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SUMMARY OF “REVISED COMMON RULE” CHANGES TO IRB REGULATIONS AND PROCEDURES

The Revised Common Rule (aka the Final Rule) makes the following significant changes to the Common Rule:

- Excludes certain categories of scholarly and journalistic activities, and certain types of data collection, from the definition of research that is subject to the Final Common Rule.
- Establishes a new exempt category for research with adults (educational tests, survey procedures, interview procedures, or observation of public behavior), in which identifying information is collected, provided a Limited Review is done.
- Establishes a new exempt category of research for benign behavioral interventions with adults, such as having the participants play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. This research is only exempt under certain conditions, and may require a Limited Review.
- Removes the requirement to conduct continuing review of research for studies that undergo expedited review—unless the IRB reviewer provides a justification that continuing review would enhance protection of research subjects – for research approved in 2018 or later.
- Establishes new requirements regarding the information that must be given to prospective research subjects as part of the informed consent process.
- Allows the use of broad consent (i.e., seeking prospective consent to unspecified future research) from a subject for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens.
- Creates a requirement for U.S.- based institutions engaged in cooperative research to use a single IRB (sIRB), with certain exceptions. This requirement becomes effective January 20, 2020.

Other changes of interest to the Wellesley College research community include:

- Clarifies that the terms “Written, or in writing” refers to writing on a tangible medium (e.g., paper) or in an electronic format.
- Provided new definitions of “human subject,” “private information,” and other important terms – see Appendix D.

DO THESE CHANGES AFFECT MY ONGOING (PRE-2018) RESEARCH STUDY?

Yes. Guidance from OHRP states that pre-2018 research that was reviewed under expedited procedures no longer needs continuing review. Pre-2018 research that was reviewed by a convened full IRB will continue to receive continuing/annual review.

At Wellesley College, we sent investigators a final continuing review/annual progress report to confirm the status of pre-2018 research. Once those forms are returned to the IRB office/email, that study has been transitioned to the 2018 Revised Common Rule.

Note that, while you may not need continuing review, Investigators should report to the IRB, on at least an annual basis, the withdrawal of subjects after informed consent for reasons related to the research study, or complaints from subjects or their legally authorized representatives (for example, parents or guardians). If there are no such events, investigators do not need to
provide an annual report to the IRB. See also the sections on changes in IRB-approved research, and on unanticipated problems and adverse events.

[1] WHY DO WE NEED AN IRB?

Federal policy for the protection of human subjects requires that Wellesley College establish an IRB. The Final 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 (45 CFR part 46) 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 was revised in 2018; these revisions went into effect, as the Revised Common Rule, as of 1/21/19.

The Common Rule was 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 who are vulnerable to coercion or undue influence, 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.

All disciplines have codes or guidelines addressing the ethics of research with living individuals. For example:
Sociology: http://www.asanet.org/membership/code-ethics
Psychology: www.apa.org/ethics
Anthropology: http://ethics.americananthro.org/category/statement/
Political Science: http://www.apsanet.org/RESOURCES/For-Faculty/Ethics
Oral History: http://www.oralhistory.org/information-about-irbs/
International Research Ethics Codes: http://www.codex.uu.se/en/index.shtml

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 provides the Wellesley College community with information about IRB regulations and ways to protect human subjects, reviews all planned research involving human subjects prior to initiation of the research, approves research that meets established criteria for protection of human subjects, and monitors 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 IRB review of any federally-funded or sponsored research 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 (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens,1 or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens2.

Institutions receiving federal funding, such as Wellesley College, are required to have a policy governing other research that meets the above requirements but is not federally-funded.

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1 “Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., 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.

2 “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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
RESEARCH EXCLUDED FROM IRB REVIEW, UNDER THE REVISED COMMON RULE

The following activities are deemed not to be research subject to IRB review:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Please consult with the IRB chair if you are not sure if your research requires IRB review.

WHO CONDUCTS REVIEWS AT WELLESLEY COLLEGE?

At Wellesley College, the Wellesley College IRB reviews all research supported by external funds (i.e., proposals submitted through the Wellesley College Office of Sponsored Research or Wellesley Centers for Women) including foundation, federal- and state-funded research projects, all research that requires human subjects assurance for other outside funding sources, institutional research at Wellesley College, research conducted by investigators external to Wellesley College using data from Wellesley College students, faculty or staff, or from the Child Study Center, and certain types of student research (see “Student Investigators,” below).

Individual departments are responsible for human subjects protection for all other research conducted at, or under the auspices of, Wellesley College, including student research not subject to IRB review and pilot studies.

The IRB, also known as the Committee for the Protection of Human Subjects, reports to the Wellesley College Provost, and consists of a minimum of five members of varying backgrounds, including one non-scientist, and one member who is not affiliated with Wellesley College. The IRB members are selected from the College faculty – representing a range of academic departments that conduct research subject to IRB review – and from WCW research scientists. Members, and the IRB chair, are appointed by the Provost. A list of current members is available on the Wellesley College IRB Sakai site (PROV-IRB).

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.
Types of IRB Reviews

There are five types of IRB reviews: (1) a full committee, or convened, review; (2) an expedited review; (3) a limited review and (4) a continuing review. In addition, some research with human subjects is (5) exempt from review. You may also submit an amendment to a previously IRB-approved research study - See "Changes in IRB-Approved Research."

Exemption from Review

Federal regulations stipulate that you are exempt from IRB review if your research fits in one of the specified categories; see Appendix B: Requesting Exemption from IRBReview for details.

The Wellesley College IRB encourages investigators to request a memo from the IRB documenting the exemption. Because journals and publishers are increasingly requiring IRB review or documentation of exempt status, this memo protects your publication options in the future.

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

Guidance on changes to Exempt categories is available.

Limited Review

Limited IRB Review is a new concept added by the Revised Common Rule and is relevant to certain new exemptions (Categories 2(iii), 3(i)(C), 7, and 8) in the Revised Common Rule. In a limited IRB review, an IRB must conduct a review and make certain determinations as a condition of exemption.

For research exempt under categories 2(iii), 3(i)(C), and 8, the IRB must determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For purposes of conducting the limited IRB review required for exemption category 7, the IRB need not make the above determinations, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § II.116(a)(1)–(4), (a)(6), and (d); (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § II.117; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

The Limited IRB Review can be conducted through an expedited review procedure by the IRB chair or a designated member of the IRB.

Guidance on Limited Review is available.
EXPEDITED REVIEW

Research that involves only minimal risk to the subject may receive expedited review by the IRB chair or a designated member of the IRB, if it meets other criteria (see Appendix C). “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. If a Principal Investigator wishes to apply for an expedited review, please read the guidelines on Requesting an Expedited Review in Appendix C and follow IRB submission instructions under section [5] “What do I submit to the IRB?”

FULL REVIEW

Research that is not exempt from review, and not eligible for expedited review, receives a full review by the convened IRB Committee. Full reviews are scheduled as needed; therefore, Principal Investigators should communicate with the IRB Administrator or the IRB Chair prior to submitting the IRB proposal so that a meeting can be scheduled in as timely a manner as possible. During the academic year, meetings can be scheduled within a month; during the summer, it may take longer.

CONTINUING REVIEW

The IRB is required by the Revised Common Rule (Section II.109(e)) to conduct continuing review of research requiring review by the convened IRB (aka full review) at intervals appropriate to the degree of risk, not less than once per year. Each year, the IRB Administrator will send PIs an Annual Progress Report to complete. Continuing reviews are required until the research involves only data analysis, or “accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care” – unless the IRB reviewer provides a justification that continuing review beyond this point would enhance protection of research subjects.

Under the Revised Common Rule (Section II.109(f)), continuing review is not required for research subject to expedited review or limited review, or that is exempt, unless the reviewer explicitly justifies why continuing review would enhance protection of research subjects. Investigators still have the obligation to report various developments (such as unanticipated problems, adverse events or proposed changes to the study) to the IRB.

PRE-2018 RESEARCH. Research that received expedited review prior to 2018 has been transitioned to the 2018 Revised Common Rule. At Wellesley College, we sent investigators a final continuing review/annual progress report to confirm the status of pre-2018 research. Once those forms are returned to the IRB office/email, that study has been transitioned to the 2018 Revised Common Rule.

ANNUAL REPORTING. The discontinuing of continuing review for most research means that the IRB Administrator will no longer send Annual Progress Reports to PIs. However, Investigators should report to the IRB, on at least an annual basis, the withdrawal of subjects after informed consent for reasons related to the research study, or complaints from subjects or their legally authorized representatives (for example, parents or guardians). If there are not such events, investigators do not need to provide an annual report to the IRB. See also the sections on changes in IRB-approved research, and on unanticipated problems and adverse events, below.
CHANGES IN IRB-APPROVED RESEARCH

The Revised Common Rule allows the IRB to use expedited review procedures for minor changes in previously approved research during the period for which approval is authorized. For research that received full committee review, discuss with the IRB chair whether the changes require a full review, and can be reviewed under expedited procedures.

Changes that should be submitted to the Wellesley College IRB for review include:

- Significant changes\(^3\) in your subject recruitment or selection/exclusion procedures, or in your research protocol (including in questionnaires, interviews or other data collection procedures, or in research sites/locations).
- Changes in the informed consent procedures or the informed consent form(s) that alter the information given to participants with respect to procedures, risks and/or benefits, or that might affect their willingness to participate.
- Changes in data monitoring procedures to protect the safety of participants, such as monitoring for suicidal ideation, or other risks of harm to self or others.
- Changes in procedures that were designed to reduce any risks to participants, such as procedures to protect confidentiality.
- Other changes that may affect the risks to subjects, or the balance of risks and benefits.
- Changes in the PI or other key personnel (you do not need to report changes in student assistants, research assistants or other staff, unless they are key personnel. Key personnel = contribute to the science of the research, through theory, design, analysis or interpretation).

You do not need to submit amendments for minor changes, such as:

- Minor changes to wording of the recruitment materials that do not alter the risks or benefits to study participants (e.g., addition of a sentence to provide more information about timing or scheduling ["Participants needed over the next two weeks. Study will last 30 minutes."])
- Minor procedural changes that do not alter the risks or benefits to study participants or that would reduce risk to participants (e.g., changes in the order of task administration; minor adjustment of the number of trials used; discontinuing the use of an approved self-report measure; omitting a portion of an approved experimental task).
- Editorial changes that clarify but do not alter the existing meaning of an approved document (including the consent form) or instrument.
- Correction of typographical errors on the consent form.
- Inclusion of new Wellesley College student research assistants with appropriate human subjects training and under the supervision of a faculty mentor.

The IRB office must have copies of the most up-to-date protocols and consent documents, even if they did not require an IRB amendment. When in doubt, consult with the IRB chair, Nancy Marshall, nmarshall@wellesley.edu. Please email revised recruitment materials, informed consent forms and descriptions of minor changes to the research protocol to irb@wellesley.edu.

\(^3\) “Significant changes” include changes that might affect the risks to subjects, or their willingness to participate, as well as changes in the sample selection criteria that might alter the distribution of the benefits or burden of the study to subpopulations.
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 specific instructions, below, for Initial Reviews (Full committee or Expedited Reviews), requests for Exemption and Amendments for previously approved research.

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

HOW TO SUBMIT

We prefer submissions be sent by email to irb@wellesley.edu. Forms with signatures may be scanned for email – we do not require original “wet” signatures. Please indicate in subject line the Type of Review or request.

If you are submitting hardcopy, please send your IRB submissions to:

Campus mail: Kenji Thrash-Correia, WCW-Cheever
Off-campus: Kenji Thrash-Correia, IRB Administrator, Wellesley College, 106 Central Street, Wellesley, MA 02481

Fax: (781) 283-2504

If you are requesting an expedited review, or an exemption, and need a response in less than one week, please also email a copy of your submission to Nancy Marshall, IRB Chair, at nmarshall@wellesley.edu.

CRITERIA FOR IRB APPROVAL

The IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:
   (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
   (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (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 subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
(4) Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by, § II.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § II.117.

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

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

(8) For purposes of conducting the limited IRB review required by § II.104(d)(7)), the IRB need not make the determinations at paragraphs (1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § II.116(a)(1)–(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § II.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

FOR INITIAL REVIEWS (FULL REVIEW OR EXPEDITED REVIEWS):

When you submit your proposal to the IRB for an initial review, please include the following documents:

1. A completed and signed Wellesley College IRB Cover Sheet (see Appendix A or IRB website Forms).
   a. If you are an external researcher (do not hold a Wellesley College appointment), please indicate on the cover sheet that you have received OIR approval or CSC approval (see External Researchers).
   b. If you are a Wellesley College student, please see the section on Student Investigators.

2. A 2-3 page project description (see the IRB website Forms for an optional template). The project description should focus on the issues important to an IRB review; be sure to include:
   a. **Overview.** An overview of your research, including research questions. Extensive background literature is not necessary.
   b. **Participants.** 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.
c. **Informed Consent.** Description of informed consent procedures (see Guidance). 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. Attach informed consent forms or include a justification for waiver of documentation of consent.

d. **Procedures.** Information about the data you will collect on these subjects -- what information 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.

e. **Measures.** 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. If you are using standard measures, please briefly describe the content and purpose of the measure (as you would in a journal article or proposal); you do not need to include copies of standard measures. If the measures are not yet developed, please describe the expected content; the IRB may request that you submit the final measures before beginning the research.

f. **Risks.** 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.

g. **Benefits.** 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. → this is where you would briefly describe the scientific gains of your research; do not include as much detail as you would for a funding proposal.

h. **FDA.** Indicate if your research is subject to The Food and Drug Administration (FDA) regulations. The FDA is an HHS agency that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices. The FDA may require additional human subject protections for your project.

3. If applying for an expedited review, please also attach a completed and signed ‘Requesting an Expedited Review’ form (see the IRB website Forms or Appendix C, below).

**TO REQUEST AN IRB EXEMPTION MEMO**

Please include:

1. A completed and signed Wellesley College IRB Cover Sheet (see Appendix A).
2. A 2-3 page project description (see the IRB website Forms for an optional template). You do not need to include copies of informed consent forms, measures or experimental protocols.
3. A completed and signed ‘Requesting Exemption from IRB Review’ form (see the IRB website Forms, or Appendix B, below).
FOR EXEMPTIONS REQUIRING A LIMITED REVIEW

For Exemption categories 2(iii), 3(i)(C), and 8:
1. Submit the above (Cover Sheet, Project Description, Exemption form), plus:
2. Sufficient description of the “provisions to protect the privacy of subjects and to maintain the confidentiality of data” for the IRB to determine that there are adequate provisions for privacy and confidentiality.

For Exemption category 7:
1. Submit the above (Cover Sheet, Project Description, Exemption form), plus:
2. Description of the broad consent procedures, and a copy of the broad consent form, sufficient for the IRB to determine whether:
   a. Broad Consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § II.116(a)(1)–(4), (a)(6), and (d);
   b. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § II.117; and
   c. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Note: As best as we can tell, from the guidance currently available, whether the study requires both an Informed Consent form and a Broad Consent form depends on the content of the study. Contact the IRB chair to discuss any questions about this as you prepare your application.

FOR AMENDMENTS TO AN IRB-APPROVED STUDY

Please submit changes to an IRB approved research study as an amendment:

1. A completed and signed Wellesley College IRB Cover Sheet (see Appendix A), using the same principal investigator’s name and the same title of the protocol as the Approved Research –
2. Add to the title “Amendment N,” where “N” is the number of the IRB amendment (1, 2, etc).
3. A brief description of the changes that need to be reviewed, including a description of the original/approved procedures, subjects or methods.
4. A ‘Requesting an Expedited Review’ form with the appropriate category checked.

See “Changes in IRB-Approved Research,” above, for more information about when an amendment is necessary.
GUIDANCE ON INFORMED CONSENT

INFORMED CONSENT. Informed consent is not just a signed form, but also a process of communication between researchers and participants that conveys respect for the individual. We provide a narrative on the required elements here, as well as guidance on specific situations.

The IRB website provides a checklist for informed consent, and an optional template for informed consent forms for research eligible for an expedited review in Forms.

For adults able to exercise full autonomy in making choices about participating in a research study, the informed consent process, including the informed consent form, 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;
- 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 as to whether any compensation, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what the treatments consist of, or where further information may be obtained;
- 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, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
- A notice about whether or not a participants' identifiable private information or identifiable biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future.

New informed consent requirement. The Revised Common Rule (45 CFR 46.116(a)(5)(i)) requires that informed consent forms begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research (referred to as a “preamble” or “summary” by some). This part of the informed consent must be organized and presented in a way that facilitates comprehension.

WRITTEN CONSENT AND WAIVER OF WRITTEN CONSENT. Informed consent should usually be obtained in writing (“writing on a tangible medium (e.g., paper) or in an electronic format”); a copy should be given to the person signing the informed consent form. There is also a “short form” option described in the regulations at §.117(b)(2).

The IRB can sometimes waive the written consent requirement; if written consent is waived, oral consent is still required and must provide all of the above information. When the written documentation of consent is waived and oral consent is approved, the IRB may require that participants be given a written copy of the above information.

The IRB may waive the requirement of a signed informed consent form for some or all participants if it finds any of the following:
i. That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality.

ii. 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; or

iii. If the participants or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

PARENTAL CONSENT/CHILD ASSENT. 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.

WAIVER OR ALTERATION OF INFORMED CONSENT. Informed consent may be waived or altered under certain conditions.

Waiver. An IRB may waive the requirement to obtain informed consent provided the IRB finds and documents that:

i. The research involves no more than minimal risk to the subjects;

ii. The research could not practicably be carried out without the requested waiver or alteration;

iii. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

iv. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

v. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Alteration. If a total waiver is not approved, an IRB may approve a consent procedure that omits or alters some of the elements of informed consent. However, there are complicated restrictions on alterations, and the Revised Common Rule does not allow the IRB to approve alterations of the general requirements under §___.116(a), including requirements that (1) informed consent is obtained prior to beginning the research, (2) without coercion and under circumstances that allow opportunity to discuss and consider whether or not to participate, (3) with information presented in language that is understandable to the participant or legally authorized representative, (4) the participant is provided with the information a “reasonable person” would want to have, (5) the informed consent begins with a concise and focused presentation of the key information, and (6) does not include any exculpatory language that waives or appears to waive “any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.” Alterations must also meet the same conditions as those for a waiver of informed consent.
If a broad consent procedure is used, an IRB may not omit or alter any of the elements required for broad consent.

**WAIVER OF INFORMED CONSENT FOR SCREENING, RECRUITING, OR DETERMINING ELIGIBILITY.** An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant or the participant’s legally authorized representative, if either of the following conditions are met:

i. The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, **or**

ii. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

**BROAD CONSENT.** The Final Common Rule allows the use of “broad consent” (i.e., seeking prospective consent to unspecified future research) from a research participant for storage, maintenance, and secondary research use of identifiable private information and identifiable biospecimens. Broad consent is an optional alternative that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, requesting an institutional review board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study. See the Revised Common Rule, §___.116(a)(1)–(4), (a)(6) and (d). Guidance on Broad Consent is available from OHRP.

If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
INVESTIGATOR RESPONSIBILITIES

(Adapted from OHRP) Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB. Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include, in summary:

- obtaining and documenting informed consent of subjects or subjects’ legally authorized representatives prior to the subjects’ participation in the research, unless these requirements have been waived by the IRB;
- obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects; and
- ensuring that amendments, requests for continuing review and approval, and notification of completion of the research study are submitted to the IRB in accordance with IRB policies and procedures.
- providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others;
- providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB; and
- keeping certain records, including informed consent forms, as required by the HHS regulations for at least three years after completion of the study.

EXTERNAL RESEARCHERS/NO WELLESLEY COLLEGE APPOINTMENT

Step 1: Institutional Approval

Research with Wellesley College students, faculty or staff. If you are an external researcher (i.e., you do not have a Wellesley College appointment), or your co-PI is an external researcher, AND you are conducting research using members of the Wellesley College community (students, faculty or staff), please review and comply with the Wellesley College Office of Institutional Research (OIR) policy on external researchers, prior to contacting the Wellesley College IRB. NOTE: If you are an external researcher working with a Wellesley College faculty member or a WCW research scientist, you may still need OIR approval.

Research conducted at the Child Study Center (CSC). If you are an external researcher (i.e., you do not have a Wellesley College appointment) AND you are conducting research at the Child Study Center, please contact the Child Study Center Director first info@childstudycenter, who will coordinate all approvals.

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4 If all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished, then the human subjects research study has been completed.
Step 2: IRB Approval (by which institution?)

If Wellesley College is only a recruitment or data collection site (no College faculty or researcher is a member of the investigator team with scientific oversight), IRB review should be done by your home institution before contacting Wellesley College.

If the PI is located at Wellesley College, and the external researcher is a colleague at another institution, the IRB review will be done at Wellesley College, after OIR/CSC approval.

If the PI is located elsewhere, and the Co-PI is a faculty or staff member of Wellesley College, contact the Wellesley College IRB at irb@wellesley.edu to determine which IRB should do the initial IRB review. Include "IAA" in the subject line.

If the PI or Co-PI is a Wellesley College student, see Student Investigators.


Once an IRB review is done by the appropriate body, and OIR has approved the research, request an IRB Authorization Agreement (IAA) between the IRB at your home institution and Wellesley College IRB.

If the IRB review was done by Wellesley College, use the "IRB Authorization Wellesley College" template, available in Forms.

If the IRB review was done by the external researcher's home institution, use the "IRB Authorization Other Institution" template, available in Forms.

Any questions, please email the IRB at irb@wellesley.edu. Include "IAA" in the subject line.

STUDENT INVESTIGATORS

Students conducting research subject to IRB regulations, or with questions about IRB review should refer to the Wellesley College IRB Guide for Student Investigators and complete the Application for IRB Review: Student Investigator, available on the IRB website. Students do not need to complete the IRB Cover Sheet, or the forms for requesting Exempt Review or Expedited Review.

TRAINING REQUIREMENTS

Before research can begin, all research personnel, including research assistants, must complete the above training. You cannot receive IRB approval until the certificate is on file or available to the IRB through the Office of Sponsored Research.

According to guidance from the Office for Human Research Protections, “The HHS regulations for the protection of human subjects (45 CFR part 46) do not require investigators to obtain training in the protection of human subjects in research. However, an institution holding an OHRP-approved Federalwide Assurance (FWA) is responsible for ensuring that its investigators conducting HHS-conducted or -supported human subjects research understand and act in accordance with the requirements of the HHS regulations for the protection of human subjects.”
All researchers (faculty; researchers; research assistants, including students; external researchers) are required to:

- Review the IRB Guide (which you are now reading)
- Complete the CITI Responsible Conduct of Research training, which includes a human subjects module. See the IRB website for customized instructions on completing Citi training.
- **If you are a faculty or WCW PI or Co-PI**, it is recommended that you also take the "Revised Common Rule" course before January 21, 2019 (course is now available). **Research assistants and student investigators do not need to take this course.** NOTE: If you attended the December 7, 2018 training, you do not need to complete this online course; the slides from the December training are available online. Questions? Contact the IRB chair, Nancy Marshall.

See the IRB website for customized instructions on completing Citi training.

Link to Citi: [https://www.citiprogram.org](https://www.citiprogram.org)

Upon completion of the course, the Office of Sponsored Research will automatically receive a completion notification.

**Note:** The Office of Sponsored Research requires certain personnel on externally-funded research projects to complete a separate Responsible Conduct of Research course - this includes an IRB module as well, which the IRB will accept to meet the IRB training requirement. View the Research Integrity Policy [here](#).

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**SECURE DATA STORAGE AT WELLESLEY COLLEGE**

Investigators are required to describe “the extent, if any, to which confidentiality of records identifying the subject will be maintained” as part of the informed consent procedure. Investigators therefore often seek to provide the maximum confidentiality for identified data about research participants. Wellesley College provides guidance on storage of data files. Per this policy, “Library and Technology Services will provide secure file storage space, maintain the servers and provide back-up for the data. The Chief Information Officer has responsibility for this policy.” Investigators should be familiar with these options, and address any questions or concerns to the Chief Information Officer.

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**RESEARCH WITH CHILDREN AND OTHER VULNERABLE PARTICIPANTS**

“When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IRB shall determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects.”

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. For more information, see OHRP guidance.
REPORTING UNANTICIPATED PROBLEMS AND ADVERSE EVENTS

The Office of Human Research Protections (OHRP) defines an Adverse Event as “any untoward or unfavorable medical occurrence in a human subject, temporally associated with a research study, whether or not it is related to the study.” This includes both psychological and physical harms.

**Most Adverse Events are not Unanticipated Problems.** OHRP defines an Unanticipated Problem as “any incident, experience, or outcome that meets all of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.”

**Investigators are required to report Unanticipated Problems to the IRB and other officials promptly.** OHRP recommends the following time frames for reporting:

1. Unanticipated problems that are serious adverse events should be reported to the IRB within one week of the investigator becoming aware of the event.

2. Any other unanticipated problem should be reported to the IRB within two weeks of the investigator becoming aware of the problem.

3. All unanticipated problems should be reported to appropriate institutional officials (at Wellesley College, that person is the Provost), the supporting agency head (or designee), and OHRP within one month of the IRB’s receipt of the report of the problem from the investigator.

Adverse events that are not unanticipated problems are not subject to these reporting requirements. However, the Wellesley College IRB expects investigators to report any adverse events to the IRB; adverse events are considered in determining whether and when continuing review is required.

Because much of the research at Wellesley College is social or behavioral research, we provide here an example from OHRP of an adverse event that is not an unanticipated problem, to illustrate the importance of anticipating risks, describing risks during informed consent, and establishing procedures to reduce risks.

From OHRP: “An investigator is conducting a psychology study evaluating the factors that affect reaction times in response to auditory stimuli. In order to perform the reaction time measurements, subjects are placed in a small, windowless soundproof booth and asked to wear headphones. The IRB-approved protocol and informed consent document describe

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5 A Serious Adverse Event is an Adverse Event that results in hospitalization or a persistent or significant disability/incapacity, is life-threatening or results in death, or may jeopardize the subjects health such that it requires medical/surgical intervention to prevent disability/incapacity or death.
claustrophobic reactions as one of the risks of the research. The twentieth subject enrolled in the research experiences significant claustrophobia, resulting in the subject withdrawing from the research. This example is not an unanticipated problem because the occurrence of the claustrophobic reactions – in terms of nature, severity, and frequency – was expected.” Additional guidance on unanticipated problems and adverse events is available from OHRP.

ADDITIONAL GUIDANCE

Additional guidance on IRB regulations, informed consent procedures and forms, exemptions and expedited reviews, etc. can be found on the Wellesley College IRB website, as well as on the Office for Human Research Protections (OHRP) website.
APPENDIX A: IRB COVER SHEET

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

Researcher/Principal Investigator: __________________________
Academic Department/Institution: __________________________ Date of IRB Submission ________
Start date of Project: _________ Anticipated completion date:\(^6\): _________
Title of Project: __________________________________________________________

Purpose of the Project:

Funding Source (proposal submitted to, or project funded by) (check all that apply)
[ ] federal agency; [ ] other external funding source; [ ] Wellesley College; [ ] unfunded
Specify source: ___________________________________

Type of Project (check all that apply; See IRB Guide for more information):
[ ] Institutional research (OIR or other Wellesley College administrative office):
  * Has your project been approved by the Office of Institutional Research? [ ] yes [ ] no
[ ] External researcher (PI or Co-PI) using Wellesley College students, faculty or staff:
  * Has your project been approved by the Office of Institutional Research? [ ] yes [ ] no
[ ] External researcher using the Child Study Center:
  * Has your project been approved by the Child Study Center? [ ] yes [ ] no
[ ] Student Investigator: → Use the separate Student Investigator application, not this cover sheet.

Required Training (See IRB Guide for instructions):

Have you completed the required IRB training? [ ] yes [ ] no

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 act 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:

__________________________________________________________    ______________

Signature of Researcher or Principal Investigator                                              Date

________________________

\(^6\) If all research-related interventions or interactions with human subjects have been completed, and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished, then the human subjects research study has been completed.
APPENDIX B: REQUESTING ‘EXEMPTION FROM IRB REVIEW’

If you would like to request an exemption, please complete and submit the following form. If you have any questions, please email Nancy Marshall, IRB Chair. If only portions of your project are exempt, please submit an application for full or expedited review, as appropriate, and indicate which portions you think are exempt. Contact Nancy Marshall, IRB Chair at nmarshal@wellesley.edu if you have any questions.

PIs are reminded that research that is exempt from IRB review should still meet the ethical standards for research within the PI’s academic discipline.

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

See the IRB Guide, or the IRB website, for instructions on what to submit for an Exemption review.

PI: ______________________________________

Protocol Title: ______________________________________

Which of the Exemption categories apply? ______________________________________
Please include the i, ii, iii for exemptions with multiple parts.

NOTE: Limited Review is required for Exemption Categories 2(iii), 3(i)(C), 7, and 8.

DO EXEMPTIONS APPLY TO CHILDREN, PREGNANT WOMEN, PRISONERS?

All of these exemptions may be applied to research subject to subpart B (additional protections for pregnant women, human fetuses, and neonates) if the conditions of the exemption are met.

None of these exemptions may be applied to research subject to subpart C (additional protections for prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners. See the definition of “prisoners” in Appendix D.

Some of these exemptions may be applied, and others may not be applied, to subpart D; these variations are noted in the following list of exemption categories.
**EXEMPTION CATEGORIES**

**Exemption 1.** Research, conducted in established or commonly accepted [educational settings](#), that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Exemption 2 (adults).** Research that only includes interactions involving [educational tests](#) (cognitive, diagnostic, aptitude, achievement), [survey procedures](#), [interview procedures](#), or [observation of public behavior](#) (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

(ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § II.111(a)(7). **Limited Review required for category 2 (iii)**

**Exemption 2 (children).** Research that only includes interactions involving [educational tests](#) (cognitive, diagnostic, aptitude, achievement), or [observation of public behavior](#) (including visual or auditory recording) when the investigator(s) do not participate in the activities being observed if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

(ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation.

Note: research with children that involves survey procedures or interview procedures with the children is not exempt. In addition, exemption 2(iii) cannot be applied to research with children.

**Exemption 3.** (i) Research involving [benign behavioral interventions](#) in conjunction with the collection of information from an [adult](#) subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; OR
(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § II.111(a)(7). ** Limited Review required for 3(i)(C)

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Exemption 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Exemption 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.
Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

**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.

**Exemption 7. Storage or maintenance for secondary research for which broad consent is required:** Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §II.111(a)(8). **Limited Review required**

**Exemption 8. Secondary research for which broad consent is required:** Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: **Limited Review required**

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §II.116 (a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §II.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §II.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i)of this section; and (iv)The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
APPENDIX C: REQUESTING AN ‘EXPEDITED REVIEW’

Instructions
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 “What To Submit”) of your project to the IRB Administrator, Kenji Thrash-Correia, irb@wellesley.edu. If you have any questions, please email Nancy Marshall, IRB Chair.

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.

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.

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.

Request an Expedited Review
Please complete the following questions to request an expedited review.

PI ____________________________

Protocol Name: ____________________________

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 or mark one of the following:

- Yes, the proposed research involves greater than minimal risk – you are not eligible for an expedited review. Please contact the IRB Administrator, Kenji Thrash-Correia, irb@wellesley.edu, for information on a full (convened) IRB review.
- No, the proposed research involves no or minimal risk. Please continue.

If no, which of the categories (below) describes your research: ____________________________

Principal Investigator Signature: ____________________________ Date: ____________________________
RESEARCH CATEGORIES ELIGIBLE FOR EXPEDITED REVIEW

The categories in this list apply regardless of the age of subjects, except as noted.

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, 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 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) uncanulled 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.)

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). In Massachusetts, the age of consent for medical treatment is 18.
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 under Exemption 4 -- 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 under Exemptions 2 or 3 -- 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
   (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
APPENDIX D: DEFINITIONS

Definitions effective as of 1/21/2019

§1.102 Definitions for purposes of this policy. (numbering and order adapted for readability)

1. Certification means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

2. Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3. Department or agency head means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

4. Federal department or agency refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

5. Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

6. An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

7. Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

9 Federal departments or agencies implementing this policy shall: (i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of “identifiable private information,” as defined in paragraph (e)(5) of this section, and “identifiable biospecimen,” as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate “identifiable private information,” as defined in paragraph (e)(5) of this section, or an “identifiable biospecimen,” as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the Federal Register after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.
8. **Institution** means any public or private entity, or department or agency (including federal, state, and other agencies).

9. **Interaction** includes communication or interpersonal contact between investigator and subject.

10. **Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

11. **IRB** means an institutional review board established in accord with and for the purposes expressed in this policy.

12. **IRB approval** means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

13. **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.

14. **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.

15. **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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

16. **Public health authority** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

17. **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 conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

   (1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

   (2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to perform its public health duties.
health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

18. Written, or in writing, for purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

Additional definitions

19. Prisoner. The regulations define “prisoner” as follows:

“Prisoner” means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).

Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.

Common examples of the application of the regulatory definition of prisoner are as follows:

- Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.

- Individuals with psychiatric illnesses who have been committed involuntarily to an institution as an alternative to a criminal prosecution or incarceration are prisoners; however, individuals who have been voluntarily admitted to an institution for treatment of a psychiatric illness, or who have been civilly committed to nonpenal institutions for treatment because their illness makes them a danger to themselves or others, are not prisoners.

- Parolees who are detained in a treatment center as a condition of parole are prisoners; however, persons living in the community and sentenced to community-supervised monitoring, including parolees, are not prisoners.

- Probationers and individuals wearing monitoring devices are generally not considered to be prisoners; however, situations of this kind frequently require an analysis of the particular circumstances of the planned subject population. Institutions may consult with OHRP when questions arise about research involving these populations.
20. For Exemption Category 3: *benign behavioral interventions* are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.