PROTECTING THE RIGHTS AND WELFARE OF INDIVIDUALS PARTICIPATING IN RESEARCH STUDIES (HUMAN SUBJECTS):
IRB GUIDE FOR STUDENT INVESTIGATORS

The Wellesley College Institutional Review Board (IRB) is charged with meeting federal regulations for the protection of individuals participating in research (human subjects); see the Wellesley College IRB Guide for more information about research conducted by faculty and staff researchers.

Wellesley College students are also engaged in research as student investigators. A Wellesley College faculty or staff member (“Academic/Research Advisor”) must supervise any research conducted by students while the student is on campus, as well as any research under the aegis of Wellesley College (with the exception of research conducted at another institution – see below).

GUIDELINES FOR WHEN RESEARCH NEEDS IRB REVIEW

The IRB is responsible for review of any research project or proposal “that involves research (“a systematic investigation… designed to develop or contribute to generalizable knowledge”) with living individuals about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Your answers to the following questions determine whether your research needs IRB review:

1. Are you doing research with living individuals? AND

2. Are you collecting data or information directly from living individuals (through interviews, surveys, questionnaires, observations, participant observation or other social, behavioral science or biomedical science method) OR are you using data collected by others that contains identifiable private information? AND

3. Is your research designed to contribute to generalizable knowledge, that is, will what you learn apply to people or settings beyond your specific research, AND will you be making the results of your research available outside of Wellesley College? If you are not sure whether your research meets this criterion, but you want to protect the option of publishing the research results, including in an online journal or student journal, or presenting the results at an off-campus professional conference, you should answer yes to this question.

If you answer yes to all three questions, then your research needs IRB review. We will refer to research for which the investigator answers yes to all three questions as “research that is subject to IRB review.”

SPECIFIC CATEGORIES OF STUDENT RESEARCH THAT IS “SUBJECT TO IRB REVIEW”

1. Research Assistants. Research conducted as research assistants to faculty, researchers or staff at Wellesley College (paid or volunteer). The principle investigator (PI) of that research project is responsible for ensuring that their research has IRB approval, when required. See the Wellesley College IRB Guide for more information for Wellesley College faculty/staff research. However, if the student research is different from the PI’s approved research, AND the research is “subject to IRB review,” students should complete and submit an Application for IRB Review: Student Investigator. NOTE: If the student is a research assistant on research at another institution (such as through MIT’s Undergraduate Research Opportunities Program), that institution is responsible for IRB oversight of that research. Wellesley College IRB does not require documentation of that review.
2. **On-campus Internships.** Research conducted as part of an on-campus internship, such as Sophomore Early Research Program (SERP) internships. If the internship research is part of a previously IRB-reviewed research project, additional review is not needed. If the student’s research is substantively different from the ongoing research, or involves new data collection not covered under an existing IRB review, AND the research is “subject to IRB review,” students should complete and submit an Application for IRB Review: Student Investigator.

3. **Off-campus Internships.** Research conducted as part of an off-campus internship, or other off-campus research opportunity. If the research meets the definition of research that is “subject to IRB review,” then the student investigator should ensure that a review is done, and keep a record of that review for their future use. If the off-campus sponsor/supervisor cannot provide IRB review, students should ask a Wellesley College faculty member to provide additional ethics supervision, and complete and submit an Application for IRB Review: Student Investigator.

4. **Senior Theses; Independent Studies (250/250H/350/350H) or similar courses, such as Psych-R Courses, WGST313, STAT218.** Student investigators conducting human subjects research that is “subject to IRB review” need an IRB review; course-related research that is not “subject to IRB review” does not need an IRB review.

   - If the research is for a senior thesis, the student researcher should complete and submit an Application for IRB Review: Student Investigator. The Wellesley College IRB reviews all senior theses, regardless of where the research is being conducted.

   - If the research is for an independent study (250/250H/350/350H) or similar course, AND the research is “subject to IRB review,” the student needs an IRB review. If the research is being conducted at Wellesley College, or solely under the supervision of a member of the Wellesley College faculty or staff, the student researcher should complete and submit an Application for IRB Review: Student Investigator.

     If the research is being conducted as part of a course at another institution, such as MIT, MGH, or Harvard - even if a Wellesley College faculty member is supervising the work for Wellesley College course credit – that institution is responsible for IRB oversight of that research. Wellesley College IRB does not require documentation of that review.

   *Note:* Research that is conducted while a student is registered for a course through another institution, such as MIT or Harvard, or as part of a Study Abroad program, should follow the guidelines for IRB review at that institution.

**OTHER COURSE-RELATED RESEARCH**

The Wellesley College IRB policy differentiates between student research that is designed to meet pedagogical goals and student research that is subject to IRB review. Course-related research is often designed solely to meet pedagogical goals – to provide opportunities for students to develop research skills, or to explore a topic through their own research. Faculty are expected to serve as mentors and advisors, and to provide guidance on research ethics for this type of course-related research; most such course-related research does not need IRB review. If there are questions, faculty are invited to contact the IRB chair to discuss their course; individual students should talk with their professors, rather than contacting the IRB chair directly.
WHAT TO DO IF YOU NEED A REVIEW AT WELLESLEY COLLEGE

1. Read the rest of this Student Guide for more information about requirements.

2. Talk with the professor or other person who is supervising your research (“Academic/Research Advisor”) and discuss the review process.


4. Sign the application, and have your Academic/Research Advisor sign it as well. The IRB accepts scanned forms and signatures; a hard copy is not required.

5. Once your Academic/Research Advisor approves your application, they should forward the application and supporting materials to the designated member of the IRB Committee; a list is available on Sakai>PROV-IRB>Resources. If that person is not available, the IRB chair will do the second review.

6. The designated IRB Committee member will do an expedited review, and submit all materials to the Wellesley College IRB Administrator, via irb@wellesley.edu.

WHAT TO DO IF YOU NEED A REVIEW FROM YOUR OFF-CAMPUS INTERNSHIP OR COLLEGE OR UNIVERSITY

1. Contact your research advisor or supervisor at your internship or the other college or university and request a review.

2. If the off-campus sponsor/supervisor cannot provide IRB review, you should ask a Wellesley College faculty member to provide additional ethics supervision, and complete and submit an Application for IRB Review: Student Investigator.
ETHICAL PRINCIPLES RELEVANT TO ALL RESEARCH

In the United States, the rights and welfare of individuals participating in research studies are protected under federal regulations, known as “The Common Rule”. The Common Rule requires an institution that is conducting research to assure the federal government that it will provide and enforce protections for human subjects of research conducted under its auspices. The Common Rule was first promulgated by the U.S. Department of Health and Human Services (then known as DHEW) in 1974, and extended to 16 U.S. governmental agencies in 1991.

The Common Rule is based on the ethical principles articulated in The Belmont Report (1979; issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research). The three basic principles are:

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

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

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

ELEMENTS OF HUMAN SUBJECTS PROTECTION

There are three core elements to ‘human subjects’ protection, based on the three basic principles of The Belmont Report:

[1] ensuring that individuals can make informed choices about their participation in research, and protecting those individuals with diminished autonomy;

[2] ensuring that the potential risks of a study are minimal, or are justified by the potential benefits;

[3] ensuring that the selection of research participants is fair, and not based simply on their easy availability, their willingness to participate, or other considerations not directly related to the problem being studied.

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

[1] 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.

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

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

- a statement that the study involves research, an explanation of the purposes of the research, and a description of what participation in the study will involve;
- a description of any reasonably foreseeable risks and benefits to the participant;
- if the study involves health treatments, the participant must be informed of alternative procedures or courses of treatment (this usually does not apply to student research);
- 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, an explanation of the treatment or resources available if any harm occurs (student research should not involve more than minimal risk);
- identification of whom to contact for further information about the study (e.g., the Student Investigator and the Faculty Advisor), and about participants’ rights in the event of research-related harm (usually the Chair of 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 in otherwise entitled (if applicable), and that the participant may discontinue participation at any time.

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

New informed consent requirement. The Final 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. 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.

[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.

Definitions of terms (from federal regulations):

(a) 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.
   (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.

(b) 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.

(c) 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.
(d) **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.

(e) **Children** are 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. [In Massachusetts, this is generally age 18.]

(f) **Assent** means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(g) **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(h) **Parent** means a child's biological or adoptive parent.

(i) **Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

(j) **Written, or in writing** refers to writing on a tangible medium (e.g., paper) or in an electronic format.