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SUMMARY OF REVISED IRB REGULATIONS AND PROCEDURES EFFECTIVE JULY 19, 2018

The Revised Common Rule makes the following significant changes to the Common Rule, as of July 19, 2018. Other changes are expected in January 2019.

- 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.
- 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.

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 will send investigators a final continuing review/annual progress report to confirm the status of pre-2018 research. Please return these forms promptly.

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 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 Revised 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 Final Common Rule, a revision of the Common Rule, goes into effect in January 2019; however, certain changes may be implemented as of July 19, 2018 (see above for a summary).

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 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:
- Anthropology: http://ethics.americananthro.org/category/statement/
- Oral History: http://www.oralhistory.org/about/principles-and-practices/
- Political Science: http://www.apsanet.org/ethics/code/
- Psychology: http://www.apa.org/ethics/code/
- Sociology: http://www.asanet.org/about/ethics.cfm
- 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

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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.
biospecimens. 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.

RESEARCH EXCLUDED FROM IRB REVIEW, UNDER THE FINAL RULE

NEW: 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.

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.
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). You will need to login to MyWellesley to view this Sakai page.

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.

[4] TYPES OF IRB REVIEWS

There are four types of IRB reviews: (1) a full committee, or convened, review; (2) an expedited review; and (3) a continuing review. In addition, some research with human subjects is (4) exempt from review.

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 IRB Review 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.

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 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. **NEW:** 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.

**NEW:** Under the Revised Common Rule, continuing review is not required for research that is eligible for expedited 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.

**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 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, below.

**PRE-2018 RESEARCH.** 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 will send investigators a final continuing review/annual progress report to confirm the status of pre-2018 research. Please return these forms promptly.

**CHANGES IN IRB-APPROVED RESEARCH**

The 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).

\(^3\)“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.
• 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).

These changes should be submitted to the IRB for review as an amendment, using the IRB Cover Sheet (see below) and a brief summary of the changes, as well as copies of any revised informed consent forms. On the IRB Cover Sheet, please use the principle investigator’s name used in the original submission, and the same title of the protocol – but add to the title “Amendment N,” where “N” is the number of the IRB amendment (1, 2, etc).

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.

[5] 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 of this Guide, which describes the criteria for IRB review, and outlines ways to protect the rights and welfare of individuals participating in the project.

Proposals may be submitted via email, to irb@wellesley.edu or in hard copy (see Section 7 of this Guide). Forms with signatures may be scanned for email – we do not require original “wet” signatures.
When you submit your proposal to the IRB, please include the following documents:

1. A completed and signed Wellesley College IRB Cover Sheet (see below).
   - If you are an external researcher, please see the section of this Guide on external researchers, and check the appropriate boxes on the Cover Sheet.
   - If you are a Wellesley College student, please see the section on Student Investigators (below).

2. A 2-3 page description of the project (see the website for a template). The project description should focus on the issues important to an IRB review; be sure to include:
   - A one paragraph overview of your research, including research questions. Extensive background literature is not necessary.
   - 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.
   - 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.
   - 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 for review before beginning the research.
   - Description of informed consent procedures. 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 written consent.
   - 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.
   - 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. \( \text{→ this is where you would briefly describe the scientific gains of your research; do not include as much detail as you would for a funding proposal.} \)
3. 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.

4. If applying for an exemption from review, please attach a completed and signed ‘Requesting Exemption from IRB Review’ form (see Appendix B).

5. If applying for an expedited review, please attach a completed and signed ‘Requesting an Expedited Review’ form (see Appendix C).

6. If submitting an amendment to an already-approved protocol, please see the instructions under “Changes in IRB-Approved Research.”

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

[6] TRAINING REQUIREMENTS

Before research can begin, all research personnel, including research assistants, must complete appropriate human subjects training. You cannot receive IRB approval until the Citi completion report is on file. This training must be renewed every three years.

All researchers (faculty; WCW researchers; research assistants, including students; external researchers) are required to:

1. Review the IRB Guide available here.
2. Complete the CITI Human Subjects Research training in "Social & Behavioral Research."
3. If you are a faculty or WCW PI or Co-PI, you should also take the "Revised Common Rule" course (this was not yet available, as of 7/1/18). Research assistants and student investigators do not need to take this course.
4. To take the Citi training(s), follow these steps:
   a. Click this Link to reach the Citi training page.
   b. Click on the login button (top right). If you don't have an account, at the login page, click on "Register" to create an account.
   c. After you login, click "Wellesley College courses." This shows the courses you have completed, plus provides a list of additional tasks you can perform.
   d. Click "add a course." This takes you to a screen that asks you which courses you want to take. If you have questions, email the IRB chair, Nancy Marshall. The questions may vary in order, but here are the answers that will give you only the courses you need to take.

   - **Human Subjects Research.** Select your role - most are "investigators."
   - **Responsible Conduct of Research.** Check "not at this time." (see Note, below)
   - **[Question about Biosafety courses]**. Leave blank.
   - **Conflicts of Interest course.** Check "No."
   - **Animal Care and Use course.** Check "not at this time."
   - **Revised Common Rule course.** PIs and Co-PIs should take this course.
e. Click "submit." Screen will say you are now enrolled in the course you selected.

f. From your course list, select/click "Social and Behavioral Research" - this is the Human Subjects course.

   - Take all 9 required modules. Consider taking optional modules related to your research project.
   - For each page, read the webpage & watch any videos, before taking the quiz.

g. After completing the course, access your completion report ("post-course completion options").

h. Download the report (not the certificate) and email it to irb@wellesley.edu. Thank you. The report shows your score, while the certificate does not; the IRB requires the report be submitted.

**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](#).

**What the regulations say:** According to guidance from the Office for Human Research Protections (OHRP), "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."

The FWA requires that Wellesley College provide training "to ensure that investigators maintain continuing knowledge of, and comply with, the following:

   - relevant ethical principles;
   - relevant federal regulations;
   - written IRB procedures;
   - OHRP guidance;
   - other applicable guidance;
   - state and local laws; and
   - institutional policies for the protection of human subjects."

Reading the Wellesley College IRB Guide and completing the Citi training, described above, meets this requirement at a basic level. In addition, the IRB recommends that all researchers stay current on guidance and information from their professional associations and from OHRP.
INVESTIGATOR RESPONSIBILITIES DURING THE CONDUCT OF IRB-APPROVED RESEARCH

(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 study4.

NON-WELLESLEY COLLEGE RESEARCHERS (“EXTERNAL RESEARCHERS”)

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. 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.

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.
The sequence of approvals for external researchers is:

1. 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.

2. Institutional approval from OIR (and from the Child Study Center, if using CSC).

3. 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 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 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.

4. 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. Please email the IRB for next steps, at irb@wellesley.edu

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; See Student Investigators. Students do not need to complete the IRB Cover Sheet, or the forms for requesting Exempt Review or Expedited Review. Student investigator research does not receive continuing review.

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.

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 events⁶ 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 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 at the [OHRP website](https://ohrp.osirb.gov).

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⁶ 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.
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, visit the OHRP website on “Subpart D research.”

Research with Children FAQ
Research with Prisoners and others in the criminal justice system

INTERNATIONAL RESEARCH

Are you planning to conduct research in countries other than the U.S., or with individuals living outside of the U.S.? If so, you are responsible for complying with any regulations that apply in those countries. See the right Side Bar on the IRB main webpage for links for information. If you are conducting research with individuals living in the European Union, you also must comply with new EU General Data Protection Regulations (GDPR).

The IRB is not responsible for approving or advising on your compliance with these additional regulations.

ADDITIONAL GUIDANCE AND RESOURCES

Additional guidance on IRB regulations, informed consent procedures and forms, exemptions and expedited reviews, etc. can be found on the Wellesley College IRB Sakai site (PROV-IRB) and on the IRB website.

ELECTRONIC SIGNATURES AND ALTERNATIVES

Guidance from OHRP allows the use of faxes of signed informed consent forms, which we interpret to also allow PIs to accept scans of signed informed consent forms. The Wellesley College IRB will also accept faxed or scanned signed IRB applications/proposals. These faxed or scanned documents do not need to be supplemented with hard copy or an electronic signature.

OHRP Guidance on faxed informed consent forms:

Is a faxed copy of the signed consent or parental permission form acceptable to document informed consent?

Yes, if it is more convenient for the subjects or parents of children who are subjects to fax a signed copy of the consent or permission form to the investigator, the research subjects or...
parents may fax the signed form. The subjects or parents need not provide the investigator with the original signed consent or parental permission documents.

**OHRP Guidance on electronic signatures:**

**Can an electronic signature be used to document consent or parental permission?**

Yes, under certain circumstances. First, the investigator and the IRB need to be aware of relevant laws pertaining to electronic signatures in the jurisdiction where the research is going to be conducted.

Unless the IRB waives the requirement for the investigator to obtain a signed consent or permission form based on the HHS regulations at 45 CFR 46.117(c), a written consent or permission form, which may be an electronic version, must be given to and signed by the subjects or the subjects’ legally authorized representatives or the parents of subjects who are children. Some form of the consent document must be made available to the subjects or the parents of subjects who are children in a format they can retain. OHRP would allow electronic signature of the document if such signatures are legally valid within the jurisdiction where the research is to be conducted.

OHRP does not mandate a specific method of electronic signature. Rather, OHRP permits IRBs to adopt such technologies for use as long as the IRB has considered applicable issues such as how the electronic signature is being created, if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject. One method of allowable electronic signatures in some jurisdictions is the use of a secure system for electronic or digital signature that provides an encrypted identifiable “signature.” If properly obtained, an electronic signature can be considered an “original” for the purposes of recordkeeping.

**Wellesley College Guidance on electronic signatures is available here.**

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**INFORMED CONSENT**

Please review [Protecting the Rights and Welfare of Individuals Participating in Research Studies](#) to ensure the study meets the basic informed content process.

Additional guidance on IRB regulations, informed consent procedures and forms, exemptions and expedited reviews, etc. can be found on the Wellesley College [IRB Sakai site (PROV-IRB)](#), as well as on the [Office for Human Research Protections (OHRP) website](#). Of particular interest is the [guidance on informed consent procedures](#).

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**SOCIAL MEDIA**

The Secretary's Advisory Committee on Human Research Protections (SACHRP) developed guidance on the use of social media for recruitment, data collection and as a research site. These recommendations, while not formally adopted by OHRP (the body that regulates IRBs), provide useful guidance for researchers using social media in their research:

[Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations, with Revisions 2013](#)
[8] PLEASE SEND YOUR IRB SUBMISSIONS TO:

IRB Administrator  
email: irb@wellesley.edu  
Campus mail: Kenji Trash-Correia, WCW-Cheever  
Off-campus: Kenji Trash-Correia, IRB Administrator, Wellesley College, 106 Central Street, Wellesley, MA 02481

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 nmarshal@wellesley.edu.

Questions? Please contact Nancy Marshall, Chair, Wellesley College IRB  
email: nmarshal@wellesley.edu.
IRB COVER SHEET

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

Researcher/Principal Investigator: _____________________________________

Academic Department/Institution: _____________________________________

Start date of Project: _________________ Anticipated completion date\(^7\): ________________

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: ___________________________________

Are you (check all that apply):
[ ] Wellesley College faculty or WCW researcher

[ ] Wellesley College OIR or other administrative office conducting research:
  * Has your project been approved by the Office of Institutional Research? [ ] yes [ ] no

[ ] External researcher (PI or Co-PI), no Wellesley College appointment:
  * Has your project been approved by the Office of Institutional Research? [ ] yes [ ] no

[ ] External researcher using the Child Study Center as a research site:
  * Has your project also 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 Principal Investigator Date

\(^7\) 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 A: CRITERIA FOR IRB APPROVAL

§46.111 CRITERIA FOR IRB APPROVAL OF RESEARCH

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

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

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

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

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

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

THE KEY ELEMENTS OF A STUDY THAT MEET THESE GOALS

[1] THE INFORMED CONSENT PROCESS. Informed consent is not just a signed form, but also 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.

For a checklist of informed consent requirements, see this link.

**Written consent.** Informed consent should usually be obtained in writing (“writing on a tangible medium (e.g., paper) or in an electronic format”). 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).

**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.

[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’

If you would like to request an exemption, please complete and submit the following form, the IRB Cover Sheet and a 1-2 page summary (see “What To Submit”) of your project to the IRB Administrator, irb@wellesley.edu. 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.

PI: _____________________________________________  Date: _______________

Protocol/Study Name:_________________________________________________________

Which of the following exemptions apply? _______________________________________

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, 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.

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.

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

(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, you will not be granted the exemption. Moreover, research with children that involves survey procedures or interview procedures with the children is not exempt.

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.

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.

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.

**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.

The work is conducted outside of the United States. *The International Compilation of Human Subject Protections* is a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations:
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 ____________________________ Date: __________________

Protocol/Study 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: __________________________
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 children⁹, 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

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⁹ 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.
for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 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

1. **Department or agency head** means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

   *Institution* means any public or private entity or agency (including federal, state, and other agencies).

   *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.

   *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

   *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

2. **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

3. **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.

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

6. **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.
7. **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.

**Certification** means the official notification by the institution to the supporting department or agency, 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.

**Additional definitions**

8. **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.

9. 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.

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