board approves a research protocol, it stipulates in writing the requirements for continuing review of the research.

When the Board disapproves a research protocol, it states in writing its reasons for disapproval, and invites a response from the Principal Investigator.

When the Board requires modifications in a research protocol, it details those modifications in writing and requires from the Principal Investigator written verification that the modifications have been made, before final approval is granted.

Applications that have been evaluated and all Board correspondence concerning them become part of the Board's records.

6. Suspension or termination of approval of research. The Board has authority to suspend or terminate approval of research that is not being conducted in accordance with the Board's requirements or that has been associated with unexpected serious harm to subjects. When the Board exercises this authority, it promptly communicates its action and the reasons for the action in writing to the Principal Investigator, the Vice President for Research, and the extramural sponsor of the research, if any.

7. Research undertaken in cooperation with another organization. University research with human subjects may be undertaken in cooperation with another organization, provided the University enters into a written agreement with the other organization that allows the University to have adequate control of project activities for which it is responsible. If such research is funded by an extramural sponsor and if the University is the grantee or prime contractor, that responsibility extends to safeguarding the rights and welfare of human subjects of research conducted by the cooperating organization.

In such cases, the Board may rely upon the review of another qualified institutional review board, may engage in joint review with such a board, or may enter into a similar arrangement to avoid duplication of effort.

8. Board record-keeping and reporting. The University supports the record keeping requirements of the Board by providing in the Office of the Vice President for Research, storage space and staff to maintain records in good order. Records include:

a. Copies of all applications reviewed; scientific evaluations, if any, that accompany the applications; approved sample consent documents; progress reports submitted by Principal Investigators; reports of injuries to subjects; all correspondence pertaining to the application or to the research; and records of monitoring and continuing review activities. These records are maintained as active files for 3 years after completion of the research.

b. Minutes of Board meetings in sufficient detail to show attendance, actions taken, the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring modifications in or for disapproving research; and written summaries of the discussion of controverted issues and their resolution.

c. Annual reports of the Board.

d. Other reports generated by the Board or its subcommittees.

e. Other correspondence of the Board.

f. A list of Board Members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the University.

g. Written procedures for the Board.

All records are accessible for inspection and copying, at reasonable times and in a reasonable manner, by representatives of governmental agencies responsible for regulating research with human subjects, by representatives of extramural sponsors of research, by members of the Board itself, and by any other person so authorized by the President or by the Vice President for Research.

The Board reports to the Vice President for Research the actions it takes on all applications for approval of research, including actions pertaining to research supported by extramural funding or proposed for such support.

The Board reports to the Vice President for Research at once any action to suspend or terminate approved research, any unexpected serious harm to human subjects of research, and any

serious or continuing non-compliance by investigators with the Board's requirements and determinations. It also reports such incidents to any extramural sponsor of the research in question.

The Board also reports to the Vice President for Research at least annually a record of Board activities, including its annual review of the University's policies and procedures for the protection of human subjects and any recommendations for modifications resulting from that review.

C. Application for Approval of Research with Human Subjects.

1. General requirements. Application forms and instructions may be obtained from the <http://www.umaine.edu/research/Ethical/irbapp.pdf>. It is essential that all questions be answered fully and in detail. The application must describe the problem or question addressed by the research, the objectives of the research, and the methods to be used in sufficient detail to enable the Board to judge the merits of the research proposed. It must also assess the potential risks and benefits to the subjects, and describe the measures taken to minimize the risks.

In describing risks, the application should indicate the specific nature of potential short- or long-term risks, physical, psychological, social, legal, or other. Risks might include physical discomfort or harm, adverse psychological reaction, invasion of privacy, breach of confidentiality, or any other threat to the dignity, rights, or welfare of human subjects. The application should assess both the likelihood and the seriousness of potential risks, and discuss the relative advantages and disadvantages of alternative procedures.

In describing benefits, the application should consider benefits to the individual subjects, benefits to persons similarly situated, and benefits to society in general.

In describing safety measures, the application should detail all procedures for protecting against or minimizing potential risks. Such measures might include screening procedures, follow up procedures, debriefing, separating identifiers from data, and training staff. The likelihood of the effectiveness of such measures should also be assessed.

2. Informed consent. The application for approval of research must describe the procedures for gaining and documenting the informed consent of the human subjects. Except as detailed below, no investigator may involve a human being as a subject in research 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 subject's 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 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 University, or its agents from liability for negligence.

In seeking informed consent, the following information shall be provided to each subject:

- 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 an identification of any procedures which are experimental;

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- 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;
- 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
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

In addition, one or more of the following elements of information, when appropriate, shall also be provided to each subject:

- 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;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by the subject;
- 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,
- The approximate number of subjects involved in the study.

3. Exceptions to the general requirements for informed consent. The Protection of Human Subjects Review Board may approve a consent procedure which does not include, or which alters, some or all of the elements generally required for informed consent, or may waive the requirement to obtain informed consent, provided that the Board finds and documents one of two sets of circumstances.

a) Such exceptions may be granted if the Board finds and documents that: the research is to be conducted for the purpose of demonstrating or evaluating (1) Federal, state, or local benefit or service programs which are not themselves research programs, (2) procedures for obtaining benefits or services under these programs, or (3) possible changes in or alternatives to these programs or procedures; and the research could not practicably be carried out without the waiver or alteration of general requirements for informed consent.

b) Such exceptions may also be granted if the Board finds and documents that: (1) the research involves no more than minimal risk to the subjects; and (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

4. Documentation of informed consent. Unless the Protection of Human Subjects Review Board explicitly waives the requirement, informed consent shall be documented by the use of a written consent form approved by the Protection of Human Subjects Review Board and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be either of the following:

A written consent document that embodies the required elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give the subject or the representative adequate opportunity to read it before it is signed.

A "short form" written consent document stating that the required elements of informed consent 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. The Protection of Human Subjects Review Board's approval of a written summary of what is to be said to the subject or the representative is also necessary. 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 obtaining consent shall also sign a copy of the summary. Finally, a copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

The Protection of Human Subjects Review Board may waive the requirement of a signed consent form for some or all subjects, if it finds:

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. In this case each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes in the matter must govern; or

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.

When the Board waives the documentation requirement, it may require the investigator to provide subjects with a written statement regarding the research.

D. Additional Protections for Children Involved as Subjects of Research.

The University recognizes an obligation to provide additional protections for human subjects who have not attained the legal age for consent to treatments or procedures involved in the research.

1. Fewer categories of exempt activities. The Human Subjects Review Board may find that a research protocol is exempt from all requirements of further review. For research with most adult subjects, there are six categories of review activities eligible for such exemption, (See Appendix A). When the human subjects are children, however, only five of those categories apply, namely those numbered (1), (3), (4), (5), and (6). Exemption (2), for research involving survey or interview procedures or observations of public behavior, does not apply to research with children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

2. Research that presents no greater than minimal risk to children. Research that presents no greater than minimal risk to children will be approved only if the Protection of Human Subjects Review Board finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

3. Research that presents greater than minimal risk to children, but also the prospect of direct benefit to the individual subjects. If the proposed research presents greater than minimal risk to children, but also the prospect of direct benefit to the individual subjects, the Protection of Human Subjects Review Board may approve the research only if it finds that:

- a. The risk is justified by the anticipated benefit to the subjects;
- b. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- c. Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

4. Research that presents greater than minimal risk to children and no prospect of direct benefit to individual subjects. If the proposed research presents greater than minimal risk to children and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's condition or disorder, the Protection of Human Subjects Review may approve the research only if it finds that:

- a. The risk represents a minor increase over minimal risk;
- b. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- c. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' condition or disorder; and
- d. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

The Protection of Human Subjects Review Board will not approve research with children that does not meet one of the sets of conditions detailed above.

5. Assent of the subjects. In otherwise approvable research with children, the Board normally requires that adequate provisions are made for soliciting the assent of the children, whenever the Board judges the children to be capable of providing assent, given the ages, maturity, and psychological state of the children involved. The Board may make this judgment for all children involved in research under a particular protocol, or for each child individually, as it deems appropriate. If the Board determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, it may waive the requirement for assent. If the Board determines that the children are capable of assenting, it may waive the requirement for assent only in circumstances in which the consent of adult subjects would be waived. When the Board determines that assent is required, it also determines whether and how assent must be documented.

6. Consent of the parents or guardians. In all research with children, the Board normally requires that adequate provisions are made for soliciting the permission of each child's parent or guardian. If the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, and if permission is to be obtained from parents, the Board requires the permission of both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or unless only one parent has legal responsibility for the care and custody of the child. Permission by parents or guardians must be documented in the same manner and to the same extent required for informed consent of adult subjects.

The Board may waive the requirement of parental or guardian permission in circumstances in which the consent of adult subjects would be waived. It may also waive the requirement if it determines that a research protocol is designed for conditions or for a subject population for which such permission is not a reasonable requirement to protect the subjects, provided an appropriate mechanism for protecting the children is substituted, and provided further that the waiver is not inconsistent with applicable law.

7. Wards. The Board will approve the inclusion in otherwise approvable research of children who are wards of the state or of any other agency, institution, or entity, only if such research is either:

- a. Related to their status as wards; or
- b. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If such research is approved, the Board shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the Board) with the research, the Investigator, or the guardian organization.

E. Additional Protection Pertaining to Other Vulnerable Research Populations.

If the Board approves research involving fetuses (or, by extension, pregnant women), prisoners, or other persons of diminished autonomy, it establishes additional requirements, including at a minimum those contained in federal regulations.

IV. Appendices

A. [The Belmont Report](#)

B. [Code of Federal Regulations](#)

C. Exemption Categories

D. Expedited Review Categories

Appendix A

Research Activities that may be Exempt from Further Review

Research involving children, fetuses, pregnant women, prisoners, mentally disabled persons, or other adult subjects of diminished autonomy is subject to special restrictions. For adult subjects of undiminished autonomy, capable of making a truly voluntary and uncoerced decision whether or not to participate as subjects in research, the categories of research exempt from further review requirements are:

- (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 (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 May Be Reviewed by the
through an Expedited Review Procedure

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) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- (F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

- (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
- (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
- (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and 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. (Children are defined in the Health and Human Services (HHS) regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.”)

(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. 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. 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.