

WELLESLEY COLLEGE INSTITUTIONAL REVIEW BOARD IRB Review Guidelines

[1] Why do we need an IRB?

The Wellesley College IRB is required by federal policy for human subjects protection -- this federal policy is known as "The Common Rule". **The Common Rule** requires an institution that is conducting research to assure the federal government that it will provide and enforce protections for human subjects of research conducted under its auspices. The Common Rule was first promulgated by the U.S. Department of Health and Human Services (then known as DHEW) in 1974, and extended to 16 U.S. governmental agencies in 1991.

The Common Rule is based on the ethical principles articulated in The Belmont Report (issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). The three basic principles are:

[a] **Respect for persons:** [1] individuals should be treated as autonomous agents, capable of making autonomous choices; [2] persons with diminished autonomy, such as children and prisoners, are entitled to protection -- the extent of protection (ranging from ensuring that activities are undertaken freely and with an awareness of possible adverse consequences to "extensive protection") depends on the risk of harm and likelihood of benefit, as well as the capacity for self-determination of the individual.

[b] **Beneficence:** [1] do no harm -- when there is a risk of harm, this is only justifiable when the benefits are considered to outweigh the harm; [2] maximize possible benefits and minimize possible harms.

[c] **Justice:** the benefits and burdens of research should be justly and fairly distributed.

[2] What is the purpose of the Wellesley College IRB?

The goal of the Wellesley College IRB is to assist Principal Investigators at Wellesley College in their efforts to protect the rights and welfare of individuals who participate in research conducted at or under the auspices of the College, and to ensure Wellesley College's compliance with federal regulations regarding the protection of human subjects. To meet these goals, the IRB will provide Principal Investigators with information about ways to design their research projects in a manner to minimize potential harm to human subjects, review all planned research involving human subjects prior to initiation of the research, approve research that meets established criteria for protection of human subjects, and monitor approved research to ensure ongoing protection of human subjects. The IRB does not review the scientific merit of research studies; however, the IRB does evaluate the risks to subjects in light of the potential benefits of the study, which requires a consideration of the scientific merit of the study.

[3] Does my project or proposal need IRB Review?

Federal regulations require that any project or proposal that involves **research** (“a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”) with **living individuals** 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** must be reviewed either by the Wellesley College IRB or by individual departments of the College. “*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.”¹

The Wellesley College IRB reviews all federally- and state-funded research proposals and projects, all proposals that require human subjects assurance for other outside funding sources, as well as research conducted by investigators external to Wellesley College that uses data from Wellesley College students. Individual departments are responsible for human subjects protection for all other research conducted at, or under the auspices of, Wellesley College, including pilot studies and students' studies.

Exemption from Review

Federal regulations stipulate that **you do not need a review** if you are using existing data that is publicly available, or if you are using existing data from which the investigator records data in such a way that subjects cannot be identified. **You also do not need a review** if you are conducting research using educational tests, survey procedures, interview procedures or observation of public behavior, **UNLESS** (I) subjects are identified in, or identifiable from, the data collected; **AND** (ii) any disclosure of subjects' responses could place subjects at risk of criminal or civil liability or be damaging to subjects' financial standing, employability or reputation. If you are not sure if your research is exempt, consult Appendix B: Requesting “Exemption from IRB Review” guideline, or the IRB chair. **Note:** Protocols that have been granted exemption from Wellesley College IRB Review may still be subjected to review mandated by study sites, schools, or collaborating institutions.

Because certain categories of individuals, such as children, are viewed as more vulnerable to harm by research, and less able to give fully-informed consent, extra safeguards are included for children. Federal regulations require that **all research with children, including adolescents, must be reviewed, except:** observations of children's public behavior with no interaction with the children; research conducted in education settings of normal educational practices (e.g., on instructional strategies or curricula); research using existing records or data, if these sources are publicly available or if the information is recorded in such a way that the child cannot be identified. When in doubt, consult the IRB chair.

Expedited Review

Research that involves only minimal risk to the subject may receive “expedited review” by the IRB chair. “Risk” is defined as the probability of physical, psychological, social or economic harm or injury as a result of participation in a research study. “Minimal risks” are those where the probability of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those

¹ OHRP. “Guidance on Important Considerations for When Participation of Human Subjects in Research is Discontinued,” Date: November 7, 2008 (DRAFT). <<http://www.hhs.gov/ohrp/requests/200811guidance.html>> accessed 12/1/08.

ordinarily experienced in daily life or during the performance of routine psychological or physical examinations or tests. If a Principal Investigator wishes to apply for an expedited review, please read the guideline on Requesting an “Expedited Review” on Appendix C and follow IRB submission instructions on page 3.

Training Certification for NIH Proposals

Since October 1, 2000, the National Institutes of Health (NIH) has required all key personnel on funded NIH proposals **involving human subjects** to complete an educational course on the protection of human subjects. At Wellesley College, our training program has two parts:

- 1) Reviewing the written IRB guidelines (which you are now reading)
- 2) A web-based training course, at <http://phrp.nihtraining.com/users/login.php>. You will need to register first before taking the course. Read the “tips” link before you take the course.
- 3) Be sure to print out the certificate at the end of the web based course and send it to the IRB (via Sue Wang, Cheever House). Faculty should also send a copy to Lori Friedman, Sponsored Research.

Once funded, all key personnel must complete this training. You can not receive IRB approval until the certificate is on file. The time to complete the web-based training is approximately one hour.

[4] What do I submit to the IRB?

The IRB needs enough information about your study to review it for human subjects protection, and to offer you advice, as needed, on ways to improve human subjects protection. See Appendix A for these guidelines, which outlines ways to protect the rights and welfare of individuals participating in the project.

When you submit your proposal to the IRB, please include the following documents:

**For a full review, please submit 8 copies of each, for expedited review please submit 1 copy.*

1. A completed Wellesley College IRB Cover Sheet
2. A 1-2 page description of the project (this does not need to follow this format -- if the proposal already includes this information, simply submit the appropriate pages from the proposal). Be sure to include:
 - [a] Information about who will be the subjects of the research -- who are you studying? Outline the characteristics of the study population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any group (e.g., on the basis of gender, race/ethnicity, poverty-status, etc.). Explain the rationale for the inclusion of any “special classes” of research participants, such as children, institutionalized individuals, or others who are likely to be vulnerable.
 - [b] Description of informed consent procedures (attach informed consent forms). Include a description of plans for the recruitment of research participants and the consent procedures to be followed - the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective participants, and the method of documenting consent.
 - [c] Information about the data you will collect on these subjects -- what information will you collect, how will you collect it, from whom or from what source will you collect it (interviews with the study participants, questionnaires completed by teachers, doctors’ records, observations, etc.), will the information collected include identifiable private information, or involve intervention or interaction with the subject of the study? Indicate whether the material or data will be obtained specifically for research purposes, or not, and whether you will be using existing records or data.
 - [d] If the measures being used are not ones commonly known to members of the IRB, attach copies of the measures, so that the IRB can make an informed review of the risks involved in

the study, and the adequacy of the procedures for protecting human subjects.

- [e] A discussion of the risks of the study, and their likelihood and potential seriousness. If the study involves more than minimal risk, explain why the benefits justify the risk. Include a discussion of what will be done to minimize the risks, including risks to confidentiality, and what provisions have been made in the event that the participants are harmed by the research.
 - [f] a discussion of the benefits of the research, and analysis of the risks to the participants relative to the anticipated benefits to the participants and to the importance of the knowledge that may reasonably be expected to result.
 - [g] *If applying to NIH:* NIH requires that all PIs complete training on the protection of human subjects (see above). Please attach a copy of NIH Training Certificate, if not already on file.
3. If applying for an exemption from review, please attach a completed 'Requesting Exemption from IRB Review' form.
 4. If applying for an expedited review, please attach a completed 'Requesting an Expedited Review' form.

If you have any questions when preparing these materials, feel free to consult with the IRB chair.

[5] Annual Reviews

The IRB is required by 45 CFR 46.109(e) to conduct a continuing review of every "minimal risk or deception" IRB-approved protocol. After a proposal is approved by the IRB, PIs are required to submit an Annual Progress Report form to the IRB for continued review – your approval letter will tell you the review date, and the IRB Administrator, Sue Wang, will send you an Annual Progress Report form each year, until your study is completed. Annual reviews are required as long as human subjects are involved.²

² OHRP considers a research project to continue to involve *human subjects* as long as the investigators conducting the research continue to obtain: (1) data about the subjects of the research through intervention or interaction with them; or (2) identifiable private information about the subjects of the research..... OHRP interprets *obtain* to include an investigator's use, study, or analysis for research purposes of individually identifiable private information or biological specimens already in the possession of the investigator.

As long as a non-exempt human subjects research project continues to involve analysis of individually identifiable private information by the investigator, the research continues to involve human subjects and must undergo continuing review by an IRB at least annually. Even when the participation of all subjects in a research project has been completed or discontinued, that research project can continue to involve human subjects. Source: OHRP, op cit.

**WELLESLEY COLLEGE INSTITUTIONAL REVIEW BOARD
IRB Cover Sheet**

Please complete the following information and sign at the space provided below:

Researcher/Principal Investigator:

Date this form submitted to the IRB:

Start date of project:

Title of Project:

Purpose of the Project:

Type of Project:

Proposal submitted to a federal agency: Agency: _____

Proposal submitted to other funding source: Funding source: _____

Institutional research (i.e., using Wellesley College students or staff)

Has your project been approved by the Office of Institutional Research? yes no

Other project (pilot study, student investigator, unfunded research)

[please specify _____]

Outside Financial Interests:

Do you or any other person responsible for the design, conduct, or reporting of this research have an economic interest in, or acts as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by, the research.

No **Yes.** *If you checked yes, please explain:*

Signed

Signature of Researcher or Principal Investigator

APPENDIX A

Protecting the Rights and Welfare of Individuals Participating in Research Studies

Based on the three basic principles of The Belmont Report, there are **three core elements to human subjects protection**:

- [1] ensuring that individuals can make **informed choices** about their participation in research, and **protecting those individuals with diminished autonomy**;
- [2] ensuring that the potential **risks of a study are minimal**, or are **justified by the potential benefits**;
- [3] ensuring that the **selection of research participants is fair**, and not based simply on their easy availability, their willingness to participate, or other considerations not directly related to the problem being studied.

The key elements of a study that meet these goals are:

[1] **The informed consent process.** Informed consent is not just a signed form, but a process of communication between researchers and participants that conveys respect for the individual.

For adults able to exercise full autonomy in making choices about participating in a research study, the informed consent process should include the following:

- a statement that the study involves research, an explanation of the purposes of the research, and a description of what participation in the study will involve;
- a description of any reasonably foreseeable risks and benefits to the participant;
- if the study involves health treatments, the participant must be informed of alternative procedures or courses of treatment;
- a statement describing the extent to which confidentiality of records or data identifying the subject will, or will not, be maintained;
- for research involving more than minimal risk (see below), an explanation of the treatment or resources available if any harm occurs;
- identification of whom to contact for further information about the study (e.g., the Principal Investigator), and about participants' rights in the event of research-related harm (usually the Committee for the Protection of Human Subjects [IRB]);
- a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time.

Informed consent should usually be obtained in writing. However, the IRB can sometimes waive the written consent requirement (e.g., under conditions of minimal risk, or where written consent would jeopardize the benefits of the study). For a checklist of informed consent requirements, see <<http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm>>

For individuals with “diminished autonomy” (for example, children), informed consent procedures typically involve obtaining consent from an individual who has the legal authority to make decisions about the individual's participation in research. In the case of children, The Ethical Standards for Research with Children of the Society for Research in Child Development suggest that informed consent should be obtained from parents, legal guardians or those who act *in loco parentis* (e.g., teachers, school superintendents). Where feasible, children should also be given the opportunity to assent to participate, even if they do not fully comprehend the full significance of such assent, as well as the opportunity to refuse to participate.

[2] **Identification of the risks and benefits of the study.** “Risk” is defined as the probability of physical, psychological, social or economic harm or injury as a result of participation in a research study. “Minimal risks” are those where the probability of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily experienced in daily life or during the performance of routine psychological or physical examinations or tests. The investigator has three responsibilities: one is to reduce the risks (and maximize the benefits); the second is to explain the risks to potential participants so that participants can decide for themselves whether or not they want to take the risk; the third is to provide appropriate remedies or treatments for individuals who are harmed by the research. Where the risks are more than minimal, the investigator must provide evidence to the IRB that the benefits justify the risk.

[3] **Sample selection.** Sample selection is important because it addresses the third ethical principle of The Belmont Report: justice. Much of the research that has been done to date can be criticized on two different grounds. First, when research involves only white, middle-class males, the benefits of that research are only available to white, middle-class males (both to those who participate in the study, and to those whose health care, employment or other benefits are improved as a result of the study). A related problem associated with samples limited to white, middle-class males is that the results of those studies have been presumed, often inaccurately, to apply to men of color, women, and working class or poor individuals -- such an assumption potentially deprives these groups of the benefits of research. Second, when research uses readily-available subjects, such as soldiers, prisoners, or institutionalized individuals, or uses subjects who are disenfranchised in other ways, such as the poor, the risks of those studies fall disproportionately on the disenfranchised. Therefore, investigators are encouraged to use sampling designs that allow the benefits and risks to be fairly shared among those populations appropriate for inclusion in the study on scientific grounds.

APPENDIX B

Requesting 'Exemption from IRB Review'

The IRB guidelines describe the IRB policies, as implemented at Wellesley College. These guidelines provide details about requesting an exemption from IRB review. If you would like to request an exemption, please complete this checklist and submit it with the IRB Cover Sheet, a one-page summary of your research to Sue Wang, IRB Administrator, Wellesley Centers for Women. If only portions of your project are exempt, please submit an application for full review (see IRB Review Guidelines page 3), and indicate which portions you think are exempt. Contact Nancy Marshall, IRB Chair at x2551 if you have any questions.

Note: Protocols that have been granted exemption from Wellesley College IRB Review may still be subjected to review mandated by study sites, schools, or collaborating institutions.

Protocol Name: _____

Circle all that are true for your research:

a. Exemption 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. This exemption can apply to adults or children.

b. Exemption 2 (adults). Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior with adults, 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.

*If (i) and (ii) are true, exemption will not be granted.

c. Exemption 2 (children). Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behavior when the observer does not interact with the children, 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**
- (iii) 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.

*If (i) and (ii) are true, you will not be granted the exemption. Moreover, research with children that involves survey procedures or interview procedures with the children is not exempt.

d. Exemption 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior 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. Exemption 3 (ii) applies to children as well as adults.

- e. **Exemption 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. “Existing data” means that the data was collected prior to the start of this study, for example, court records that were on file before the initiation of a research study of court records. “Information recorded by the investigator...” would include secondary analysis of datasets without identifiers linked to subjects. It also includes studies, such as the court record review, in which the investigator records data from identified files, but does not include the identifiable information in the research dataset – that is, the investigator uses IDs that are random and unrelated to the primary data.
- f. **Exemption 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. This exemption applies to research with children as well as adults.
- g. **Exemption 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. This exemption applies to research with children as well as adults.

Note the following are not necessarily grounds for an exemption:

1. The work is not supported by a federal department or agency. Federal regulations require that non-federal research that meets eligibility requirements for review must be reviewed and approved.
2. The work is conducted outside of the United States. See source document for more details. Source: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.110>

Principal Investigator Signature: _____ Date: _____

Print Name: _____

APPENDIX C

Requesting an 'Expedited Review'

The IRB Guidelines describe the IRB policies, as implemented at Wellesley College. These guidelines provide details about requesting an exemption an expedited review by the IRB. If you would like to request an expedited review, please complete and submit this form, the IRB Cover Sheet and a 1-2 page summary (see page 3 of the Wellesley College IRB Guideline) of your project to the IRB Administrator for review. If you have any questions, please email or contact Nancy Marshall, IRB Chair, x2551.

Expedited reviews are quicker – all PIs are encouraged to request an expedited review if the circumstances warrant it, and your funder does not require a full (convened) committee review. *However, the IRB chair may still require a full, convened review of an eligible research study, if she/he considers it useful or appropriate.*

PIs 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.

Definition

“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.”

Please complete the following questions to request an expedited review.

Protocol Name: _____

1. Does your proposed research involve more than minimal risk?
“Risk” is defined as the probability of physical, psychological, social or economic harm or injury as a result of participation in a research study. “Minimal risks” are those where the probability of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily experienced in daily life or during the performance of routine psychological or physical examinations or tests.

Circle one of the following:

- a. Yes, the proposed research involves greater than minimal risk – you are not eligible for an expedited review. *Please contact the IRB Administrator for information on a fully convened IRB review.*
 - b. No, the proposed research involves no or minimal risk. *Please continue.*
2. If no, circle which of the following categories describes your research. The categories **a** through **i** in this list apply regardless of the age of subjects, except as noted.
 - a. 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 under Exemption 4 -- 45 CFR 46.101(b)(4). This listing refers only

to research that is not exempt.)³

- b. Collection of data from voice, video, digital, or image recordings made for research purposes.⁴
- c. 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 under Exemptions 2 or 3 -- 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)⁵
- d. 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.⁶
- e. 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.⁷
- f. 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 children⁸, 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.⁹
- g. 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

3 CFR 46.101 Category 5

4 CFR 46.101 Category 6

5 CFR 46.101 Category 7

6 CFR 46.101 Category 8

7 CFR 46.101 Category 9

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

9 CFR 46.101 Category 2

washings; (j) sputum collected after saline mist nebulization.¹⁰

- h.** 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.¹¹

- i.** 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.¹²

Principal Investigator Signature: _____ Date: _____

Print Name: _____

10 CFR 46.101 Category 3
11 CFR 46.101 Category 4
12 CFR 46.101 Category 1