



Brandeis University

Human Subjects Research

Investigator Manual

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PURPOSE OF THIS MANUAL

The Department of Health and Human Services (HHS) has issued regulations governing research involving human subjects (Code of Federal Regulations, Part 45 Title 46) which require all institutions requesting and receiving funds for human subjects research from a federal department or agency to operate under an assurance for the protection of human subjects. Brandeis University has negotiated a Federalwide Assurance (FWA) with the Office of Human Research Protections (OHRP), within HHS, which requires all federally funded non-exempt human subjects research conducted under the auspices of the university be reviewed and approved by the Brandeis University Institutional Review Board (IRB) before the research is begun.

In addition, Brandeis University has committed itself to the equal treatment of all human subjects research conducted under its auspices; thus, all human subjects research, whether federally funded or not, and whether conducted by administrators, faculty, staff or students, shall be under the jurisdiction of the Brandeis University Human Research Protection Program (HRPP) and must undergo Brandeis University IRB and/or administrative review.

The Brandeis University HRPP is responsible for determining and assuring that 1) the welfare and rights of human subjects are adequately protected and informed consent given, if necessary; 2) human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research; 3) the necessity and importance of the research outweighs the risks to the subjects; and 4) the investigator(s) is (are) qualified to conduct research involving human subjects.

The review of human subjects research at Brandeis University is a collaborative process intended to result in research procedures that aid investigators in accomplishing their scientific objectives while protecting the rights and welfare of research subjects. Every effort is made to reduce administrative burdens on investigators and to maximize attention to the most important ethical issues. To this end, the Brandeis University HRPP endeavors to make use of the flexibility that is built into the federal regulations and reviews each project as a separate case, rather than rigidly imposing requirements without considering the specifics of a particular research project.

The Brandeis University Human Research Protection Program has developed this Human Subjects Research Investigator Manual to provide comprehensive information and guidance to investigators planning to conduct research involving human subjects at Brandeis University, thereby supporting institutional initiatives to guarantee compliance with federal regulations governing the protection of human subjects.

This manual is intended to serve as a guide to the investigator as s/he plans his/her research project. Rather than regarding the process as simply bureaucratic red tape, we hope you can view it as a useful planning tool that can help you refine your research methods and procedures in such a way as to maximize the benefits of your research to science and society, while minimizing risks to research subjects.

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WHAT IS THE HUMAN RESEARCH PROTECTION PROGRAM AND THE IRB?

1. THE HUMAN RESEARCH PROTECTION PROGRAM

The Brandeis University Human Research Protection Program (HRPP) oversees all aspects of human subjects research conducted under the auspices of Brandeis University, including all administrative duties, education, and review of human subjects research applications. The HRPP encompasses the IRB, the Institutional Official (IO), the Research Integrity team of the Office of Research Administration, the Vice Provost for Research, and the Associate Provost for Research Administration. The purpose of the HRPP is the protection of individuals, and the groups they represent, involved in research conducted under the auspices of Brandeis University.

2. THE INSTITUTIONAL REVIEW BOARD: A BRIEF HISTORY

History is replete with incidences of unethical research on human subjects. With regards to the development of the IRB, the story customarily begins with World War II. Below is a list of some of the most infamous examples of unethical research and how together they gave slow rise to the modern-day IRB and the federal regulations that govern human subjects research in the United States and around the world today.

During World War II Nazi doctors committed medical experiments on thousands of concentration camp prisoners. Some of these experiments were designed to gain knowledge that would help the Axis soldiers survive in the field – such as deliberately freezing prisoners to find an effective treatment for hypothermia – while others were designed to support the racial and ideological Nazi worldview – such as exposing different racial groups to various diseases and harvesting tissue samples and body parts.

In 1946-47, 23 medical doctors and administrators were tried in Nuremberg, Germany for conducting the human experimentation on prisoners of Nazi concentration camps. Dr. Leo Alexander, a key medical advisor during the trial, submitted six ethical principles for research to the Counsel for War Crimes by which to try the defendants. The Counsel adopted these principles, which, along with four others submitted by Alexander and Dr. Andrew Ivy of the American Medical Association, became known as the Nuremberg Code. The principles covered such things as voluntary consent, benefit-risk analysis, freedom of subjects to withdraw, and the qualifications of investigators.

As the Nuremberg trials were wrapping up, the 2nd General Assembly in Geneva adopted, in 1947, the World Medical Association's (WMA) Declaration of Geneva. The declaration, which focused on clinical research trials, builds on the principles of the Hippocratic Oath, the ancient Greek pledge taken by doctor's vowing to uphold specific ethical standards of nonmaleficence. One significant departure from the Nuremberg Code was the relaxation of the requirement of consent. Where the Nuremberg Code's first tenet is that the voluntary consent of the human subject is "absolutely essential," the Declaration of Geneva allows for proxy consent to be given in cases where the subject him/herself is unable to give consent (e.g., is incapacitated or under age).

Though an important document, the Declaration of Geneva's language was felt to be vague and quickly out-of-date. A discussion by the WMA began in 1953, which re-examined and sought to clarify the duties of the medical research investigator. In 1964 the WMA issued new ethical guidelines for the regulation of clinical medical research and protection of research subjects in the *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*. Revised in 1975, 1983, 1989, and 1996, the declaration defines rules for both clinical research combined with care and without. For the first time, the concept of an ethics review board to help guide the investigator is discussed. In addition, the declaration addresses the need for informed consent, that benefits should outweigh the risks involved in the research, that investigators must be medically and scientifically qualified to conduct the research, and that laboratory and animal experimentation should always precede research on humans.

In the United States, Henry Beecher, a prominent clinical investigator in the 1940-60s, was intensely interested in the Nuremberg trials. He became concerned with what he considered to be unethical clinical research practices

with human subjects and, in 1966 published an article in the *New England Journal of Medicine* entitled Ethics and Clinical Research. In this article Beecher gave voice to his concerns, citing 22 real life examples of unethical clinical research in which patients' lives were put at risk – many whom he claimed were being exploited, including some from vulnerable populations. Beecher's main point was that clinical investigators could not be trusted to manage the ethicality of their own research, and, while he did not call for better ethical oversight, he did believe that journal editors should be more critical about how research was being conducted, and should not accept articles where research appeared to be unethically conducted. This notion, as well as other ethical principles, was adopted by the International Committee of Medical Journal Editors when the Uniform Requirements for Manuscripts Submitted to Biomedical Journals was updated in 1997.

Despite these efforts, unethical research continued. In 1971 a study was conducted at a birth control clinic in San Antonio, Texas on the efficacy of oral contraception. The subjects were 70 indigent Mexican-American women who had come to the clinic seeking birth control. The women agreed to participate in a study on the side effects of oral contraceptives. While all of the subjects were told they were receiving oral contraceptives, in reality, half were given a placebo. Halfway through the study, the women were switched so that those who had been receiving the actual contraceptives began receiving the placebo, and those who had been receiving the placebo were given the contraception. The study resulted in ten unplanned pregnancies.

From 1932-1972, the US Public Health Service enrolled 400 low-income African-American males with syphilis in a research project, dubbed the Tuskegee Study, which studied the effects of untreated syphilis on the human body. While the men were told they were being treated for “bad blood” (the term used at that time to describe a number of ailments including anemia and fatigue, as well as syphilis), in fact, they were not: treatment was withheld throughout the study, despite the advent of penicillin and “Rapid Treatment Centers” to treat syphilis in the 1940s. In 1968 concerns were raised about the ethics of the study, however the Centers for Disease Control and Prevention, American Medical Association, and National Medical Association continued to support the study. In 1972 the Associated Press ran a story about the Tuskegee study and the study was ended as a result of the publicity.

In 1974, as a result of the publicization of the Tuskegee Study, the National Research Act was passed. This Act initiated federal oversight (45 CFR 46) of human subjects research funded by what is today the Department of Health and Human Services (HHS). The Act called for the development of ethical review boards – first introduced in the Declaration of Helsinki – and the formation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to develop ethical guidelines for human subjects research.

In 1978 these regulations became known as Subpart A of 45 CFR 46, when regulations regarding research with pregnant women, fetuses, and in vitro fertilization were added (Subpart B), as well as research with prisoners (Subpart C). In 1983, Subpart D was added to address research with children.

In 1979, the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* was published, which outlined three basic principles on which to guide human subjects research. These basic principles were codified in the federal regulations and, in 1991 Subpart A of the regulations became known as the Common Rule after it was adopted by 16 other federal agencies to cover research conducted with funds from those agencies. The regulations were revised in 2018, and govern human subjects research conducted today.

3. IRB GUIDING PRINCIPLES AND REGULATIONS

Published in 1979, the Belmont Report serves as the ethical framework for the protection of human subjects and discusses three fundamental principles by which human subjects research has since been guided:

1. **Respect for persons**, or treating individuals as autonomous agents (“capable of deliberation about personal goals and of acting under the direction of such deliberation”) and protecting persons with diminished autonomy

2. **Beneficence**, or protecting individuals from harm by maximizing potential benefits and minimizing potential for harm (risk)
3. **Justice**, or distributing the risks and potential benefits of research equally among those who may benefit from the research

The federal regulations, which established and guide the IRB, were first published in 1974 in 45 CFR 46. They were extensively revised as a result of the Belmont Report, and again in 2018. The regulations include five parts:

- Subpart A: Basic HHS policy for the protection of human research subjects
- Subpart B: Additional protections for pregnant women, human fetuses and neonates involved in research
- Subpart C: Additional protections pertaining to biomedical and behavioral research involving prisoners
- Subpart D: Additional protections for children involved as subjects in research
- Subpart E: Registration of Institutional Review Boards

Subpart A of the regulations – known as the Common Rule for its codification by 16 federal departments and agencies – transforms the three principals of ethical research discussed in the Belmont Report into well-defined protocols, and outlines the functions and operations of the IRB and criteria for IRB approval of research. Subparts B-D are concerned with the welfare of what the regulations refer to as vulnerable populations and outlines additional provisions that must be followed when engaging these populations as research subjects. Subpart E discusses the administrative details of the IRB.

Respect for Persons Operationalized

Of the Belmont Report's three ethical principles operationalized by the regulations, respect for persons gets the most attention. The cornerstone of this principal is the informed consent process; for to treat a subject as an autonomous agent, one must give that subject the opportunity to make a choice to act based on the facts of the research and their own beliefs and values.

In addition to informed consent, respect for persons includes the protection of those with diminished autonomy. 45 CFR 46 Subparts B-D are an outgrowth of the principal of respect for persons, which discusses the protection of persons who may not have the ability to fully weigh their choices, or do not feel they have a choice. For research involving children or others with diminished capacities, informed *consent* must be given by a legally authorized representative (LAR) and informed *assent* must be given by the subjects. For research involving prisoners, the investigator must pay special attention to the ability of the subjects to make a truly voluntary and uncoerced decision to participate.

Beneficence Operationalized

The principle of beneficence is concerned with weighing the potential for harm to the subjects participating in the research against the benefits the research may produce, or the conducting of a risk-benefit analysis of the proposed research. In many ways, beneficence is the most difficult of the three principals to operationalize. The Belmont Report refers to the Hippocratic oath, which requires physicians to "benefit their patients according to their best judgment." However, when the potential for benefits apply not to the subjects themselves, but to future or simply other populations, it becomes even more difficult to weigh the potential for these future benefits against the potential for current and/or ongoing risk to the research subjects. The Belmont Report further acknowledges one's "obligation to recognize" and take into account the longer-term benefits of the research, such as the potential for its overall contribution to science.

Justice Operationalized

The concept of equality in the distribution of burdens and benefits forms the backdrop of the Belmont Report's discussion of the principle of justice. In the realm of human subjects research, justice is concerned with ensuring the potential benefits of the research apply to the population from which the subjects were recruited, and the potential harms be distributed fairly. In other words, subjects should not be recruited simply because they are easily available (a "convenient" population), but be a random sampling of subjects representative of the population which stands to benefit from the research.

4. JURISDICTION OF THE IRB

The federal regulations stipulate that all human subjects research funded by an agency that has signed on to the common rule must be conducted under a Federalwide Assurance or contract entered into by the institution with oversight for the research and the Office of Human Research Protections (OHRP) under the Department of Health and Human Services (HHS). This contract stipulates that such federally funded research conducted under the auspices of that institution will comply with the federal regulations. Brandeis University operates under Federalwide Assurance #FWA00004408.

While the regulations apply only to federally funded research, Brandeis University believes the protection of human subjects in research is vital and has determined that all research conducted under the auspices of the university will be reviewed by one or more members of the IRB and/or IRB administrative staff (the IRB) and held to the same standards, whether federally funded or not.

The IRB is required, as well, to conduct a continuing review of all research considered higher than minimal risk. The regularity of this review is determined by the IRB, however it must be conducted at a minimum of once per year. Research that is not higher than minimal risk may be subject to continuing review, as well, subject to the IRB. At the time of each review, the IRB may withdraw its approval or require modifications to the research. In addition, all investigator-initiated planned modifications to human subjects research – regardless of risk level – must undergo IRB review and requires IRB approval before they are commenced.

Note that, while it is the responsibility of the IRB to review the proposed and ongoing research, it is the responsibility of the principal investigator to accurately report to the IRB its planned and conducted research during the review processes. Should the IRB become aware of research being conducted without, or not in accordance with, its approval, it has the authority to suspend or terminate the research. This authority to suspend or terminate research extends, as well, to research that is thought to have resulted in unexpected serious harm to its subjects.

Research that has been reviewed and approved by the IRB may be subject to further review, and may be disapproved by the Institutional Official (IO) of the institution. However, the IO may not approve research that has been disapproved by the IRB.

5. IRB RESPONSIBILITIES

The overriding responsibility of the IRB is to safeguard the rights and welfare of human subjects in research. In so doing, the IRB ensures its members:

- Have the accumulated professional competency necessary to review all proposals
- Participate in mandatory and ongoing training, including completion of the CITI course for IRB members and any relevant special topics courses
- Understand the ethical principles, federal regulations, and institutional policies and standard operating

procedures related to human subjects research

- Follow all applicable written procedures
- Review all submitted research applications, modification requests, and continuation requests according to federal regulations
- Attend monthly meetings and actively participate in discussions, each offering their unique point of view
- Seek appropriate expertise from non-members for the review of proposals that require knowledge or expertise beyond or in addition to that of the members of the IRB
- Avoid conflicts of interest by each member refraining from participating in that part of an IRB meeting in which their research is being reviewed or in which they have a vested interest
- Keep confidential all documents and other information acquired as IRB members
- Review all allegations of investigator non-compliance and suspend or terminate approval when deemed necessary
- Review all instances of unexpected serious harm to subjects and suspend or terminate approval when deemed necessary

6. HRPP STAFF RESPONSIBILITIES

The overriding responsibility of the HRPP staff is to support the IRB in its safeguarding the rights and welfare of human subjects in research. In so doing, the HRPP staff:

- Ensures their availability to investigators in need of guidance regarding the application for human subjects research, as well as its continuing review and termination
- Assures compliance with the Brandeis University Federalwide Assurance
- Participates in ongoing training and stays informed of current events related to human subjects research
- Understands and provides interpretation of federal regulations and institutional policies and standard operating procedures related to human subjects research
- Acts as liaison between the IRB and principal investigator/student researcher
- Follows all applicable written procedures
- Pre-reviews all submitted research applications
- Determines the level of review for all submitted research applications
- Reviews all submitted (non limited IRB review) exempt research applications for approval
- Is delegated authority by the IRB chair to select reviewers for expedited applications
- Forwards each expedited protocol to selected IRB member(s) for review

- Forwards expedited modification requests to IRB reviewer of initial application or other selected IRB member
- Maintains documentation of IRB activities:
 - Complete files on all research applications, including (but not limited to):
 - The initial and all revised protocols
 - Approved consent documents
 - Recruitment materials
 - Scripts
 - Study instruments
 - Permission letters
 - Continuation requests
 - Modification requests
 - Termination and final reports
 - Correspondence related to the project
 - Statements of significant new findings
 - Reports of unanticipated problems and instances of non-compliance
 - Detailed minutes of IRB meetings including
 - Committee member attendance
 - Names of consultants, investigators, or other guests present
 - Details of non-review related committee discussions
 - Determinations of conflict of interest of committee members
 - Details of committee discussions related to reviewed applications, including:
 - Risk level
 - Results of determination votes
 - Approval period
 - A list of applications reviewed as expedited since the last convened meeting
 - Any additional business discussed

- Date of next meeting
- Coordinates monthly IRB meetings, ensures a nonscientific member (and prisoner representative, when appropriate) will be present, and ensures a quorum will be reached and maintained
- Compiles all relevant materials for monthly IRB meeting and distributes to IRB members one week prior to meeting:
 - Agenda for upcoming meeting
 - New and revised applications to be reviewed (including cover sheet; assurance; protocol, including all revised versions, if applicable; consent documents; recruitment materials; study instruments; permission letters; and any other relevant documents)
 - Continuation and modification requests to be reviewed, including all previous applications and requests
 - Minutes from previous meeting
- Attends and takes minutes for every convened IRB meeting
- Forwards all allegations of investigator misconduct and instances of unexpected serious harm to subjects to the IRB chair and institutional official, when appropriate
- Keeps confidential all documents and other information acquired as HRPP staff
- Conducts training and education for prospective investigators and student researchers, as well as IRB members

7. INSTITUTIONAL OFFICIAL RESPONSIBILITIES

The institutional official (IO) within the Office of the Provost is the signatory official on the university's Federalwide Assurance with OHRP. The IO oversees the administration of the IRB and has the authority to disapprove all research conducted under the auspices of the university. (The IO may not however, overturn a decision by the IRB to disapprove a research project.)

The IO ensures the Human Research Protection Program has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official, and assumes the obligations of the institution's Assurance

The institutional official, in their effort to safeguard the rights and welfare of human subjects in research, ensures:

- The IRB has the accumulated professional competency necessary to review all proposals
- The IRB members are selected based on appropriate diversity including consideration of race, gender, cultural backgrounds, and specific community concerns
- The IRB includes, at a minimum, one member with formal education and training in scientific areas relevant to the research it reviews, one whose formal education and training are in non-scientific areas, and one who is not otherwise affiliated with the institution in any way, who is sensitive to and can represent community attitudes

- The IRB consists of at least five members
- They participate in mandatory and ongoing training, including completion of the CITI course for IRB members and any relevant special topics courses
- They understand the ethical principles, federal regulations, and institutional policies related to human subjects research
- They follow all applicable written procedures
- They review all allegations of serious investigator non-compliance and instances of unexpected serious harm to subjects brought to their attention and for their action

8. COMPOSITION OF THE IRB

The federal regulations stipulate that each IRB must have at least five members with varying backgrounds including, at a minimum:

- One member who has formal education and training in scientific areas relevant to the research it reviews. For example, an IRB that reviews primarily social scientific research must include a minimum of one social scientist, whereas an IRB that reviews primarily biomedical research must include at a minimum one member with a biomedical background.
- One member whose formal education and training are in non-scientific areas, who can provide input from a non-scientific vantage point.
- One member who is not otherwise affiliated with the institution in any way, who is sensitive to and can represent community attitudes. If possible, this member should be representative of the population from which the research draws its subjects.
- When reviewing research involving prisoners, one member who is a prisoner or prisoner representative with the appropriate experience to serve in this capacity.

In addition, the committee members must be diverse, taking into consideration race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes; must be knowledgeable in institutional regulations, applicable law, and standards of professional conduct and practice; and, if the IRB Regularly reviews research with a specific vulnerable population, include a member who is knowledgeable about the experience in working with this population.

The Brandeis University IRB is a diverse group and includes members of the faculty, administration, and community with scientific knowledge; an understanding of community mores; familiarity with institutional commitments, policies and procedures; and specific knowledge about regulations and the protection of human subjects research.

In addition, there are times when the Brandeis University IRB invites individuals with expertise in specific areas to assist in the review of issues that require a proficiency or perspective beyond or in addition to those of the IRB members. Although these individuals may attend meetings and take part in the discussion of research protocols, they may not vote.

The Institutional Official appoints members to the Brandeis IRB, including the IRB chair, and ensures the IRB has the accumulated professional competency necessary to review all proposals

In appointing the IRB chair, the IO is mindful that they should be a highly respected individual from within the institution, and fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of ensuring that the IRB is a respected part of the institutional community falls primarily to this individual. The IRB must be – and be perceived to be – fair, impartial, and immune to pressure from the institution's administration, investigators whose protocols are brought before it, and other professional and nonprofessional sources.

Members of the IRB with a conflict of interest in a research proposal may not participate in the review process of that proposal and must be absent during both the discussion and voting of the proposal, with the exception of providing information requested by the IRB.

DO I NEED TO SUBMIT MY PROJECT TO THE IRB?

9. WHEN IRB REVIEW IS REQUIRED

For a project to require IRB review, it must 1) constitute research, and 2) involve human subjects, as defined by the federal regulations (see unit 10: *Defining Human Subjects Research*). All projects constituting human subjects research must undergo review.

For activities determined not to be human subjects research, the investigator may begin their activities immediately. Any modifications that occur in the activities that change its status to human subjects research must be reported to the IRB administrator immediately.

Examples of projects/studies that *are not* subject to IRB review include, but are not limited to:

- Validation of study instruments
- Oral history
- Journalism
- Biography
- Literary criticism
- Legal research
- Historical scholarship
- Literature searches
- Data collection such as surveys, interviews, or focus groups involving things, products or policies only – and no opinions
- Data collection regarding a specific individual that is not meant to be generalizable to others
- Quality assurance activities or evaluation projects designed for self-improvement or program evaluation
- Data collection for internal departmental, university, or administrative purposes

- Course-related activities designed for educational purposes only

10. DEFINING HUMAN SUBJECTS RESEARCH

It is the responsibility of the principal investigator to ensure all their human subjects research be reviewed by the IRB. The principal investigator may determine whether their activity constitutes human subjects research based on the federal regulation's definitions of human subject research, past experience, or they may consult with HRPP staff for guidance.

The office of Human Research Protections (OHRP) has specific definitions to determine whether a research project is human subjects research:

Research: *A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge*

Human Subject: *A living individual about whom an investigator conducting research:*

1. *Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens*
— or —
2. *Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens*

Other helpful definitions include:

Systematic Investigation: *A project that methodically tests (quantitatively or qualitatively) a hypothesis or research question by gathering and analyzing data with the intention of drawing conclusions*

Examples of systematic investigations are:

- Surveys
- Questionnaires
- Interviews
- Focus groups
- Participant observation
- Existing data analysis
- Program evaluation
- Social or psychological experiments
- Drug trials

Generalizable Knowledge: *Data designed to apply to a population beyond the research subjects themselves and contribute to current academic understanding*

Generalizable knowledge generally refers to:

- Published papers
- Oral presentations
- Posters at a conference
- Dissertations or theses

About Whom: Refers to information the subject discloses about him/herself (including their opinions), as opposed to information/facts the subject shares regarding an external topic (such as a program, product, or procedure) about which the subject can be considered an expert

Intervention: 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: Communication or interpersonal contact between investigator and subject

Identifiable: The identity of the subject is or may readily be ascertained by the investigator or associated with the information

Private Information: 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

11. STUDENT RESEARCH

Projects conducted by students for educational purposes within a course alone do not fall within the purview of the IRB as they are not conducted for the purpose of contributing to generalizable knowledge and so do not fit the OHRP definition of research. Such projects occur in a course designed, at least in part, to provide training in research methodology. These projects are commonly conducted as part of a research methods course or research practicum, which involve the supervised practical application of previously studied theories of research methods.

Note that, if a student plans to use the data collected from a course-related project for future human subjects research activities (as a pilot study, for example), the project will require IRB review prior to beginning the project, as IRB approval is not retroactive.

Independent projects conducted by students that include systematic data collection from human subjects and that are intended to produce generalizable results are considered research as defined by OHRP and so do fall within the purview of the IRB. Such projects include honors theses, graduate theses, and doctoral dissertations.

It is Brandeis University's policy that all students involved in human subjects research must complete the online CITI training in human subjects research prior to initiating or participating in human subjects research.

Note that, to the extent that students will be interacting with human subjects, regardless of whether their project meets the OHRP definition of human subjects research, care must be taken to ensure that those subjects are treated with respect and courtesy, do not have their privacy invaded, and are not subjected to unnecessary discomfort (physical or emotional). It is important that the instructor fully understand the classroom projects that are proposed and conducted by their students, and that they provide clear and unambiguous guidelines to those students with respect to their interactions with their subjects.

12. FAILURE TO SUBMIT HUMAN SUBJECTS RESEARCH FOR IRB REVIEW

The implications of engaging in activities that qualify as human subjects research subject to review without obtaining such review are significant. To do so is a violation of the Federal Regulations and Brandeis University policy that will result in a prohibition of publication or presentation of the research data or use of the data to satisfy thesis or dissertation requirements.

The IRB review process – including initial review, continuing review, and review of modifications – is intended to *prospectively* ensure the protection of the rights and welfare of the human research subjects. If approval was not obtained prospectively, the investigator should cease study procedures, including data analysis, and contact the IRB administrator. The investigator will be asked to submit an application for review and include an explanation of why approval was not prospectively obtained.

Any human subjects research initiated or completed will be reviewed by the IRB to determine the extent of noncompliance and whether the procedures used in the research violated any of the university's standards for the ethical conduct of human subjects research.

In these cases, the IRB will decide if the investigator may continue the research. *Note that the data compiled prior to IRB approval may, under no circumstance, be used for the research project.*

The IRB chair will formally notify the principal investigator, indicating what actions the IRB is requiring, the reasons for the IRB's decision, and an opportunity to respond to the board. A copy of the notification will be sent to the faculty advisor if the investigator is a student, or to the chair of the department if the investigator is a faculty member, and the Institutional Official.

The Brandeis University IRB will not approve applications where the investigator has attempted to knowingly circumvent IRB policies and procedures regarding human subjects research by collecting human subjects data without approval and then applying to use the collected data as previously existing data. It is therefore in the investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek approval prior to commencing the work.

Brandeis University is required to report all "serious or continuing noncompliance" with the federal regulations for human subjects research to the institutional official, OHRP, and any applicable funding agencies.

WHO AND WHAT IS A PI?

13. THE PRINCIPAL INVESTIGATOR (PI)

The principal investigator (PI) is the scientist or scholar with primary responsibility for the design and conduct of the research project.

PI Requirements

Only qualified Brandeis University faculty or staff scientists (as well as other staff with appropriate expertise and prior HRPP approval) may serve as principal investigators on IRB applications.

Student (undergraduate, graduate, and postdoctoral scholar)–initiated research requires a member of the faculty or staff to serve as principal investigator with the student/scholar serving as supervised researcher.

Staff members who are conducting human subjects research in fulfillment of a degree program must also have a faculty sponsor serve as principal investigator.

PI Responsibilities

The principal investigator is ultimately responsible for ensuring the protection of the rights and welfare of subjects, and that their human subjects research is conducted ethically and is in compliance with all applicable federal, state, and university laws, regulations, policies, and procedures.

The principal investigator is responsible for:

1. Requesting IRB guidance when uncertain whether a study is human subjects research and/or qualifies for exempt status.
2. Ensuring all applicable investigators' compliance with training requirements prior to application submission, and throughout the research project.
3. Adhering to the principles of Respect for Persons, Beneficence, and Justice as set forth in the *Belmont Report*. (See unit 3: *IRB Guiding Principles and Regulations* for an explication of these principles.)
4. Obtaining review and approval prior to the initiation of activities determined to be human subjects research, including recruitment, collection of data about or samples from human subjects, or engagement in interventions or interactions with human subjects.
5. Obtaining review and approval from all other applicable institutional committees such as the Institutional Biosafety Committee (IBC) or the Institutional Animal Care and Use Committee (IACUC) prior to IRB review.
6. Replying to all Brandeis University HRPP staff requests for additional information and/or clarification necessary to make a determination.
7. Disclosing on the IRB application or via modification request any real or apparent conflicts of interest involved with the study before the study begins and as they arise during the duration of the study.
8. Ensuring all research personnel are fully conversant in, and strictly abide by, the study procedures, informed consent requirements, data collection and management procedures, and any additional requirements as approved by the IRB.
9. Ensuring compliance of all research personnel with all applicable provisions of the Brandeis University Federalwide Assurance.
10. Ensuring the informed consent of every subject (including the opportunity to ask and have answered any questions regarding the study), unless this requirement has been waived.
11. Ensuring any commitment to the maintenance of privacy and confidentiality of all subjects and their data.
12. Promptly reporting to the IRB administrator any injuries or other unanticipated problems involving risks to subject or others as a result of their research.
13. Promptly reporting to the IRB administrator any forms of non-compliance with Brandeis University policies, federal regulations, the protocol as approved, or applicable provisions of the Brandeis University Federalwide Assurance.
14. Requesting a continuation of IRB approval for all research approved by the fully convened IRB at the interval set by the IRB and no less often than once per year
15. Requesting approval for all modifications to currently approved research.

16. The timely submission of all continuation requests and modification requests, and ensuring that no research – including changes to formally approved research – takes place without current approval, unless necessary to eliminate an unanticipated problem or risk of harm to subjects.
17. Promptly reporting to the IRB administrator any changes or new information that may affect the risks and/or benefits to subjects.
18. Retaining and maintaining accurate records of research data and documented informed consent in compliance with the Brandeis University policy on data retention.
19. Making all research records available for review by the IRB if it determines an audit is appropriate and/or necessary.
20. The timely submission of a final report to the IRB administrator at study closure.
21. Maintaining copies of the Brandeis University IRB's written determinations as to the approval of their human subjects research.
22. Signing and abiding by the Brandeis University Statement of Assurance for human subjects research.

Only Brandeis University faculty and staff may serve as principal investigators on human subjects research conducted under the auspices of Brandeis University. Faculty and staff serving as the principal investigator on student/scholar-initiated research are also responsible for:

23. Ensuring the student researcher is familiar with the ethical practices, regulations, and policies that pertain to human subjects research.
24. Ensuring that the student researcher has sufficient training and academic preparation to conduct the proposed research.
25. Reviewing the initial application and all subsequent modification and continuation requests, ensuring these are complete and accurate.
26. Monitoring the research to ensure that no deviations from the approved protocol are made.
27. Meeting with the student researcher on a regular basis to monitor the progress of the research.
28. Remaining available, personally, to supervise the student researcher in solving problems should they arise during the course of the research.
29. Arranging for an alternate faculty or staff advisor to assume responsibility during periods of absence (sabbatical leave or vacation), and advising the IRB administrator via modification request of such arrangements.
30. Being the primary contact for all HRPP office correspondence and interactions, from original submission through the termination and final report.

14. THE SUPERVISED RESEARCHER

Research initiated by undergraduate students, graduate students, and postdoctoral scholars (including staff conducting human subjects research in fulfillment of a degree program) requires a qualified Brandeis University

faculty or staff advisor to serve as principal investigator (see *unit 13. The Principal Investigator* for specific PI requirements). In these cases the student/scholar serves as supervised researcher.

Students and postdoctoral scholars planning to conduct a research project involving human subjects must submit a protocol through their faculty or staff advisor (the principal investigator), who is then responsible for ensuring the application is complete and accurate. All interactions, from original submission through the termination and final report, will take place between the HRPP staff and the principal investigator.

Note that the PI responsibilities 1-22 listed above are applicable to the supervised researcher, as well, and the supervised researcher must sign the same assurance form signed by the PI.

HOW DO I APPLY FOR IRB REVIEW?

15. CATEGORIES OF REVIEW

There are three categories under which human subjects research is reviewed: Exempt, Expedited and Full Committee Review. The category of review determines what type of application to submit and how/by whom the application will be reviewed. Note that the IRB/HRPP staff makes the final determination under which category a research project falls.

Exempt Research

Note that a pdf version of the [exempt research categories](#) is available.

The regulations identify eight specific categories of research activities that are exempt from the federal regulations on the protection of human subjects in research. Brandeis University recognizes six of these.

While a project may be exempt from the regulations, the ethical principals for conducting research with humans still apply (minimizing risk, maximizing benefit, and ensuring privacy) and all of the rights and protections afforded to human subjects in research are required.

Note that while a research project may be exempt from the regulations, it is not exempt from review and the HRPP staff makes the final determination: The investigator must complete a full exempt application.

The six categories of exempt research include:

1. Research conducted in established or commonly accepted educational settings that specifically involves:
 - Normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content
 - The assessment of educators who provide instruction

Note: This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination.

Note: This category may only be applied to research with children when educational tests or the non-participant observation of public behavior are involved and either criterion 1 or 2 are met.

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

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination

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

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

Note: This category may not be applied to research involving children.

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

- Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects
 - The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)
 - The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 USC 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 USC 552a, and if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 USC 3501 *et seq.*
5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
6. Taste and food quality evaluation and consumer acceptance studies:
- If wholesome foods without additives are consumed
 - 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

Note: This category may be applied to research involving children; however, the Brandeis University IRB requires written parental consent to include children in taste testing or odor studies

The two exempt categories not recognized by Brandeis University are:

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

information or identifiable biospecimens for secondary research use, if the following criteria are met:

- a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § ____.116(a)(1) through (4), (a)(6), and (d)
- b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § ____.117
- c. An IRB conducts a limited IRB review and makes the determination required by § ____.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section
- d. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results

Expedited Review

Note that a pdf version of the [expedited review categories](#) is available.

Expedited review can be considered when research activities present no more than minimal risk to human subjects and involve only procedures listed in one or more of the nine categories identified in the regulations.

Minimal risk, as defined in the regulations, means the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.

Applications that qualify for expedited review require fewer reviewers and are reviewed on a revolving basis.

The nine categories of expedited review include:

1. Clinical studies of drugs and medical devices only when:
 - Research is 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.)
 - Research is on medical devices for which:
 - An investigational device exemption application (21 CFR Part 812) is not required
 - 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:
 - From healthy, non-pregnant adults who weigh at least 110 pounds (note: 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)

- From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected (note: 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 include:

- *Hair and nail clippings in a non-disfiguring manner*
 - *Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction*
 - *Permanent teeth if routine patient care indicates a need for extraction*
 - *Excreta and external secretions (including sweat)*
 - *Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue*
 - *Placenta removed at delivery*
 - *Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor*
 - *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*
 - *Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings*
 - *Sputum collected after saline mist nebulization*
4. Collection of data on subjects 18 years of age or older 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 (note: studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples include:

- *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*
- *Weighing or testing sensory acuity*
- *Magnetic resonance imaging*
- *Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography*

- *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. 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. 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:
 - Where 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
 - Where no subjects have been enrolled and no additional risks have been identified
 - 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 2-8 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

Note: 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.

Full Committee Review

Research that involves greater than minimal risk and does not fall into an exempt or expedited review category must undergo review by a fully convened IRB.

Examples of such research include:

- *Survey research that involves sensitive questions or information about sexual practice or illegal behavior*
- *Surveys or interviews that are likely to be stressful for the subject*
- *Research involving adults with impaired capacity, prisoners, and other vulnerable populations*

- *Experimental drugs or devices, invasive procedures*

16. THE PROTOCOL

When compiling a research protocol, the printable [Application Checklist](#) helps ensure all necessary elements are included with the application. In addition, reviewing the [10 Most Common IRB Application Mistakes](#) can help to ensure the application travels through the review process as smoothly as possible. The [Initial Protocol Application Sample Questions](#) lists the questions that will be found on the application, for preparing the application ahead of time.

The Initial Protocol

The initial protocol is a compilation of documents that starts with the online [Initial Protocol Application](#), which will guide you through the application process. Note that before beginning, you will want to know whether your research falls under an [exempt category](#) and/or whether it involves *only* secondary data analysis (no original data collection). The Initial Protocol consists of the following:

1. [The Application Form](#)

Complete the online [Initial Protocol Application](#). As you complete the application, you will be asked to upload the additional necessary documents (listed below).

2. [Informed Consent/Assent Documents](#)

All applications must include an informed consent form or a request, within the application, for a waiver of documented informed consent or alteration to/waiver of informed consent.

Informed consent is one of the most important requirements of human subject research. *Additional information regarding the process of informed consent can be found in unit 35: Informed Consent.*

3. [Recruitment Materials](#)

If recruiting subjects, the application must include all of the recruitment materials including such things as recruitment fliers, emails to potential subjects, scripts for calling potential subjects, and letters enlisting the help of others (institutions, programs, organizations) in the recruitment of subjects.

4. [Study Instruments](#)

Study instruments include such things as surveys, questionnaires, interview guides, tests, photographs, etc. If using equipment, diagrams or photographs should be included.

5. [Translated Research Materials](#)

If the research will be conducted in a language other than English, a translation of all research materials (informed consent form/script, recruitment materials, study instruments), in every language in which the research will be conducted, must be included.

7. [Translation Certification](#)

If the research will be utilizing research materials in a language other than English, a completed [Translation Certification](#) – for each language – must be included.

8. [Permission Letters](#)

If entering into such things as Memorandums of Understanding (MOU) and Data Use Agreements (DUA), these must be included in the application.

In addition, permission may be needed to recruit and/or conduct research in some forums/research sites. In these instances, letters of permission from these forums/sites must be included in the application. *Additional information regarding permission letters can be found in unit 44: Site Permissions for Off-*

campus Research

9. International Research Addendum

If the research will be conducted in a foreign country, a completed [International Research Addendum](#) must be attached.

17. SUBMISSION DEADLINES

The IRB meets monthly and reviews all applications requiring full committee review. Materials for review are disseminated to the committee one week prior to the committee meeting. Ask the HRPP office for a current schedule of meetings.

Research applications that qualify for exempt status or expedited review may be reviewed and approved without convening a meeting of the full IRB. These applications are reviewed on a rolling basis and can be submitted at any time.

WHAT IS THE REVIEW PROCESS?

18. CRITERIA FOR REVIEW

To fulfill its responsibility for the protection of human research subjects, the IRB, guided by the federal regulations, reviews each research application by the following criteria:

Risks to subjects are minimized.

All human subjects research incurs some risk and the IRB reviews each protocol to determine if these risks to subjects are minimized. Some common risks include, but are not limited to:

Physical Risks: Physical risks include physical discomfort, pain, injury, severe fatigue, illness, or disease brought about by the methods and procedures of the research. These risks are not commonly encountered in social and behavioral science research.

Psychological Risks: Psychological risks include such things as anxiety, stress, fear, confusion, depression, embarrassment, guilt, shock, flashbacks, loss of self-esteem, and altered behavior. These effects may be experienced during the research, directly after the subject's participation in the research, or after a period of delay.

Social Risks: Social risks include alterations in relationships with others that are to the disadvantage of the subject, including embarrassment, loss of respect of others, stigmatization, and diminished opportunities and status in relation to others.

Economic Risks: Economic risks include loss of wages or income or damage to employability or insurability as a result of the research.

Legal Risks: Legal risks include risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has engaged, or will engage, in conduct for which the subject or others may be criminally liable.

Loss of Confidentiality: Risks from breach of confidentiality include invasion of privacy, as well as the social, economic and legal risks outlined above. Breach of confidentiality is the most common type of risk encountered in social and behavioral science research. *Note: It is presumed that the investigator will maintain subjects' confidentiality unless a subject provides express permission to do otherwise.*

While some risks are unavoidable, their effects on the subjects can at times be mitigated through a debriefing. The debriefing is conducted at the end of the subject's participation and may be a simple discussion regarding the subject's participation in the research or may involve the subject being provided with services they may utilize in future if the subject experiences delayed effects, such as psychological trauma due to the research directly or as a result of a breach of confidentiality in the future.

The IRB will review the research application to ensure that procedures are consistent with sound research design that does not expose subjects to unnecessary risks.

Though the Brandeis University IRB encourages freedom in research design, they do consider the research plan, including the research design and methodology, to determine that there are no flaws that would place subjects at unnecessary risk.

The IRB also considers the qualifications and experience of the research team. Investigators should possess the professional and academic qualifications and experience, along with the resources to conduct the research project and to protect the rights and welfare of subjects.

Risks to subjects are reasonable in relation to anticipated benefits

Potential for harm must be warranted based on the possibility and probability of the benefits. The IRB will consider such benefits as those that may be gained directly from the research; possible benefits for the future, however, (e.g., possible effects of the research on public policy) will not be considered.

Selection of subjects is equitable

Subject criteria and recruitment procedures involved in the research must be equitable. The IRB seeks to determine that the burdens and benefits of the research are being distributed equally across such things as gender, race, etc.

Such things as the inclusion/exclusion criteria; appropriateness of potential subjects; distribution of potential benefits; recruitment methods; and possibility for coercion, including compensation offered, are considered.

The IRB requirement to make a specific determination that the selection of subjects is equitable is based on the principal of justice, and helps ensure that the burdens and benefits of research will be fairly distributed. The Belmont Report recommends that, as a matter of social justice, there should be an order of preference in the selection of classes of subjects: adults before children, competent individuals before incompetent individuals, and non-institutionalized persons before institutionalized persons.

In addition, those individuals who may already be burdened (e.g., by disabilities or institutionalization) should not be asked to accept the burdens of research unless there is the possibility of direct benefit, or if other appropriate subjects cannot be found (i.e., if the research concerns their particular disability or circumstance). The IRB will consider the extent to which a proposed subject population may already be burdened by poverty, illness, or chronic disabilities in deciding whether they are a suitable subject population.

Informed consent will be appropriately documented

Legally effective informed consent must be sought from each prospective subject (or their legally authorized representative) and effectively documented. The IRB will review the procedures for informed consent to ensure that all elements of informed consent are provided for. (For an explication of the elements of informed consent, see unit 35: *Informed Consent*.)

The IRB will also assess the protocol for any situations that could lend themselves to the perception of coercing subjects to participate in the study.

Waivers for documented informed consent may be requested under any of the following conditions:

- If the consent document would provide the only link to the subject and the principal risk of the research would be a breach of confidentiality
- If the risk to the subjects is minimal and consent would not be required outside the research context
- If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained

In addition, waivers of or alternation to informed consent may be requested under the following conditions:

- The research could not practicably be carried out without the waiver
- The research involves no more than minimal risk to the subjects
- The waiver will not adversely affect the rights and welfare of the subjects
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
- If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

Note that obtaining informed consent is one of the cornerstones of conducting ethical human subjects research and any plan for informed consent and/or waiver or alteration is closely scrutinized by the IRB. Additional information regarding the informed consent process and its requirements can be found in unit 35: Informed Consent.

Research plan makes adequate provisions for monitoring the research data, and adequate provisions are made to protect the privacy of subjects and maintain the confidentiality of their data

A plan for the monitoring of collected data for the safety of the subjects, especially where risks to the subjects are substantial, must be included.

The IRB will review the data safety plan to ensure it is appropriate for the risk level of the project. Consideration will be given to where it will be stored, how it will be stored, and for how long it will be stored.

A plan for the protection of the subjects' privacy and data confidentiality must be discussed. The IRB will consider the nature, probability, and magnitude of harms that would be likely to result from a disclosure of collected information outside the research. It will evaluate the effectiveness of proposed de-identification techniques, coding systems, encryption methods, storage facilities, access limitations, and other relevant factors in determining the adequacy of confidentiality protections.

Additional information regarding data retention, management, and protection can be found in unit 46: Data Management and Protection and unit 47: Data Retention.

Additional safeguards for Vulnerable Subjects

If the research includes vulnerable subjects such as children, prisoners, pregnant women, persons with impaired decision-making capacity or those who are economically or educationally disadvantaged, the IRB will review the application to determine that appropriate additional safeguards have been included in the research to protect the rights and welfare of these subjects.

19. THE INITIAL REVIEW PROCESS

All IRB applications undergo an initial administrative review by HRPP staff. At this time the IRB administrator may request additional information about the research, additional documentation, and/or revisions to the application. Once these revisions are submitted, HRPP staff will review the application for an initial review category determination.

Exempt Review:

Projects that meet the requirements for one or more of the exempt status categories specified in the federal regulations; involve no more than minimal risk to subjects; do not place subjects at risk for criminal or civil liability, or damage their financial standing, employability, or reputation; do not involve deception (incomplete disclosure may be allowed if subject agrees to the incomplete disclosure prospectively); do not involve children unless expressly allowed by the category of review; and do not involve prisoners or their data undergo review by a qualified HRPP staff member and/or by an IRB member designated by the Chair. *Note that exempt projects subject to a limited IRB review will be reviewed by one IRB member.*

Possible outcomes of review for exemption status:

- Exempt: The application is exempt and the research may proceed
- Does not Qualify for Exempt Status: The application does not qualify for exemption status and the applicable review process is observed

Expedited Review:

Projects are eligible for expedited review if they involve no more than minimal risk to subjects and meet one of nine categories specified by the federal regulations. For applications qualifying for expedited review, the IRB chair or their designee assigns one or more designated reviewers to evaluate the submission and make a final determination about the acceptability of the research protocol. IRB members are assigned to review applications based on relevant disciplinary and regulatory knowledge and experience with study contexts and populations. By applying this expertise during the review process, IRB members document the extent to which study design manifests the ethical principals of the Belmont Report and related institutional, local, state, and federal regulations and policies governing the conduct of research involving human subjects.

Possible outcomes of an expedited review are:

- Approval: The application is approved and no changes are required or recommended. Research may proceed.
- Conditional Approval: The application is approved contingent on minor revisions being made.
- Requires Revision: The application cannot be approved without revisions, clarifications, or additional documents. Once these are submitted, the review process is repeated.
- Does not qualify for Expedited Review: The application does not qualify for expedited review and the applicable review process is observed.

Note that assigned reviewers of an expedited review may not disapprove a research application. If the reviewer believes the research should not be approved, it must be referred to the full committee for a final determination.

Full Committee Review:

Projects that involve more than minimal risk, vulnerable populations or prisoners, or those that do not fit into one or more of the categories for exempt or expedited review must be reviewed by the full board at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary interests are non-scientific.

In the event the IRB lacks the appropriate expertise to assess the proposed research, the IRB may seek outside expertise to assist its evaluation.

Approximately one week prior to the next scheduled board meeting, all application materials scheduled to be reviewed are distributed to the full board. It is the expectation that all members of the committee review the application materials prior to the meeting and be prepared to participate in the discussion of the significant concerns, raise additional concerns, necessary clarifications, and/or propose resolutions.

The meeting is called to order by the board chair once a quorum of committee members is reached. If a quorum of members is not reached or is lost once the meeting has begun, all proposals not reviewed are tabled and reviewed at the next scheduled meeting or the meeting is rescheduled for such a time that a quorum of members are present.

Once the application has been sufficiently discussed by a quorum of committee members, the members present vote on the review determination. In order for a given project to be approved, it must receive the approval of a majority of the members present at the meeting.

Possible outcomes of a full committee review are:

- Approval: The application is approved and no changes are required or recommended. Research may proceed.
- Conditional Approval: The application is approved contingent on minor revisions being made.
- Requires Revision: The application cannot be approved without revisions, clarifications, or additional documents. Once these are submitted, the review process is repeated (at this point a subset of the committee may be designated by the chair to review the revised application on a rolling basis).
- Disapproval: The application cannot be approved due to issues the committee believes are non-revisable and inherent in the research.

Note: For an application to be approved, a majority of the committee members present must vote to approve the application.

In addition to determination of approval/disapproval of the research application, the reviewer(s) will assess the level of risk to subjects involved in the research and determine a continuing review schedule that will be no less than annual.

Note: Any application approved by the IRB may be subject to further review by officials of the institution. The institution may not, however, override the IRB's decision to disapprove an application.

Once the initial review process is complete, the IRB administrator notifies the principal investigator of the determination and next steps to be taken:

- For research that has been approved, the IRB administrator emails a formal approval letter to the principal investigator listing the approval start and end dates, and the requirements for requesting a continuation, modification, or termination of the research.

- For research approved conditionally, the principal investigator is informed by the IRB administrator via email of the conditions that must be met for approval. Once these conditions are met, the IRB administrator emails a formal approval letter to the principal investigator listing the approval start and end dates, and the requirements for requesting a continuation, modification, or termination of the research.
- For research requiring revisions, the principal investigator is informed by the IRB administrator via email of the necessary revisions. Once the revisions are made, the IRB administrator forwards the revised protocol to the reviewing IRB member(s).
- For research that has been disapproved, a formal letter outlining the reasons for the IRB's decision is emailed to the principal investigator with the steps they might take to respond to the determination.

A copy of the determination notification is placed in the application file and a signed hard copy is available to the principal investigator upon request.

20. IRB MEMBER CONFLICT OF INTEREST

An IRB member will disclose to the IRB administrator any conflicts of interest they may have with a particular research application under review by the IRB.

If an IRB member has a conflict of interest with an application, they may not review the application under the expedited review process. If the IRB member finds an application in which they have a conflict of interest is assigned for their review, they will inform the IRB administrator of the conflict and recuse him/herself from its review. The application will then be assigned to another IRB member for review.

An IRB member will not be present for full-committee review of any application in which they have a conflict of interest. If the IRB member finds an application in which they have a conflict of interest comes before the committee for review, they will inform the IRB administrator of the conflict and remove him/herself from the room prior to the committee's review of the application.

If an IRB member recuses him/herself from review, they will not be counted to reach the necessary quorum. If a quorum is no longer reached, the application will be tabled and reviewed at the next convened meeting in which quorum is reached without the inclusion of the IRB member with the conflict of interest.

The IRB member's recusal will be listed in the meeting minutes.

Situations in which an IRB member will recuse him/herself:

- The IRB member is listed in the application as a member of the research team, including as principal investigator on a student's research project
- The IRB member has a significant financial interest in the research
- The principal investigator is a member of the IRB member's family
- The IRB member feels they have personal biases which may interfere with their ability to conduct an impartial review

In addition, the IRB may determine if any of the following reach the level of a conflict of interest:

- The IRB member has a fiduciary relationship with the sponsor of the research
- The IRB member is in competition with the principal investigator for funding, sponsorship, or research subjects
- The IRB member has a relationship with the principal investigator which could influence the judgment of the IRB member in reviewing the research

21. ATTENDANCE OF NON-MEMBERS AT IRB MEETINGS

The IRB administrator is in attendance at all IRB meetings.

The IRB may invite at any time and at its sole discretion additional non-members to attend a convened IRB meeting. Possible invitees and reasons for such an invitation include, but are not limited to:

1. Consultants such as outside faculty and/or staff with expertise on the topic of a research application to assist in the review and evaluation of its approvability.
2. Principal investigators (accompanied by student researcher, if applicable) to clarify and give additional information about their research to assist the IRB in the review and evaluation of its approvability.
3. Principal investigators (accompanied by student researcher, if applicable) when their research application has been disapproved.

The following guidelines shall apply regarding non-member attendance at a convened IRB meeting:

- Non-members are invited to attend a convened IRB meeting by the IRB in writing, at which time they are informed of the time to appear and the maximum length of time they may be expected to attend.
- Non-members are not considered when establishing quorum for the convened IRB meeting.
- Non-members are asked to wait outside the meeting until such time as the IRB is ready for them.
- Non-members attend only that portion of the meeting relevant to the research application on which they have been invited to consult.
- Non-members do not participate in the review or vote of any research application.
- Non-members may be asked to leave at any time, at the discretion of the IRB chair.
- Attendance of non-members will be reflected in the minutes of the meeting, as well as confirmation that the non-member did not participate in the deliberations or vote.

WHAT HAPPENS AFTER THE IRB HAS REVIEWED MY APPLICATION?

22. REVIEW DETERMINATION

Once the initial review process is complete, the IRB administrator notifies the principal investigator in writing of the determination and next steps to be taken:

- For research that has been approved, the IRB administrator emails a formal approval letter to the principal investigator listing the approval start and end dates, and the requirements for requesting a continuation, modification, or termination of the research. A signed hard copy is available on request.
- For research approved conditionally, the principal investigator is informed by the IRB administrator via email of the conditions that must be met for approval. Once these conditions are met, the IRB administrator emails a formal approval letter to the principal investigator listing the approval start and end dates, and the requirements for requesting a continuation, modification, or termination of the research. A signed hard copy is available on request.
- For research requiring revisions, the principal investigator is informed by the IRB administrator via email of the necessary revisions. Once the revisions are made, the IRB administrator forwards the revised protocol to the reviewing IRB member(s).
- For research that has been disapproved, a formal letter outlining the reasons for the IRB's decision is emailed to the principal investigator with the steps they might take to respond to the determination. A signed hard copy is available on request.

23. RECOURSE FOR A DISAPPROVED APPLICATION

The IRB is committed to working with investigators to ensure that all submitted applications are ethically sound and in compliance with the federal regulations. Rather than disapprove an application, the IRB prefers to provide guidance to make the necessary changes to secure approval or otherwise reach an appropriate resolution.

However, if the review determination is disapproval, the principal investigator will receive a statement of why it was disapproved and an invitation to respond in writing. The convened IRB will review responses to all disapproval communications. If the IRB re-affirms its disapproval of the research, the principal investigator may request to speak to the following convened meeting of the IRB, during which the investigator may argue their case. If the IRB once again re-affirms its disapproval, the investigator may not proceed with the research as outlined in their disapproved application.

WHAT HAPPENS AFTER MY APPLICATION HAS BEEN APPROVED?

24. MODIFICATIONS TO THE RESEARCH

All modifications to currently approved research require review and approval prior to implementation, regardless of the original review category of the research. A [Modification Request](#) must be submitted and approved before all changes in the research plan are implemented. If changes to currently approved research are initiated prior to approval, the research will be out of compliance and must cease immediately.

Modification requests must include:

- Change in risk level, if applicable
- A description of the proposed modification, including a discussion of the effects on the risks and benefits to the subjects and the procedures that will be taken to manage the risk(s)
- Revised consent forms, study instruments, and/or recruitment materials, if applicable
- Changes in personnel, including personnel being added and/or deleted, if applicable

- Changes in the facility/agency involved in the research activities and/or funding sources, if applicable

The only exception is the rare circumstance in which a change is necessary to eliminate apparent immediate hazards to the research subjects. In this case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with the protection of human subjects.

Examples of modifications include, but are not limited to:

- Change in principal investigator
- Addition or removal of personnel
- Increase in planned number of enrolled subjects
- Changes to the inclusion/exclusion criteria
- Minor changes to the study instruments (surveys, questionnaires, etc.)
- Changes to the informed consent document or procedures
- Changes to recruitment materials
- Changes in location of research or agency
- Changes in funding sources
- Change to procedures that do not affect participants

If the planned changes include 1) the addition of a new study population (or group of participants) **and** 2) changes in procedures (including changes to study instruments), they may not qualify for a modification and a new IRB application may be required.

Unanticipated risks to subjects or new information that may affect the risk/benefit assessment also must be promptly reported to, and reviewed by, the IRB to ensure adequate protection of human subjects.

Exempt Research

Modification requests for research whose initial review or last approved modification qualified for exempt status will be reviewed by HRPP staff unless requested modifications would result in an increase of risk level, in which case the modification request will be reviewed in accordance with the change in risks to subjects.

Note that if the original research was approved as exempt and the modifications in question disqualify the research from this exemption, an initial application protocol must be submitted with the modification request. The modification request and initial application protocol will be reviewed either as expedited or by the full committee, as appropriate.

Expedited Review

Modification requests for research whose initial review or last approved modification qualified for expedited review will be reviewed by the original reviewers or another member of the IRB designated by the chair or their designee, unless requested modifications would result in a change of risk level, in which case the modification request will be reviewed in accordance with the change in risks to subjects.

Full Committee Review

Modification requests for research whose initial review or last approved modification was subject to full committee review will be reviewed by the full committee unless requested modifications would result in a reduction of risk level, in which case the modification request will be reviewed in accordance with the change in risks to subjects.

Once the modification review process is complete, the IRB administrator notifies the principal investigator of the determination and next steps to be taken:

- For modification review requests that have been approved, the IRB administrator informs the principal investigator via email of the approval.
- For modification review requests that have been approved conditionally, the principal investigator is informed by the IRB administrator via email of the conditions that must be met for approval. Once these conditions are met, the IRB administrator emails approval to the principal investigator.
- For modification review requests requiring revisions or additional materials, the principal investigator is informed by the IRB administrator via email of the necessary revisions or additional materials. Once the revisions are made, the IRB administrator forwards the revised protocol to the reviewing IRB member(s).
- For modification review requests that have been disapproved, a formal letter outlining the reasons for the IRB's decision is emailed to the principal investigator with the steps they might take to respond to the determination.

A copy of the determination notification is placed in the application file, and a signed hard copy is available on the request of the principal investigator.

25. CONTINUING REVIEW

All human subjects research initially reviewed by the full committee must be reviewed by the IRB at an interval determined by the IRB at the time of its initial review or last requested modification, and based upon the nature of the study, the level of risk to subjects, and the vulnerability of the subject population, but no less than annually.

Human subjects research initially reviewed as expedited may require continuing review at the discretion of the reviewer.

The continuing review timetable is indicated on the research application approval letter by the end date of the IRB's last approval of the research. If the research continues beyond this end date, the investigator must submit a [Continuation Request](#) at least 30 days prior to this end date. The research requires continuing review if the interventions and/or data collection continue. Continuing review is not required if the investigators are only analyzing data, including identifiable private information or biospecimens, or accessing follow-up clinical data from clinical care procedures.

Continuing review must include determinations by the IRB regarding risks, potential benefits, informed consent, and safeguards for human subjects. In conducting continuing review, the IRB will review, at a minimum, the protocol and any amendments, as well as:

- A description of any complications, adverse events, or unanticipated problems involving risks to subjects or others; withdrawal of subjects from the research; or complaints about the research
- An explanation of any unapproved modifications made to the research since last review

- A summary of changes in the literature that would affect the research

In addition, when conducting continuing review of research involving interactions or interventions with subjects, the IRB will review a status report on the progress of the research, including:

- The number of subjects originally approved to be enrolled in the research
- The number of subjects currently approved to be enrolled in the research
- The number of subjects currently enrolled in the research
- The total number of subjects still planned to be enrolled in the research
- The number of subjects who refused to participate at the time of screening/informed consent
- The number of subjects who withdrew their participation after informed consent was given

Exempt Status Research

Research whose initial review or last approved modification deemed the research exempt by the IRB office is not subject to continuing review.

Expedited Review

Research whose initial review or last approved modification was reviewed as expedited is subject to continuing review at the discretion of the reviewer, and will be reviewed by the initial reviewer (if initial reviewer is unavailable, another reviewer will review the continuing review request).

Full Committee Review

Continuing review requests for research whose initial review or last approved modification was subject to full committee review will be reviewed by the full committee unless changes in level of risk to subjects has been reduced to less than minimal, in which case continuing review will no longer be necessary.

Note that research whose subjects include prisoners or their data (unless incidentally) are not eligible for a downgrade in review.

Once the continuing review process is complete, the IRB administrator will notify the principal investigator of the determination and next steps to be taken:

- For continuing review requests that have been approved, the IRB administrator informs the principal investigator via email of the approval start and end dates.
- For continuing review requests requiring revisions or additional materials, the principal investigator is informed by the IRB administration via email of the necessary revisions or additional materials.
- For continuing review requests that have been disapproved, a formal letter outlining the reasons for the IRB's decision is emailed to the principal investigator with the steps they might take to respond to the determination.

A copy of the determination notification is placed in the application file, and a signed hard copy is available on request of the principal investigator.

26. AUDITS AND MONITORING

In order to help ensure compliance with federal regulations and local IRB policies regarding research with human subjects, and to ensure that human subjects are adequately protected, the Brandeis IRB may conduct routine, targeted or random audits of research.

These activities may include, but are not limited to the following:

- Requesting progress reports from investigators
- Examining research records
- Contacting research subjects
- Dispatching observers to the sites where research involving human subjects and/or the informed consent process is being conducted
- Auditing advertisements and other recruiting materials
- Verifying from sources other than investigators that no material changes in the study have occurred since previous IRB review
- Other monitoring or auditing activities deemed appropriate by the IRB

Possible reasons for the Brandeis IRB to conduct audits include, but are not limited to:

- Complaints received from research subjects
- Concerns raised by a third party
- Research involves a high risk of harm to subjects
- An occurrence of an unanticipated problem or adverse event
- A history of noncompliance by an investigator

Reporting of Audit Results to Full Board

The results of any targeted or random audits will be reported to the full IRB on the agenda of the next regularly scheduled meeting. If the auditors believe the subjects are being put at immediate risk due to the occurrence of material changes they may suspend or terminate approval of the research and/or a special meeting may be called.

A report of the committee's review of the audit is communicated electronically to the principal investigator, the institutional official, and the department or agency head as appropriate. A copy is placed in the IRB file and a signed hard copy is available upon request.

If the auditors suspect noncompliance by the research team, procedures for the reporting of noncompliance are initiated (see unit 28: *Investigator Noncompliance* for more information on reporting procedures for noncompliance).

27. UNANTICIPATED PROBLEMS AND ADVERSE EVENTS

If an investigator believes an unanticipated problem or adverse event has occurred, they must report it to the IRB via an [Incident/Unanticipated Problem Report](#) form.

Unanticipated problems that are *serious adverse events* must be reported within one week of the investigator becoming aware of the event.

Unanticipated problems that are *non-serious adverse events* must be reported within two weeks of the investigator becoming aware of the event.

Included in this report must be:

1. The appropriate identifying information for the research protocol, such as the title, principal investigator's name, and IRB project number.
2. A detailed description of the adverse event, incident, experience, or outcome.
3. An explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem.
4. A description of any changes to the protocol or other corrective actions that have been taken – if it is determined by the principal investigator that such corrective actions are in the best interest of individual subjects currently participating in the study – or are proposed in response to the unanticipated problem.

Once a report has been filed, the IRB chair or their designee reviews the report along with materials from the protocol file (e.g., initial protocol, continuing reviews, modifications) and determines whether the event qualifies as an unanticipated problem and/or adverse event.

If it is determined the event does not qualify as an unanticipated problem or adverse event, this is communicated to the principal investigator. A copy of the report and notification is placed in the IRB file and the issue is considered closed.

If the determination is made that the event was, indeed, an unanticipated problem or adverse event, the report is reviewed at the next convened IRB meeting, or a special meeting is called if deemed necessary by the reviewer. The IRB administrator notifies the principal investigator of the IRB's determination and actions to be taken and a copy of the report is placed in the IRB file. The IRB has a number of available actions it can take, depending on the severity of the event and the continuing risk to subjects.

Possible actions the IRB may take include:

- Terminating the research
- Suspending the research
- Requiring modification to the research (such as to the informed consent process)
- Requiring additional monitoring of the research or consent process
- Requiring subjects to be notified of the event
- Requiring current subjects to be re-consented

In addition to possible actions relating to the research, the IRB administrator reports to the Institutional Official the event and action taken and/or planned. The Institutional Official then reports the event and action taken and/or

planned to the Office for Human Research Protections, sponsors of the research (if applicable), and/or any other applicable entities.

The Institutional Official will include in their report to OHRP the following:

1. The name of the institution (Brandeis University)
2. Title of the research project
3. Name of the principal investigator on the protocol
4. Project number assigned by the IRB
5. Title and funding number of the funded grant proposal, if applicable
6. Name of principal investigator on the grant, if applicable
7. A detailed description of the problem
8. An explanation of the actions taken and/or planned by Brandeis University
9. If actions include suspension or termination of the research project, an explanation of the actions taken and/or planned by Brandeis University to address the suspension or termination

28. INVESTIGATOR NONCOMPLIANCE

It is the principal investigator's responsibility to ensure that issues of noncompliance in human subject research do not occur. Allegations of noncompliance should be reported to the university's IRB administrator and will be duly investigated. If an investigator becomes aware of any issues of noncompliance within their human subjects research study, they must report it immediately via an [Incident/Unanticipated Problem Report](#).

Review and Remediation of Allegations of Noncompliance

Once an allegation or report of suspected noncompliance is reported, the IRB chair or their designee conducts an investigative review to determine whether the issue meets the definition of noncompliance. If they determine the issue does not meet the definition of noncompliance, the issue will be considered closed.

If it is determined the issue meets the definition of noncompliance, the IRB chair or their designee makes a determination of the level of seriousness and whether the issue meets the definition of continuing noncompliance.

If it is determined the issue is non-serious and non-continuing noncompliance, a corrective action plan will be developed to prevent further noncompliance, to be instituted by the principal investigator. The IRB administrator notifies the principal investigator of the corrective action plan and a copy of the plan is placed in the IRB file. The report of noncompliance and its corrective action plan is reported at the next convened meeting of the IRB. Once the corrective action plan is implemented, the issue is considered closed.

If it is determined the issue is serious or continuing noncompliance and puts the subjects at immediate risk, the research may be suspended immediately. In such a case, a report of the suspension is sent to the principal investigator and a special meeting of the IRB is convened within 10 days to review the issue and determine a further course of action. The IRB administrator notifies the principal investigator and copies of the report are placed in the IRB file and forwarded to the Institutional Official.

If it is determined the issue is serious or continuing noncompliance but does not put the subjects at immediate risk, the issue is reported and reviewed at the next convened meeting of the IRB, and a course of action is determined. The IRB administrator notifies the principal investigator and copies of the report are placed in the IRB file and forwarded to the Institutional Official.

Possible actions of the Brandeis University IRB may include, but are not limited to:

- Requiring modification of the research protocol
- Requiring modification of the consent process
- Requiring re-education of the principal investigator and research team
- More frequent continuing review schedule
- Periodic audits
- Requiring re-consent of subjects
- Suspension of the study
- Termination of the study

If noncompliance is determined and a corrective action plan developed, the IRB monitors the principal investigator's implementation of the corrective action plan. If the corrective action plan is not fully implemented within the plan's stated time frame, the IRB and the Institutional Official are informed within one week and a further course of action is determined.

Once the corrective action plan has been fully implemented, the IRB administrator drafts a final report to be reviewed at the next convened meeting of the IRB. Once finalized, the report is endorsed by the IRB chair and the principal investigator is notified. A copy of the report is placed in the IRB file and forwarded to the Institutional Official.

The Institutional Official informs and forwards all applicable reports regarding serious and/or continuing noncompliance to the Office for Human Research Protections, sponsors of the research (if applicable), and any other applicable entities.

The Institutional Official includes in their report to OHRP the following:

1. The name of the institution (Brandeis University)
2. Title of the research project
3. Name of the principal investigator on the protocol
4. Project number assigned by the IRB
5. Title and funding number of the funded grant proposal, if applicable
6. Name of principal investigator on the grant, if applicable
7. A detailed description of the problem

8. An explanation of the actions taken and/or planned by Brandeis University
9. If actions include suspension or termination of the research project, an explanation of the actions taken and/or planned by Brandeis University to address the suspension or termination

29. TERMINATION

When approved or exempt research has ended, that is after the recruitment of subjects, collection of data, and analysis of data has been completed, the investigator is required to complete and submit a [Termination and Final Report](#) to the IRB administrator. This report must include a synopsis of the study and a short discussion of any adverse events that occurred and the significance they had for the study. *Note that a student protocol for a thesis project should not be formally terminated until a successful defense has been made.*

WORKING WITH SPECIAL POPULATIONS

30. RESEARCH WITH VULNERABLE SUBJECTS

The Federal regulations identify specific populations (special classes of subjects) as being especially vulnerable and requiring additional protections, including:

- Children
- Prisoners
- Individuals with impaired decision-making capacity
- Economically or educationally disadvantaged persons

When working with a vulnerable population, investigators should outline how they plan to create additional protections for the rights of these subjects.

Some factors to consider are:

- Inclusion and exclusion criteria for selecting and recruiting subjects
- Informed consent and voluntarism
- Coercion and undue influence
- Confidentiality of data
- Group characteristics such as economic, social, physical, and environmental conditions, so that the research incorporates additional safeguards
- Not over-selecting or excluding certain groups based on perceived limitations or complexities associated with, or the easy availability of, those groups (for example, it is not appropriate to target prisoners as research subjects merely because they are a readily available “captive” population)

- Knowledge about applicable laws that bear on the decision-making abilities of potentially vulnerable populations
- Having adequate procedures in place for assessing subjects' capacity, understanding, and informed consent or assent

31. RESEARCH WITH CHILDREN AND STUDENTS

The federal regulations consider children to be a particularly vulnerable population, and require that IRBs give special consideration to protecting their welfare.

Children are defined by the 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 research will be conducted.” [§46.402(a)] In Massachusetts persons under the age of 18 are considered children, but this varies state to state and country to country. If using children as subjects outside of the Commonwealth of Massachusetts, the investigator must confirm the applicable laws in that state/country.

When an investigator plans on using children as subjects, they must justify their use in detail in their IRB application.

Allowable Categories of Research

There are three categories of research involving children that the federal regulations state can be approved by the IRB. A proposal involving children that does not fall into one of these three categories cannot be approved by the IRB:

1. Research not involving greater than minimal risk to the children

To be approved, the research must satisfy the following conditions:

- a. It presents no greater than minimal risk to the children
—and—
- b. Adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians

2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.

To be approved, the research must satisfy the following conditions:

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

3. Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition

To be approved, the research must satisfy the following conditions:

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

A fourth category exists, however it must be reviewed and approved by the HHS Secretary after consultation with a panel of experts and public comment:

4. Research presenting a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

To be approved, the research must satisfy the following conditions:

- a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
—and—
- b. The research will be conducted in accordance with sound ethical principles
—and—
- c. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians

Informed Consent and Assent

Special consideration must be given to the assent of children to participate in research. See unit 35: *Informed Consent* for a discussion of the informed consent/assent process for research involving children.

Research in Schools and Letters of Permission

Investigators must obtain letters of permission from the educational agencies (elementary schools, secondary schools, or school districts) in which the research is to be performed. This letter should be attached to the initial application. See Unit 44. *Site Permissions for Off-campus Research* for more information regarding letters of permission.

Research Involving Student Educational Records and FERPA

Educational records are defined as records containing information (in any medium – paper, electronic, microfilm, etc.) that directly relate to a student and are maintained by an educational institution or by a party acting for the institution.

Research involving students' educational records may be subject to the Family Educational Rights and Privacy Act (FERPA). [FERPA applies to all educational agencies and institutions that receive federal funding.] FERPA has two purposes: 1) to provide parents and students with the rights to inspect a student's records and request the correction of incorrect information, and 2) to ensure the privacy of such records. As a result, investigators must take into consideration this right to confidentiality when conducting research on students and their educational records.

When planning to do research involving students' educational records, the investigator has three options:

1. The investigator may obtain consent from each student to have access to that student's records. [Consent forms must specify the records to be disclosed, state the purpose of the disclosure, identify the party to whom the disclosure is to be made, and be signed and dated by the parent or student (if over age 18 or attending an institution of postsecondary education).]
2. A school official (other than the investigator) who has legitimate access to the records may strip the records of all personally identifying information and provide the investigator with the de-identified data.
3. The school may request one of the following exceptions to FERPA for release of the records to the investigator:
 - a. The investigator is a school official with legitimate educational interest.
 - b. The investigator is conducting studies for or on behalf of the school (i.e., developing, validating, or administering predictive tests; administering student aid programs; or improving instruction).

When requesting an exception to FERPA, the school district's superintendent (for K through 12th grade) or the University Registrar (for post secondary schools) must supply a letter allowing the exception, to be attached to the investigator's IRB application.

Note: A letter of request from the investigator is not sufficient and if the superintendent or registrar denies an investigator access to the records, the IRB cannot overrule this decision.

When using Brandeis University students' educational records, a letter from the registrar must accompany the IRB application, allowing such use.

Student Surveys, Analysis, or Evaluation Involving Sensitive Information and PPRA

The Protection of Pupil Rights Amendment (PPRA) applies to local educational agencies (elementary schools, secondary schools, school districts, or local boards of education) that receive funds from the US Department of Education and requires parental consent for research involving surveys, analysis, or evaluation in which the primary purpose is to reveal information concerning one or more of the following:

- Political affiliations or beliefs of the student or the student's parent
- Mental and psychological problems potentially embarrassing to the student or his or her family
- Sex behavior or attitudes
- Illegal, anti-social, self-incriminating and demeaning behavior
- Critical appraisals of other individuals with whom the student has close family relationships
- Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers
- Religious practices, affiliations, or beliefs of the student or student's parent
- Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program

Prior to conducting research involving any of the protected information listed above, written parental consent is required: The IRB cannot approve waivers of parental permission for surveys, analyses, or evaluations involving such protected information. In addition, parents have the right to inspect all materials involved before they are administered or distributed and to opt the student out of the surveys if they wish.

Investigators whose research is subject to PPRA should review the policies of the local educational agency.

32. RESEARCH WITH PRISONERS

The Belmont Report discusses three principles on which the federal regulations are based: *Respect for Persons, Beneficence, and Justice*. Respect for Persons demands that subjects give their un-coerced informed consent before participating in research, while Beneficence demands that the possible benefits be maximized and the possible harms be minimized, and Justice demands that no individual be disproportionately put at risk or unjustifiably targeted for inclusion in research.

Two of these principles – *Respect for Persons* and *Justice* – give historical examples (such as the war crimes of Nazi researchers using concentration camp prisoners as subjects) of the ease with which these principles may be discarded in the case of prisoners due to those potential subjects' captive availability and powerlessness to defy their keepers. As a result, the federal regulations – based in large part on the Belmont Report's three principles – deems prisoners to be a vulnerable population, and as such in need of special considerations and protections.

A prisoner is defined by HHS as any individual involuntarily confined or detained in a penal institution or facility, including individuals sentenced under criminal or civil statute or commitment proceedings which provide alternatives to incarceration, and individuals detained pending arraignment, trial, or sentencing.

Note: While individuals on probation or parole are in an extremely vulnerable situation, they are not considered to be prisoners.

Allowable Categories of Research

The regulations allow for four categories of research with prisoners as subjects that are allowable:

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
2. Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).
4. Research on practices, both innovative and accepted, which have the intent and reasonability of improving the health or well-being of the subject.

When an investigator plans on using prisoners as subjects, they must include a justification for the use of prisoners as well as an explanation of how the research falls into one of these allowable categories.

Additional Review Considerations

When an application is determined to fall into one of the allowable categories listed above, the IRB must consider in its deliberations:

- Any advantages that prisoners will realize as a result of participation in the research, when compared to general living conditions within the prison, are not so great as to impair the prisoner’s ability to weigh the risks and benefits of participation and freely choose
- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers
- Procedures for selecting subjects within the prison are fair, and free from arbitrary manipulation by prison authorities or other prisoners
- Control subjects will be selected randomly from among the group of eligible volunteers, unless the investigator justifies a different procedure
- The information presented during recruitment and consent procedures is in a language, and level of complexity, understandable to the subject population
- The IRB is assured that the parole board will not take research participation into account in making decisions about parole, and each prisoner is informed in advance that participation will have no effect on the possibility of parole
- If medical follow-up is necessary to protect the health and welfare of the subject, adequate provision is made for such care, taking into account the varying length of prisoners’ sentences

The above considerations should be taken into account when completing the application.

Note: For HHS-funded research involving prisoners, the IRB must certify to the Secretary (through OHRP) that it has reviewed the research and all additional considerations outlined above have been met. For research falling under categories 3 and 4, the Secretary will consult with experts, including experts in penology medicine and ethics, and publish a notice in the Federal Register of their intent to approve the research.

Review Classification

No initial applications, modification requests, or continuation requests using prisoners as subjects may be reviewed under expedited review, but must be reviewed by the full committee. In addition, at least one member of the review board must be a prisoner or prisoner representative with the appropriate background, experience, knowledge, understanding, and appreciation for the conditions of the prison from the prisoner’s perspective, and no other board member may have any association with the prison(s) involved other than to review the application.

33. RESEARCH WITH SUBJECTS WITH LIMITED PROFICIENCY IN ENGLISH

It is important that research be conducted in a language in which the subjects are proficient. When targeting non-English speaking subjects, research materials – recruitment fliers and letters, informed consent forms, information sheets, scripts, study instruments, etc. – must be translated into the language of your prospective subjects. These materials – those in English and those translated – must be included in the IRB application and a [Translation Certification](#) must be completed for the translator(s). If the materials will not be translated until after IRB approval, they, along with the Translation Certification, may be submitted with a [Modification Request](#). Note that the translated materials may not be used until they have been approved by the IRB.

If a non-targeted potential subject is not proficient in the language in which the research is being conducted, they should not be eligible to participate in the research unless the materials can be translated into the language of the subject. If materials are translated after the initial IRB application has been approved, a [Modification Request](#) with the translated materials and a [Translation Certification](#) must be submitted and approved prior to being used.

If the research is being conducted by an investigator who him/herself is not proficient in the language of the subject, an interpreter who is fluent in the languages of both the investigator and the subject must be obtained. This is particularly important for the informed consent process. The interpreter can either be a member of the research team or a professional interpreter. Information about the interpreter – including name, affiliations, and qualifications – must be supplied under the personnel or collaborations sections of the application.

For more detailed information specific to informed consent and language barriers, see unit 35: Informed Consent.

34. INTERNATIONAL RESEARCH

Human subjects research conducted under the auspices of Brandeis University and in a foreign country must adhere to the applicable standards, policies, laws, and norms of Brandeis University, the United States, and the foreign country in which the research is to take place (the host country).

Just as Brandeis University requires approval from the Brandeis University IRB, foreign countries often require approval from the/an IRB or ethics committee in their country. Many countries have a single IRB or ethics committee for the entire country, while other countries have many IRBs and ethics committees affiliated with many institutions scattered throughout the country, just as in the United States.

(To determine what the laws regarding obtaining approval are of the country in which the research will be conducted, see the Office for Human Research Protections [International Compilation of Human Research Standards](#), a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and international organizations.)

Many foreign countries use the same or similar standards as the United States (the Belmont Report, Common Rule, and/or 45 CFR 46), and it is easy to dismiss the necessity of acquiring approval from the host country on these grounds. It is important, however to recognize that similar standards do not equate to approval from both countries. The Brandeis University IRB is not and cannot be familiar with the cultural norms, social mores, and local laws of every country, which vary tremendously around the globe. The Brandeis University IRB may depend on the host country's IRB or ethics committee's knowledge, then, of what might put human subjects at risk in their particular country.

If the host country has an IRB that uses standards other than 45 CFR 46 and the standards, policies, laws, and norms are in conflict, the research must comply with those that are the more stringent.

While it may be the case that the host country does not require approval from the/an IRB or ethics committee in their country, the Brandeis University IRB may still require that approval be obtained. In cases where the Brandeis University IRB does not feel competent in its ability to judge what might put human subjects at risk, not obtaining this approval could be detrimental to the human subjects.

It may also be the case that the host country has no official IRB or ethics committee. It is often necessary, in such situations, to obtain approval from local experts or leaders of the country or community in which the research will be conducted. It is important, however, that the individual(s) granting the approval be as independent as possible from the human subjects, as well as the research, to avoid the appearance of coercion or undue influence.

Note that an [International Research Addendum](#) must be included with the application for every investigator traveling abroad.

Note as well that if research will be conducted in a language other than English, all translated materials, along with a [Translation Certification](#), must be submitted to the IRB for approval prior to their use.

For information regarding informed consent for international research, including language and cultural barriers, see unit 35: Informed Consent.

SPECIAL TOPICS

35. INFORMED CONSENT

The primary purpose of informed consent is to protect the human subjects. Informed consent provides the individual with the pertinent information regarding the research in which they are being asked to participate, and the opportunity to make an informed decision regarding whether or not to participate in the research. The procurement of informed consent signifies that the subject has made an informed decision and agrees to participate without coercion, force, or fraud.

Consent must also be freely given – it must be made clear to the subject that they are not required to participate and that they can withdraw at any time without fear of penalty or loss of benefits of any kind.

To ensure informed consent, investigators must work to communicate clearly and effectively with their subjects, build trust and cooperation, openly and willingly explain their research, answer questions, and be sensitive to the needs and concerns of their subjects.

Note that the consent process is not over once consent has been obtained, but it continues throughout the subject's involvement in the research. Subjects should continually be encouraged to ask questions and request clarifications, and be reminded that they may withdraw from the research at any time. Maintaining consent is particularly important in cases where the subject's participation in the research is ongoing.

The Informed Consent Form

In most circumstances, the IRB will require that informed consent be documented by the use of a written consent form approved by the IRB and signed and dated by the subject.

When using an informed consent form, the investigator reviews each component of the form with the subject, encourages and answers any questions the subject has, and allows ample time for the subject to deliberate on whether they would like to participate in the study. It is important that, when the investigator presents the information, the subjects' ability to comprehend is taken into account. In addition, the investigator must ensure that the subject knows their participation is completely voluntary and that they may withdraw from the research at any time.

Note that the consent form is not a substitute for discussion; it is a summary of what was discussed.

Because subject understanding is a necessary component of informed consent, information must be presented in a language and at a level that is appropriate for the population. In general, consent documents should be written in lay language at an 8th grade level.

The consent document cannot contain exculpatory language that waives or appears to waive subjects' rights.

The following information should be included in the informed consent document (note that a pdf of the following [elements of informed consent](#), as well as an [informed consent form template](#) are available):

Title of the study

Names and affiliations of the primary investigator

- If a student is conducting the study, state the student's information first

Purpose of the study

- Describe the general purpose of the study

Subject selection criteria

- Describe how subjects were chosen

Study procedures

- In chronological order, describe what the subject will be asked to do (an activity, completing a survey)
- Describe the total length of time for participation (how long, how often)
- If applicable, explain that the investigator will be audiotaping or videotaping and if this is optional

Potential risks and discomforts

- Describe any potential for psychological, social, legal, or financial risk or harms to the subject and their probability as a result of participation in the research (remember – there is no such thing as risk-free human subject research)

Potential benefits

- Describe any expected benefits to the subjects themselves (clearly state if subject will not benefit directly from the study)
- Describe any expected benefits to society and/or science
- Note that compensation is not considered a benefit

Cost and Compensation

- Describe any cost to the subject (include time spent)
- Describe any compensation the subject will be offered as a result of participation in the research (if partial participation will result in partial compensation, explain)

Future use of Data

If working with identifiable data:

- Explain that data may be de-identified and retained for additional or subsequent research (or, if not applicable, that the data collected will not be distributed for future research, even with the identifiers removed)

Confidentiality

- Describe the level to which subject information will be kept confidential (describe procedures that will be used to safeguard data, including where it will be kept, who will have access to it, and at what point it will be destroyed – note the difference between anonymous and confidential)
- Note that data will only be kept confidential to the extent permitted by law

Participation and Withdrawal

- State clearly that the subject may refuse to answer any questions or withdraw from the study at any time without penalty (including loss of benefits to which they would otherwise be entitled)

Contact Information

- Give the contact information of the principal investigator and student investigator (if applicable) for questions about the study
- Give the contact information of the Brandeis University Human Research Protection Program for questions about the subject's rights as a human subject or concerns about the research (hrpp-group@brandeis.edu or 781-736-8133)

Subject Consent

- Example: I have read (or had read to me) this consent form completely. I have been encouraged to ask questions, and have received helpful answers to my questions. I understand that my participation is voluntary and that I may quit at any time without penalty. I voluntarily agree to participate in this study.
- I do I do not give you permission to make audio/video recordings of me during this study (if applicable)
- Signatures of subject and investigator

Additional statement of confidentiality to be used for research involving focus groups

Example: Note that we cannot guarantee that others in the group discussion will keep what you say private. When you sign this form, you agree to not talk about what was said in the group with anyone not part of the group. Everyone in the group will have agreed to this – but we cannot guarantee that everyone will keep their promise.

Additional statement of confidentiality to be included when collecting identifiable, sensitive information for research funded by NIH or when a Certificate of Confidentiality (CoC) has been issued by NIH, CDC, FDA, HRSA, or SAMHSA

Confidentiality [continued]

Example: This research is covered by a Certificate of Confidentiality. That means any identifiable information you share cannot be used as evidence in court – unless you say it's okay. This does not mean you can't share your information with anyone if you want to. But, if you want us to share your information with anybody, you will need to sign another consent form.

Additional statement of procedure to be included when appropriate for research involving incomplete disclosure

Incomplete Disclosure

Example: Research sometimes requires that information regarding its purpose not be shared with the participant. The reason for this is that if you know what the purpose is, it could impact your answers. We will not ask you to do anything that has not been described in this form. At the end of your participation, we will explain the details of the research to you. At that time, you will have the opportunity to ask questions. You will also be given the opportunity to tell us not to use your answers. Note that if we told you the purpose of the research now, we do not believe it would change your mind to participate.

Additional statement to be used if researcher is a mandated reporter

Confidentiality [continued]

- Include a statement that if the subject reports information concerning child abuse (or other information you are mandated to report) you are obligated to report it.

The following information should be included when appropriate (generally only necessary for biomedical/clinical research)

Experimental Procedures

- A description of any procedures that are experimental

Alternative Procedures

- A description of any alternative procedures or course of treatment that might be advantageous to the subject

Possibility of Unforeseeable Risks

- A statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

Compensation or Treatments in Case of Injury

- When research involves more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained

Potential Termination Without Regard to Consent

- A statement of anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

Additional Costs

- A statement of any additional costs to the subject that may result from participation in the research

Consequences of Withdrawal

- A statement regarding the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

Provision of Significant New Findings

- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject

Number of Subjects

- The approximate number of subjects involved in the study

Commercial use of Biospecimens

- A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit

Clinically Relevant Research Results

- A statement regarding whether clinically relevant results, including individual research results, will be disclosed to subjects, and if so, under what conditions

Genome Sequencing

- A statement of whether the research will or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

Remember that the consent form is not a substitute for discussion: it is a summary of what was discussed. Once the subject agrees to participate and the investigator is confident the subject's decision to participate is an informed one, the subject's signature on the form is obtained and the subject is provided with a copy of the consent document.

Waivers of Documented Informed Consent

There are times when having subjects sign an informed consent form would be impractical or detrimental to the study. In these cases, a waiver of documented informed consent may be requested of the IRB. Such waivers may be granted under three conditions:

1. If the consent document would provide the only link to the subject and the principal risk of the research would be a breach of confidentiality.
2. If the risk to the subjects is minimal and consent would not be required outside the research context.
3. If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases where a waiver of documented informed consent is granted, it is important for the investigator to understand that the waiver involves only the *documentation* of informed consent (i.e., the subject signs the informed consent form), not the process, and active consent must still be obtained.

Oftentimes when documented informed consent is waived, the investigator will use an information sheet in its place. An information sheet follows the same format as the consent form and includes all the same elements. In lieu of the consent form, the investigator reviews and discusses the information sheet and obtains the subject's verbal consent.

Note: The IRB may approve an alteration of documented informed consent, as well, where one or more of the elements of informed consent are not included in the informed consent form.

Waivers and Alterations of Informed Consent

In exceptional circumstances the investigator may request a waiver of informed consent (if no consent procedures are to be used) or alteration of informed consent (if required elements of informed consent will be omitted from the consent document). The IRB may waive all or some the requirements of informed consent if all the following stipulations are met:

1. The research could not practicably be carried out without the waiver or alteration.
2. The research involves no more than minimal risk to the subjects.
3. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
5. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

Deception and Informed Consent

The use of deception or incomplete disclosure limits the subject's ability to make a fully informed decision of whether to participate in the research – one of the essential ethical concerns in human subjects research – and a waiver or alteration of informed consent must be requested of the IRB whenever deception or incomplete disclosure is planned.

Because subjects cannot be formally consented prior to the research, subjects must agree to participate in the research through the use of consent to participate in lieu of formal informed consent. This agreement will include all of the elements of informed consent aside from a description of the actual purpose of the study.

To mitigate the concern regarding the lack of informed consent, subjects should ideally be informed prospectively, via the consent to participate, of the use of deception/incomplete disclosure in the research in which they are being asked to participate, and consent to its use. See the elements of consent outlined above for appropriate language to include on the consent form when using deception.

Once the subject's participation in the research is complete, they must be debriefed regarding the true nature of the research. A debriefing and informed consent form giving the investigator permission to retain and use the subject's data must be signed by the subject and attached to the original consent to participate.

Additional information regarding the use of deception in human subjects research can be found in unit 37: Deception and Incomplete Disclosure.

Informed Consent and Assent of Children

Children (defined in Massachusetts as persons under the age of 18) are considered by the Federal Code of Regulations to be a "vulnerable Population" due to their (assumed) inability to fully understand how to weigh the risks and potential benefits of research (or what they are), as well as their susceptibility to undue influence.

Legally, children are not able to provide informed consent on their own behalf; therefore, obtaining informed consent for the involvement of children as research subjects is a two-step process: the investigator must obtain informed permission from the child's parent(s), guardian(s), or legally authorized representative (LAR), as well as assent from the child, assuming they are capable.

Obtaining informed permission from a child's LAR involves the same process as does obtaining informed consent from an adult on their own behalf. The pertinent information regarding the research is reviewed with the LAR, and the LAR is encouraged to ask questions to ensure an informed decision is made. When appropriate, the LAR should discuss the research with the child.

After documented informed permission has been obtained from the LAR, the investigator must, assuming the child is capable, obtain informed assent from the child. In determining whether children are capable of assenting, the investigator should take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child. When a child is capable of providing assent, they should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition.

Informed assent may be written or it may be verbal, depending on the age of the child and the appropriateness of requiring the child to give written assent: the assent process should be tailored to the age and capabilities of the child.

Note that for children who turn 18 during the course of the research, they must be re-consented, or give informed consent as an adult, and be given the opportunity to withdraw their participation in the research.

Waiver of Assent

The IRB may waive the requirements for obtaining subject assent in circumstances in which the subject population does not have the capacity to comprehend the research or associated procedures. This judgment may be made for all subjects involved in the research or for each child individually. If the IRB determines either of the following to be true, then the assent of the child is not a necessary condition for proceeding with the research:

- The capability of some or all of the subjects is so limited that they cannot reasonably be consulted

- When the research offers the subject the possibility of a direct benefit that is important to the health or well being of the subject and is available only in the context of the research

The IRB will take into account the age, maturity, and psychological state of the subjects involved in determining whether a waiver of assent is appropriate.

Waiver of LAR Permission

The IRB may waive the requirements for obtaining parental/LAR permission if the stipulations for a waiver of consent (noted earlier in this section) are met.

In addition, the IRB may, for the protection of the subjects, waive the requirements for obtaining parental or LAR permission if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or LAR permission is not a reasonable requirement (for example, neglected or abused children). In such cases, there must be another mechanism in place for the protection of the subjects.

Additional information regarding research with children can be found in unit 31: Research with Children and Students.

Third Party Consent

When an investigator conducting research obtains identifiable private information about a living individual, that individual becomes a research subject, regardless of whether that person is the individual with whom the investigator is having an interaction. For example, if the research involves asking the primary subject to provide identifiable private information about a third party, that third party then becomes a subject in the research. As such, all of the regulatory requirements for protecting that individual apply.

The IRB can determine whether informed consent needs to be sought from third party subjects, or whether it can be waived. In making this determination, the IRB relies on both the requirements for a waiver (noted earlier in this section) and the importance of the information to the research. Investigators whose research may involve so-called “secondary subjects” are encouraged to contact the IRB Staff to discuss how to best protect the rights and welfare of these subjects in a given project.

Language Barriers to Informed Consent

Much social research being done today involves subjects whose primary language is not that of the investigator and special precautions must be taken in these cases. However, informed consent must always be obtained in a language in which the subject is comfortably fluent. In those instances where the subjects do not speak English, the informed consent form should be translated into the primary language spoken and understood by the subjects and, if the investigator is not fluent in this language, an interpreter hired to translate throughout the informed consent process.

It is important that the investigator not rely on family members or friends of the subjects. Instead, a professional should be hired with whom the investigator can discuss the study in detail. Note that the interpreter should fully understand the research or they may not communicate the information accurately. In addition, it is important that the subjects feel comfortable answering and/or asking questions freely.

In those instances where a subject has some competency in English, the investigator may be tempted to forgo the use of an interpreter. The investigator must be careful, however, to be sure the subject is truly proficient in English. There are often times when a subject believes they are proficient “enough” and so does not inform the investigator – or even realize – that both they and the investigator would be better served by the use of an interpreter.

Note that for each language into which documents are translated, a [Translation Certification](#) must be submitted with the translated documents. Additional information regarding language barriers in research can be found in unit 33: Research with Subjects with Limited Proficiency in English.

Cultural Barriers to Informed Consent

Even when language is not an issue in the informed consent process, cultural barriers may still exist in both local and international research. When dealing with subjects whose culture, for example, reveres education, the subjects' inclination may be to agree to participate in the research simply out of respect for the investigator. The investigator should be aware, therefore, of the potential for cultural differences between their subjects and him/herself.

International Research and Informed Consent

When conducting research internationally, the Brandeis IRB may require the investigator to obtain approval from the local equivalent of the IRB where the research is to take place. In cases where there is no local equivalent, investigators may be required to obtain approval from local experts or community leaders in lieu of a local IRB. In such cases the investigator should be cognizant of local culture, mores, and attitudes that may affect subjects' informed consent. For example, the local IRB equivalent may be a council of elders whose own approval of the research may imply to the subjects a requirement to participate in the research. *Additional information regarding international human subjects research can be found in unit 34: International Research.*

Research Involving Audio or Video Recordings

When audio- or video-recording subjects while conducting research, the investigator must specifically ask for subjects' consent to be recorded prior to having them sign the consent form.

36. RECRUITMENT

Unless your research involves conducting secondary data analysis only, you will most likely be recruiting subjects to participate in your research.

The recruitment materials you plan to use (e.g., flyers, postings online, emails, letters) must be included in your IRB protocol to be reviewed by the HRPP/IRB. Below are some guidelines to consider when assembling your recruitment materials.

Note that in no way may materials be construed as coercive or misleading, or include exculpatory language

Recruitment materials should include

- The name of the PI or group conducting the research
- The name of the institution (Brandeis University)
- The word *research*
- Purpose of the research, in brief
- Eligibility criteria, in brief
- Expectation of subjects, in brief
- Time commitment
- Location of the research (if not online)
- A list of significant risks, if any
- A contact name with phone number/email address
- If including compensation information, you may include the amount; the terms "up to" or "at least"; the range of amounts; and/or the schedule of potential payments*

*Note that the use of any means (such as bolding or enlarging) to highlight compensation is not allowed

37. DECEPTION AND INCOMPLETE DISCLOSURE

There are times, particularly in behavioral research, when investigators will find it necessary to use deception or incomplete disclosure about the true purpose of the research. Deception and incomplete disclosure, however, should be used only when the research question could not be answered without its use.

Deception in research can be defined as *purposely misleading subjects by providing them with overt misdirection or false information about some aspect of the research.*

In contrast, **incomplete disclosure** can be defined as *the withholding of information regarding the true objectives of the research.*

As the use of deception and incomplete disclosure restricts a subject's ability to make a truly informed decision regarding their participation in the research – one of the essential ethical concerns in human subjects research – a waiver or alteration of documented informed consent must be requested of the IRB whenever deception or incomplete disclosure is planned. *Additional information regarding deception and informed consent can be found in unit 35: Informed Consent.*

While the IRB understands that research involving deception or incomplete disclosure is necessary in some circumstances, it must look closely at its use before granting the necessary waiver or alteration of documented informed consent. When reviewing the use of deception or incomplete disclosure in human subjects research, the IRB must find all of the following criteria to be met:

- The research involves no more than minimal risk to subjects
- The deception will not adversely affect the rights and welfare of subjects
- The research could not practicably be carried out without the waiver or alteration
- Whenever appropriate, the subjects will be debriefed at the earliest time feasible, preferably at the conclusion of the subject's participation in the research

Generally speaking, deception and incomplete disclosure are not allowable if the subject would not have agreed to participate in the research had they been fully informed about the research prior to consenting to participate.

Debriefing

While debriefing is a useful tool in all human subjects research, it is an essential aspect of research involving the use of deception or incomplete disclosure.

The debriefing process involves the investigator providing the subject with the following:

- A full explanation of the research
- A description of how the subject was deceived
- An explanation for the reasons why the research could not be conducted without the use of deception
- The opportunity to have any questions answered regarding the research and their participation
- The opportunity for the subject to withdraw their data from the research
- An offer to provide the subject the results of the research once complete

- Depending on the level or risk involved in the deception, a list of resources the subject may utilize if they experience any psychological trauma related to the deception or the research itself

A debriefing and informed consent form must be signed by the subject and attached to the original consent to participate.

The debriefing process should occur as early as is feasible, preferably immediately after the subject's participation in the research is complete. There may be times when the investigator feels this will be detrimental to the research. In such situations, the investigator must send a debriefing document to the subjects at the conclusion of all subjects' participation in the research.

In rare instances the investigator may feel that debriefing may increase the risks to subjects (for example, if the subjects were selected for participation because of a negative characteristic). Such cases are reviewed carefully by the IRB, who must agree that debriefing may cause more harm than the deception itself.

Whenever deception or incomplete disclosure is proposed in a research protocol, the investigator must fully explain the necessity of the deception or incomplete disclosure; if appropriate, justify why immediate debriefing is not feasible; and include in the application a debriefing and informed consent form, as well as a consent to participate form.

Research involving deception is not eligible for exempt status; however, research involving mild deception where the topic is not sensitive and the subjects are not vulnerable may be reviewed as expedited.

Research involving incomplete disclosure but no deception may be reviewed as exempt, provided the subject is informed of and agrees to its use on the consent form.

For research that poses no greater than minimal risk, the appropriate category of review will depend upon:

1. The nature of the deception or incomplete disclosure
2. The degree of risk present
3. The sensitivity of the topic
4. The vulnerability of the subjects

38. COMPENSATING SUBJECTS

Not to be confused with benefit (a valued or desired outcome of the research as a whole), compensation is meant to offset the time and inconvenience incurred as a result of participation in a research study, as well as serve as an incentive to participate.

Compensation may be in the form of monetary payments (e.g., cash or gift cards) or non-monetary payments (e.g., course credit). Compensation may also take the form of a drawing, with each subject having an equal chance of being selected to receive payment.

Compensation Amount

The amount of compensation offered must be appropriate (i.e., not excessive) for the time and effort subjects devote to participation so as not to unduly influence prospective subjects to participate in research they may not otherwise choose to participate in. For example, subjects should not be paid a month's salary for a single day of participation in research that is very risky, to entice them to participate against their better judgment.

Investigators should consider what the subjects' time is worth (this may not be the same across all groups of subjects involved in the research). For example, adults may be compensated at a rate higher than children, or overseas subjects who earn the equivalent of \$100 per month may be compensated at a rate lower than local subjects who earn \$100 per day.

In addition, compensation must not be coercive, where there is an overt or perceived threat of harm if the prospective subject does not participate. For example, faculty members who offer extra credit for participation in research must offer an alternative means for receiving the extra credit that is comparable in time and effort.

When using a drawing, subjects should be told what their chances of winning are (i.e., state the number of subjects involved in the research, as well as the amount of compensation).

Timing of Compensation

In many research studies, the interaction or intervention may occur over a short and/or single period of time (e.g., participation in a 10-minute survey or a 60-minute focus group). In these instances, compensation may be presented at the conclusion of the interaction or intervention (common for surveys) or before the subject's participation has begun (common for focus groups).

The investigator must consider the subject's ability to withdraw their participation at any time and whether the subject is required to complete the interaction or intervention in order to receive compensation, or whether they will still receive compensation if they withdraw prior to completion. For example, subjects will often receive compensation at the end of a survey, though they are given the opportunity to skip any questions along the way. On the other hand, subjects will often receive compensation prior to participation in a focus group so that they feel free to withdraw (leave) at any time.

In other studies, participation involves a number of interactions or interventions over time (e.g., completion of multiple surveys over a three-month period). In these cases, it is common for compensation to be pro-rated, allowing the subject to receive partial compensation after each interaction or intervention. Bonus payments are allowed for completion of the final interaction or intervention, generally for a percentage of the prorated compensation amounts.

Informing Subjects

Subjects must be informed of the amount and conditions for the receiving of compensation during the informed consent process (e.g., the informed consent form must explain the amount and schedule of payments).

Investigators may elect to insert compensation information into the recruitment materials (e.g., flyers, ads, emails). When doing so, it is important that compensation not be emphasized – the information should be blended into the materials instead of highlighted (e.g., using bolded, larger, or different colored fonts). In addition, conditions for the compensation must be listed, as well.

39. ANONYMITY AND CONFIDENTIALITY

In research, the terms anonymous and confidential are often confused and treated as interchangeable; they have, however, very distinct meanings and it is important for an investigator to understand the difference when developing their research study. When conducting human subjects research, the level of "risk" is an important consideration which the IRB takes very seriously and it is the investigator's responsibility to minimize the potential for harm to their research subjects. The distinction between anonymous and confidential data relates to this level of risk and the investigator must clearly define the activity as anonymous or confidential prior to conducting the research. No activity can ever be both anonymous and confidential (though, a single research study may utilize numerous methods of data collection, some of which yield anonymous data and some of which yield confidential data).

Anonymous

Anonymous refers to data that is in no way linked to information that could potentially be used to identify or trace a specific subject. When an investigator promises anonymity, even the investigator him/herself cannot link the research data collected with the individual from whom it was collected.

It is commonly believed that data is anonymous if the investigator has not collected direct identifiers, such as name, social security number, or student ID number. It should be understood, however, that indirect identifiers and demographic variables, such as age, race, or sex, could, in some circumstances, be used to identify subjects, particularly when a number of them are being collected. Therefore, if the investigator finds it necessary for their research to collect specific identifiers, they should collect only the identifiers necessary for the research objectives. In addition, the anonymity of the data may be invalidated due to small sample size and/or the diversity of the population. If precautions are not taken, it may be difficult to conceal the identity of the subjects and relatively easy to link the subjects to their data

Anonymous data collection involves the lowest level of risk or potential for harm to the subjects.

Confidential

Confidential refers to private information a subject discloses with the expectation that it will not be divulged to others without that subject's permission. When an investigator promises confidentiality, the subject is asked to supply information that could potentially identify that subject, which is then linked to the research data collected from the subject with the understanding that the investigator will not disclose the information to others outside of those for whom the subject has given the investigator explicit consent to share (e.g., the research team).

It is important to note the use of the terms divulge and disclose, as they point to an important aspect of confidentiality that the investigator must always keep in mind – that privacy cannot be guaranteed. While the investigator may promise not to share the subjects' private information, it may still be discoverable by outside parties. When dealing with confidential information, then, the investigator must ensure the information is collected and stored in such a way as to minimize discovery by outside parties.

Confidential data collection involves a higher level of risk or potential for harm to the subjects than does anonymous data collection. It should be noted that there are multiple levels of risk in confidential data collection and storage.

Protecting Confidentiality

Prior to a subject's participation in research, they must be told whether their involvement and the data collected will be anonymous or confidential. If the data are to remain confidential, it is also important for the investigator to discuss with the subject during the process of informed consent the level of confidentiality that can be offered and the potential for breach of confidentiality. This should, as well, be noted on the informed consent form.

Note that there are times when breaking confidentiality may be required. Investigators who are mandated reporters, for example, must disclose to subjects that they are legally obligated to report suspected child or elder abuse, or if the subject or others are in immediate risk of harm.

An important consideration in the use of confidential data is the investigator's responsibility to keep the data as safe and secure as possible. The investigator can do this in a variety of ways (note the following list is in no way exhaustive):

- Limit access to the data to as few individuals as possible
- Code the data whenever feasible
- Store hard copies of the data in locked cabinets in locked rooms

- Store the data, master code list, and informed consent forms in separate locations
- Transfer (from person to person, place to place) the data (field notes, recorded interviews, informed consent forms) promptly and securely
- Transcribe recorded data as soon as possible and destroy original recordings
- Store data on an encrypted computer or server*
- Upload data to an encrypted server promptly (do not wait until all data is collected)
- Delete identifiers as soon as is feasible

*At Brandeis University it is strongly encouraged that investigators use the university's encrypted server, Box.com, where the default settings provide maximum security for all accounts.

It is imperative that investigators keep in mind at all times the potential for harm (social, legal, economic, physical) to subjects that may result from a breach in confidentiality. Plans for data security must be outlined in the research protocol when discussing the provisions for managing risk, and approved by the IRB. *Additional information regarding managing risk can be found in unit 46: Data Management and Protection.*

Coding Data

A common practice for reducing the risk of a breach in confidentiality is for the investigator to code the information and data collected from the subject. When data is coded, a subject's identifying information is separated from the subject's research data and replaced with a code. The investigator then keeps a "master list" of the subjects' names and identifying codes. For security purposes, the master list is kept separately from the subjects' data.

De-identification

Another common practice— one that often leads to confusion between anonymous and confidential — is for the investigator to de-identify the data collected from the subject. De-identification is the process by which all links between the subjects' personally identifying information and their research data are severed and the investigator has no code by which to re-identify them.

Additional information regarding de-identification can be found in unit 40: De-identifying Data.

40. DE-IDENTIFYING DATA

It is the investigator's responsibility to keep their subjects' data as safe and secure as possible. Often investigators like to work with de-identified data to decrease the chance of a breach in confidentiality.

De-identification is the process by which all links between the subjects' personally identifying information and their research data are severed and the investigator has no code by which to reconnect them. Note, however, that there is always a risk of re-identification without a code, no matter how small.

Some common direct identifiers include:

- Name
- Address

- Telephone #
- Fax #
- Email Address
- Social Media Username or Handle
- URL/IP Address
- Social Security #
- Date of Birth
- Date of Death
- Student #
- License/Certificate #
- Medical Record #
- Health Plan #
- Dates of Service
- Account #
- Vehicle/Serial/Device #
- Facial Photographs or Images
- Biometric Identifiers (Voices, Fingerprints)

In addition to the direct identifiers listed above, the investigator must be cognizant of indirect identifiers, which, in some circumstances, may make it possible to identify an individual deductively (i.e., if the sample set is too small or the direct identifiers too many).

Some common indirect identifiers include:

- Gender
- Race
- Ethnicity
- Age
- Marital Status
- Household Composition

- # of Children
- Place of Birth
- Education
- Major
- Income
- Job Title
- Medical Condition
- Date of Graduation
- Date of Arrest
- Date of Marriage
- Date of Divorce
- Uncommon Characteristics
- Direct Identifiers of Family/Household Members

It is important to remember that the more indirect identifiers investigators collect, the higher the risk of re-identification. In addition, the investigator must keep in mind that there may be information publicly available on the subjects that are unconnected from the data collected for the specific research in question and cumulatively, this information may be used to re-identify the subjects.

When indirect identifiers can be used to identify subjects, they should be treated in the same manner, and with the same caution, as direct identifiers.

The IRB will consider all indirect identifiers along with sample size to determine whether a dataset is truly de-identified.

De-identification, HIPAA, and PHI

When used in relation to the Health Insurance Portability and Accountability Act (HIPAA) and Protected Health Information (PHI), de-identification is more specifically and legally defined.

PHI is an individual's personally identifiable health information, or any information related to an individual's physical or mental health, health care, or payment for health care. When dealing with PHI, The US Department of Health and Human Services refers to de-identification as 1) certification by a qualified statistician, or 2) the removal of the following 18 specific identifiers:

1. Names (individual, employer, relatives, etc.)
2. Addresses (street, city, county, precinct, zip code – initial 3 digits if geographic unit contains >20,000 people, or any other geographical codes)
3. Telephone Numbers

4. Fax Numbers
5. Social Security Numbers
6. Medical Record Numbers
7. Dates (except for years) connected to subjects, including date(s) of birth, admission, discharge, death, ages >89, and all elements of dates indicative of such age (except that such age and elements may be aggregated as "Age ≥90")
8. E-mail Addresses
9. Health Plan Beneficiary Numbers
10. Account Numbers
11. Certificate/License Numbers
12. Vehicle Identifiers and Serial Numbers (e.g., VINs, License Plate #, etc.)
13. Device Identifiers and Serial Numbers
14. Universal Resource Locators (URLs)
15. Internet Protocol (IP) Address Numbers
16. Biometric Identifiers (e.g. finger or voice prints)
17. Full Face Photographic Images (and any comparable images)
18. Any other unique identifying numbers, characteristics, or codes

Once a subject's health information has been de-identified, it is no longer considered PHI; however, de-identified data can be re-identified in some instances, if the original holder of the data has created a master code.

Additional information regarding the de-identification of PHI can be found in unit 41: Protected Health Information (PHI) and the Health Information Portability and Accountability Act (HIPAA).

41. PROTECTED HEALTH INFORMATION (PHI) AND HIPAA

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) was passed with the goal of increasing the efficiency and accessibility of health insurance coverage, and establishing minimum federal standards for protecting the privacy of an individual's identifiable health information.

The Administrative Simplification Provisions

In part a response to the technological advancements that impact the electronic standards for health data, the Act was concerned with, among other things, the computerization of patient medical records, and the transmission and sharing of patient information. HIPAA's administrative simplification provisions directed the US Department of Health and Human Services (HHS) to create privacy standards and safeguards for the use of such electronic health care information. As a response, HHS put forward five main rules:

1. The Unique Identifiers Rule (resulting in the Standard Unique Employer Identifier, the National Provider Identifier, and the National Health Plan identifier)
2. The HIPAA Privacy Rule (discussed below)
3. The Transactions and Code Sets Rule (for the uniformity of electronic data exchange transactions when submitting, processing, and paying claims)
4. The HIPAA Security Rule (for the establishment of national standards for the protection of individuals' electronic protected health information (PHI)* created, received, used, or maintained by a covered entity**)
5. The Enforcement Rule (for the enforcement of the Privacy and Security Rules)

* Protected Health Information (PHI): *Individually identifiable health information such as any information related to an individual's physical or mental health, health care, or payment for health care (covered in more detail below)*

**Covered Entities: *Those entities that handle health care information and are subject to HIPAA:*

1. *Health care providers (doctors, clinics, psychologists, dentists, chiropractors, nursing homes, pharmacies, etc.)*
2. *Health plans (health insurance companies, HMOs, company health plans, Medicare, Medicaid, VA health care programs, etc.)*
3. *Health care clearinghouses (entities that process nonstandard health information they receive from another entity into a standard electronic format or data content, or vice versa)*

Protected Health Information (PHI)

HHS defines protected health information (PHI) as information that relates to:

1. The individual's past, present, or future physical or mental health or condition
2. The provision of health care to the individual
3. The past, present, or future payment for the provision of health care to the individual, and that identifies the individual, or for which there is a reasonable basis to believe it can be used to identify the individual

Protected health information includes many common identifiers when they can be associated with the health information listed above:

1. Names (individual, employer, relatives, etc.)
2. Addresses (street, city, county, precinct, zip code – initial 3 digits if geographic unit contains >20,000 people, or any other geographical codes)
3. Telephone Numbers
4. Fax Numbers
5. Social Security Numbers
6. Medical Record Numbers

7. Dates (except for years) connected to subjects, including date(s) of birth, admission, discharge, death, ages >89, and all elements of dates indicative of such age (except that such age and elements may be aggregated as "Age ≥90")
8. E-mail Addresses
9. Health Plan Beneficiary Numbers
10. Account Numbers
11. Certificate/License Numbers
12. Vehicle Identifiers and Serial Numbers (e.g., VINs, License Plate #, etc.)
13. Device Identifiers and Serial Numbers
14. Universal Resource Locators (URLs)
15. Internet Protocol (IP) Address Numbers
16. Biometric Identifiers (e.g. finger or voice prints)
17. Full Face Photographic Images (and any comparable images)
18. Any other unique identifying numbers, characteristics, or codes

Any health information by itself, without the 18 identifiers is not considered to be PHI (nor are the identifiers by themselves, without being linked to health information); and, if the health information can be de-identified, or the link between the health information and the 18 identifiers is broken, it is no longer considered to be PHI.

The Privacy Rule

The Standards for Privacy of Individually Identifiable Health Information, known as the Privacy Rule, protects the confidentiality of a person's PHI obtained from or through health care providers and organizations by giving the person the right to limit who may have access to it.

In accordance with the privacy rule, covered entities may not use or disclose an individual's PHI without their consent except under provisions set forth by the privacy rule (detailed below). In addition, the rule gives individuals the right to access and obtain their health care records, as well as information regarding whether, why, and how their PHI has been shared.

HIPAA and Research

The Privacy Rule outlines ways in which PHI may be used or disclosed by covered entities, including for research purposes. Those investigators who are not working with covered entities are not required to comply with HIPAA. However, all investigators who work with PHI and are, or are working with, covered entities, are governed by HIPAA. This does not prohibit investigators who will not receive a subject's consent from using the subject's health information in their research; it simply puts limits on what and how their information may be used.

The HIPAA Privacy Rule balances the rights and privacy of the individual with the necessity of medical and health related research, and provides investigators with ways to have access to and use individuals' health information for research. For example, health information may be de-identified, covered entities may enter into Data Use Agreements with investigators, or investigators may request waivers of authorization.

De-identification of PHI

PHI may be de-identified using one of two methods, releasing it from HIPAA restrictions. The first method is the removal of all 18 common identifiers (listed above) so that the health information cannot be linked to the individual whose health information it is. When PHI is de-identified in this manner, the covered entity may retain a random code that links the individual to their health information, though this code may not be shared with the investigator. PHI that has been de-identified in this way may later be re-identified by the covered entity, subjecting it once again to the HIPAA restrictions.

The second method for de-identification is through the use of statistical methods. In this case, a knowledgeable and experienced statistician may use statistical and scientific methods to de-identify the health information so that there is only a “very small” risk that the information may be linked to the individual whose information it is. The statistician must then certify the de-identification and document the methods used, as well as justify their determination of de-identification.

Data Use Agreements (DUAs)

A DUA is a formal agreement entered into by the covered entity and the investigator in need of PHI for research purposes. When using a DUA, the covered entity agrees to provide the investigator with a limited data set, that is, PHI that excludes the following identifiers:

1. Names
2. Postal Address Information, except Town or City, State, and Zip Code
3. Telephone Numbers
4. Fax Numbers
5. Electronic Mail Addresses
6. Social Security Numbers
7. Medical Record Numbers
8. Health Plan Beneficiary Numbers
9. Account Numbers
10. Certificate/License Numbers
11. Vehicle Identifiers and Serial Numbers, including License Plate Numbers
12. Device Identifiers and Serial Numbers
13. Web Universal Resource Locators (URLs)
14. Internet Protocol (IP) Addresses
15. Biometric Identifiers
16. Full Face or comparable Photographic Images

A DUA may be entered into by the covered entity and the investigator, which must include:

1. Specific permitted uses and disclosures of the limited data set by the investigator consistent with the purpose for which it is being disclosed
2. Identification of who is permitted to use or receive the limited data set
3. Stipulations that the investigator will
 - a. Not use or disclose the information other than permitted by the agreement or otherwise required by law
 - b. Use appropriate safeguards to prevent the use or disclosure of the information, except as provided for in the agreement, and require the recipient to report to the covered entity any uses or disclosures in violation of the agreement of which the investigator becomes aware
 - c. Hold any agent of the investigator to the standards, restrictions, and conditions stated in the DUA with respect to the information
 - d. Not identify the information or contact the individuals

Note that a limited data set differs from a de-identified data set and remains subject to HIPAA requirements.

Waivers and Alterations of Authorization

An investigator may, under certain conditions, submit an [Application for Waiver or Modification of Authorization for Use or Disclosure of PHI](#), which would allow the investigator to use PHI without the individuals' permission. The following criteria must be met before such a waiver may be granted:

1. The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
 - a. An adequate plan to protect health information identifiers from improper use and disclosure
 - b. An adequate plan to destroy identifiers at the earliest opportunity consistent with the conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so)
 - c. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule
2. The research could not practicably be conducted without the waiver or alteration
3. The research could not practicably be conducted without access to and use of the PHI

The request for waiver of authorization is reviewed by a privacy board, which determines whether the requirements are met and approves or denies the request. While an institution's IRB often acts as that institution's privacy board, the two boards are, in fact, separate: the authority of the privacy board is limited to the review of waivers of authorization, and cannot authorize the research protocol itself. When acting as the institution's privacy board, its IRB may review all issues regarding the research protocol at one time. At Brandeis University, the university's IRB acts as its privacy board.

42. PERSONALLY IDENTIFYING INFORMATION (PII)

Personally Identifying Information (PII) is defined by the Office of Management and Budget (OMB) as information which can be used to distinguish or trace an individual's identity alone or when combined with other personal identifying information which is linked or linkable to a specific individual.

Examples of PII include

- Name, maiden name, mother's maiden name, or alias
- Personal identification number, such as social security number, passport number, driver's license number, taxpayer identification number, or financial account or credit card number
- Address information, such as street address or email address
- Telephone numbers including mobile, business, and personal
- Personal characteristics, including photographic image (especially of face or other identifying characteristic), fingerprints, handwriting, x-rays, or other biometric data (e.g. retinal scan, voice signature, facial geometry, DNA sequence)
- Information identifying personally owned property, such as vehicle registration number or title number and related information
- Information about an individual that is linked or linkable to one of the above (e.g., date of birth, place of birth, race, religion, weight, activities, geographical indicators, employment information, medical information, education information, financial information)

An important job of the IRB is to consider the level of risk, or potential for harm (social, legal, economic, physical), that might result from a breach of confidentiality of a subject's information. One aspect of risk the IRB considers is the harm that might occur if a subject's research data were linked to their PII.

Another important aspect of risk is the harm that might occur simply if a subject's PII were to be discovered. PII is considered sensitive information, and is the information an identity thief looks for in order to steal an individual's identity. Government action, in terms of legislation and administrative actions, has been taken to protect an individual's PII through restrictions of its disclosure; however the level of protection of PII in research continues to be up to the investigator. The importance of the investigator's data security plan, therefore, relates to the protection of their subjects' PII, as well as to the research data collected, and an outside individual's ability to link that data to the subject. *Additional information regarding managing risk can be found in unit 46: Data Management and Protection.*

43. RESEARCH INVOLVING OUTSIDE COLLABORATORS

When Brandeis University investigators collaborate with non-Brandeis US investigators, the Brandeis IRB will often enter into a reliance agreement with either the collaborating investigator's institution, or with the outside collaborator themselves (depending on the collaborator's institutional affiliation).

If the collaborator comes from an institution with a Federalwide Assurance (FWA – which generally means they have an IRB), Brandeis will often enter into an IRB Authorization Agreement (IAA) with the outside institution, which allows one institution with a FWA to rely on another institution's FWA. This means that one of the institutions' IRB will be the IRB of record, while the other institution cedes the IRB review to the first institution.

If the collaborator comes from an institution without an FWA (or is institutionless), Brandeis will enter into an Individual Investigator Agreement (IIA) with the individual, which allows the collaborator to conduct research under Brandeis' FWA.

It is the responsibility of the Brandeis University investigator to bring to the attention of the Brandeis University IRB administrator that they will be collaborating with an outside investigator.

It is the responsibility of the Brandeis University investigator to bring to the attention of the Brandeis University IRB administrator that they will be collaborating with an institutional investigator.

44. SITE PERMISSIONS FOR OFF-CAMPUS RESEARCH

Site permission is required for all research occurring at a non-Brandeis University private facility/space (e.g., school, closed online chat room). The site permission letter must include the following content:

- The letter should be on letterhead, if applicable.
- The letter must be dated.
- The letter must reference the IRB protocol Principal Investigator.
- The letter must reference the title of the IRB research protocol.
- The letter must describe the research in such a way as to show the signatory understands what the research entails.
- The letter must include explicit permission that the research may be conducted at the site.
- The letter must be signed, including the title of the signatory, by an individual with the appropriate authority to authorize the research.

In some instances, an email may suffice, but must include the elements listed above. In such cases, some of the elements may be included in the body of the email requesting permission. The permission email must come from the signatory's official email address. *Note that the HRPP must approve the use of a permission email.*

45. PI AND KEY PERSONNEL CONFLICTS OF INTEREST

The principal investigator, along with all key personnel, must disclose to the IRB all potential, apparent, or actual conflicts of interest in association with their human subjects research prior to the initiation of the research and within 30 days of the development of a new conflict.

All investigators and collaborators are required to outline, in the initial protocol (or through a modification request for ad hoc disclosures), all interests that could be construed as being a conflict of interest with the human subjects research they plan to conduct.

Conflicts of interest may necessitate otherwise exempt research to be reviewed as expedited or by the full board, as well as research which otherwise qualifies for expedited review to be reviewed by the full board. During their administrative review of the application or modification, HRPP staff will determine the level of review necessary for the reported interests.

If a conflict of interest is believed by the IRB to exist, the IRB may request additional information from the investigator in order to determine whether a conflict does exist, as well as the significance of the conflict and possible strategies for its mitigation.

If a conflict of interest is determined to exist, the investigator may be required to abide by a conflict management plan to mitigate the conflict of interest. If required, the conflict management plan must be in place prior to the initiation (for new applications) or continuation (for ad hoc disclosures) of the human subjects research. Some common strategies required by a conflict management plan include but are not limited to:

- Disclosure on the informed consent form of the conflict
- Re-consenting subjects with an updated informed consent form disclosing the conflict
- Public disclosure of the conflict
- Independent monitoring and oversight of the research
- Removing the conflicted investigator from participation in all or a portion of the research
- Divestiture of interests

46. DATA MANGEMENT AND PROTECTION

Note that a [Guide to Data Management and Protection](#) (a pdf of this unit) is available.

Data management protects the privacy and confidentiality of the research subjects, as well as the safety of the research data. When conducting human subjects research, the investigator must be mindful of how to protect the privacy and confidentiality of the research subjects and the safety of the research data – both while the research is being conducted and once it has been completed. The investigator is responsible for doing all they can to uphold the pledge they make to their subjects during the informed consent process to protect their privacy and keep their data safe.

Investigators conducting human subjects research are required to develop and follow protocols to manage and protect the confidentiality and integrity of research data. The risk of harm resulting from a breach of confidentiality varies with the level of sensitivity of the research data.

There are five levels of risk associated with different types of research data:

Level I

- Publicly Available Data
- Anonymous Data
- Non-confidential Data
- De-identified Minimal Risk Confidential Data

Level II

- Coded Minimal Risk Confidential Data
- De-identified Greater than Minimal Risk Confidential Data

Level III

- Identifiable Minimal Risk Confidential Data
- Coded Greater than Minimal Risk Confidential Data
- De-identified Sensitive Confidential Data

Level IV

- Identifiable Greater than Minimal Risk Confidential Data
- Coded Sensitive Confidential Data

Level V

- Identifiable Sensitive Confidential Data

General considerations that apply to research data at all risk levels include:

1. The most restrictive management option feasible should be employed.
2. Only the minimum subject identifiers – direct and indirect – necessary for the research should be collected.
3. Subject identifiers should be removed or destroyed as soon as is feasible for the research.
4. Physical and/or electronic access to any area and/or device where research data are being stored must be limited.
5. Access to all research data must be limited to investigators and key research personnel.
6. Strong passwords must always be used.
7. Only secure/encrypted modes of electronic transmission of research data should be used.
8. Computers must be protected against malware with anti-malware software approved by the Brandeis University ITS, and all software updates and patches applied.
9. The PI must report any breaches in confidentiality to the IRB within seven days of the investigators becoming aware of the event.
10. Brandeis University policy holds that human subjects research data must be retained for a minimum of three years.
11. When destroying research data stored on a computer, deleting the files is not enough as the deleted files can still be recovered. The deleted files must also be scrubbed from the computer so that the data are permanently erased. This may be done using commercial software approved by the Brandeis University ITS. Alternatively, the device may be degaussed or destroyed.
12. If keeping the research data indefinitely, data should be de-identified, at the latest, when the current project is complete.
13. If retaining de-identified research data indefinitely, storage in a data repository should be considered.
14. If conducting an online survey, the Brandeis University preference and default is that investigators use Qualtrics.

Amazon's Mechanical Turk should be used for recruitment purposes only.
15. If traveling abroad, international laws and export controls regulations must be considered as they may limit the movement of research data out of the country, both physically and electronically. The investigator must know the applicable laws and regulations of the country in which the research will be conducted before embarking on any research and, if needed, arrangements and agreements must be in place to ensure compliance.
15. As research progresses, so might the risk level – appropriate data management must be used for the level of risk at each stage of the research.

In addition to the general points outlined above, there are a number of security requirements specific to the type and risk level of research being conducted:

Risk Level 1 Data Management Options

1. Paper documents such as surveys, audio transcriptions, or field notes must be stored in a secure place such as a locked file cabinet.

Any signed consent forms must be stored in a separate locked cabinet from the remaining research data.

2. Digital recording devices/audiotapes/videotapes with recordings of interviews, field notes, etc. must be stored in a secure place such as a locked file cabinet.
3. When scanned or uploaded, paper documents and audio/video files must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected computer file
4. Digital system files such as databases, SAS/SPSS data files, or custom application record sets must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected computer file

Risk Level II Data Management Options

1. Paper documents such as surveys, audio transcriptions, or field notes must be stored in a secure place such as a locked file cabinet in a locked office.

Any signed consent forms and master keys must be stored in a separate locked cabinet from the remaining research data.

2. Digital recording devices/audiotapes/videotapes with recordings of interviews, field notes, etc. must be stored in a secure place such as a locked file cabinet in a locked office.
3. When scanned or uploaded, paper documents and audio/video files must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected computer file

When consent forms and master keys are stored digitally, they must be stored in separate accounts from the research data.

4. Digital system files such as databases, SAS/SPSS data files, or custom application record sets must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected computer file
5. The safety of all research data should be reviewed and the findings logged on a regular basis.

Risk Level III Data Management Options

1. Paper documents such as surveys, audio transcriptions, or field notes must be stored in a secure place such as a locked file cabinet in a locked office.

Any signed consent forms and master keys must be stored in a separate locked cabinet from the remaining research data.

Any master keys should be shredded as early as is feasible.

2. Digital recording devices/audiotapes/videotapes with recordings of interviews, field notes, etc. must be stored in a secure place such as a locked file cabinet in a locked office.
3. When scanned or uploaded, paper documents and audio/video files must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected and encrypted computer file

When consent forms and master keys are stored digitally, they must be stored in separate accounts from the research data.

4. Digital system files such as databases, SAS/SPSS data files, or custom application record sets must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected and encrypted computer file
5. The safety of all research data should be reviewed and the findings logged, at a minimum, on a weekly basis.

Risk Level IV Data Management Options

1. Paper documents such as surveys, audio transcriptions, or field notes must be stored in a secure place such as a locked box in a locked file cabinet in a locked office, or a locked file cabinet in a locked office with electronic door access control and/or in sight of a security camera.

When being transported, paper documents must be secured, for example in a locked briefcase or lockbox.

Any signed consent forms and master keys must be stored in a separate locked cabinet from the remaining research data – preferably in a separate room or building.

Paper documents should be scanned and shredded as early as is feasible.

2. Digital recording devices/audiotapes/videotapes with recordings of interviews, field notes, etc. must be stored in a secure place such as a locked box in a locked file cabinet in a locked office, or a locked file cabinet in a locked office with electronic door access control and/or in sight of a security camera.

When being transported, digital recording devices/audiotapes/videotapes must be secured, for example in a locked briefcase or lockbox.

Audio/video files should be uploaded and originals destroyed as early as is feasible.

3. When scanned or uploaded, paper documents and audio/video files must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server

If access to the internet is not possible, use of a password protected and encrypted USB drive or anti-virus protected, password protected, and encrypted computer file may be allowable. The device (e.g., computer or USB drive) should be stored in a locked box in a locked file cabinet in a locked office, or a locked file cabinet in a locked office with electronic door access control and/or in sight of a security camera.

When consent forms and master keys are stored digitally, they must be stored in separate accounts from the research data.

4. Digital system files such as databases, SAS/SPSS data files, or custom application record sets must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected and encrypted computer file
5. The safety of all research data should be reviewed and the findings logged on a daily basis.

Risk Level V Data Management Options

1. Paper documents, audiotapes, and videotapes should be avoided – and research data collected electronically – whenever possible.
2. Paper documents such as surveys, audio transcriptions, or field notes must be stored in a secure place such as a locked box in a locked file cabinet in a locked office, or a locked file cabinet in a locked office with electronic door access control and/or in sight of a security camera.

When being transported, paper documents must be secured, for example in a locked briefcase or lockbox.

Paper documents should be scanned and shredded as early as is feasible.

3. Digital recording devices/audiotapes/videotapes with recordings of interviews, field notes, etc. must be stored in a secure place such as a locked box in a locked file cabinet in a locked office, or a locked file cabinet in a locked office with electronic door access control and/or in sight of a security camera.

When being transported, digital recordings must be secured, for example in a locked briefcase or lockbox.

Audio/video files should be uploaded and destroyed as early as is feasible.

4. When scanned or uploaded, paper documents and audio/video files must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server

If access to the internet is not possible, use of a password protected and encrypted USB drive or anti-virus protected, password protected, and encrypted computer file may be allowable. The device (e.g., computer or USB drive) should be stored in a locked box in a locked file cabinet in a locked office, or a

locked file cabinet in a locked office with electronic door access control and/or in sight of a security camera.

5. Digital system files such as databases, SAS/SPSS data files, or custom application record sets must be stored in one of the following:
 - Brandeis-provided Box.com account
 - Brandeis-provided and Brandeis-certified file server
 - Password protected and encrypted computer file
6. The safety of all research data should be reviewed and the findings logged on a daily basis.

47. DATA RETENTION

All human subjects research data obtained through research conducted under the auspices of Brandeis University must be retained for a minimum of three years after the study has been closed by the IRB and the final report has been submitted to the funder, if applicable.

In circumstances where data is regulated by multiple retention standards (see below for common standards), the longest period of retention applies.

The principal investigator is responsible for the stewardship of all research data. The Brandeis University Human Research Protection Program is responsible for the additional stewardship of all administrative records.

Applicable Policies, Guidelines, Rules, and Regulations

There are a number of policies, guidelines, rules, and regulations regarding the retention of research data – many are outlined below.

45 CFR 46, the federal regulations for human subjects research: All research records must be retained for a minimum of three years after the completion of the research.

HIPAA: All research data must be retained for a minimum of six years after the disclosure of the health information.

NIH: All research data must be retained for a minimum of three years after the final financial report has been submitted to NIH.

NSF: All research data must be retained for a minimum of three years after the final report has been submitted to NSF.

VA: All research data must be retained indefinitely.

APA: All research data must be retained for a minimum of five years after the completion of the research.

FDA: All research data must be retained for a minimum of two years after the date of marketing application is approved for the drug for the indication for which it is being investigated.

42 CFR 93, the federal regulations on research misconduct: All research data related to research under investigation for research misconduct must be retained for a minimum of six years after the final resolution of the misconduct case.

Child Subjects: All research data involving children as subjects must be retained for at least seven years after the subjects have reached the age of majority.

Subjects with Diminished Capacity: All research data involving subjects with diminished capacity must be retained for at least seven years after the mental incapacity has been removed.

Student Researchers: For Brandeis University student-initiated research, all research data must be retained until the degree has been conferred or the student has otherwise left Brandeis University.

Intellectual Property: All research data associated with intellectual property resulting from the research, which has been or may be commercialized by Brandeis University, must be retained for as long as is necessary to protect the intellectual property.

Other Funders: Many funders have their own policies regarding the retention of research data – it is important to check with the funder for their policy.

Journals: Many journals have policies regarding the retention of research data related to articles they are publishing – it is important to check with the journal for their policy.

48. CONDUCTING RESEARCH WITH A CERTIFICATE OF CONFIDENTIALITY (COC)

A Certificate of Confidentiality (COC) provides privacy protections to research subjects by prohibiting investigators and institutions from releasing any information that could be used to identify subjects involved in a covered research project in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding unless consent is granted by the subject; if disclosure is required by federal, state, or local laws for such things as the reporting of child abuse or communicable diseases; or for the purpose of other scientific research that is in compliance with human subjects research regulations.

Effective October 1, 2017, COCs are issued by the National Institutes of Health (NIH) automatically for new and competing awards when research is fully or partially funded by NIH provided the research is biomedical, behavioral, or clinical in nature; involves human subjects as defined by 45 CFR 46; and collects or uses identifiable, sensitive information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. In addition, investigators conducting health-related studies that fall within NIH's mission but that are not funded by NIH may request a COC from the agency, and investigators may request a COC from other Department of Health and Human Services agencies (FDA, CDC, SAMSHA, HRSA, HIS) for research funded by those agencies.

Note that, while a COC protects subject information in perpetuity (if the subject was enrolled when the research was covered by a COC), if a research project continues to enroll additional participants after relevant funding ends, those subjects will not be protected by the COC unless the investigator receives a new COC for non-NIH funded research.

Informed Consent Form Requirements

When a research project is covered by a COC, the informed consent form must include language informing the subjects that a COC has been issued, and what this may mean to them. For example:

This research is covered by a Certificate of Confidentiality. That means any identifiable information you share cannot be used as evidence in court (federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding) – unless you say it's okay. This does not mean you can't share your information with anyone if you want to. But, if you want us to share your information with anybody, you will need to sign another consent form.

In addition, the IRB application must reference the COC. If a COC has not yet been awarded but has been applied for, this must be referenced in the IRB application and a [modification request](#) must be submitted with the additional informed consent language.

Note that reference to an application for a CoC may not be included on the informed consent form if the CoC has not yet been approved.

Non-disclosure Requirements

All recipients of a CoC shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimens that contains identifiable sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains.
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.
- Made with the consent of the individual to whom the information, document, or biospecimen pertains.
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

49. TITLE IX REPORTING AND RESEARCH

Under limited circumstances, an exception may be made to mandatory Title IX reporting for human subjects research projects that focus on sexual misconduct and in which there is an expectation that disclosures of sexual misconduct may be made to investigators who are responsible employees under Title IX.

A Title IX reporting exception for research may be made with the following requirements and conditions:

1. The exception applies only to disclosures of student-on-student sexual misconduct and does not extend to disclosures of faculty/staff-on-student sexual misconduct.
2. The exception does not apply if the investigator reasonably believes a student may be in danger of harm.
3. The exception applies only to research subjects 18 years of age or older.
4. The exception applies only to disclosures of sexual misconduct made in the context of the research project and does not extend to disclosures made to investigators outside of this context.

5. The exception applies only to research personnel listed in the IRB application.
6. The consenting process – including the consent documents – must make clear to subjects that a Title IX reporting exception has been granted and that the investigators are not mandated, in the context of the research, to report disclosures of student-on-student sexual misconduct provided a student is not considered to be in immediate danger.
7. The consenting process – including the consent documents – must inform subjects of the reporting and support options available to students who have experienced sexual misconduct.
8. All consent process language and documents must be approved by the IRB.
9. All research personnel must have attended Brandeis University’s Preventing Sexual Harassment and Title IX workshop or received other appropriate training in the handling of allegations of sexual misconduct and Title IX.
10. All training in the handling of allegations of sexual misconduct and Title IX must be approved by the Brandeis University Title IX Coordinator prior to submission of the application to the IRB.
11. All training in the handling of allegations of sexual misconduct and Title IX must be completed prior to the initiation – including recruitment – of the research.
12. A *Title IX Reporting Exception for Research* Application must be completed and accompany the IRB Initial Application.
13. The IRB application that includes the request will be reviewed at a convened meeting of the IRB and will not be eligible for exempt status or expedited review.
14. The IRB application that includes the request will be reviewed by the Brandeis University Title IX Coordinator, General Counsel, and Vice Provost for Research; the IRB will make its final determination in consultation with these parties.

50. CONDUCTING HUMAN SUBJECTS RESEARCH INVOLVING ANIMALS

When human subjects research involves the use of animals, the principal investigator must get approval from the Institutional Animal Care and Use Committee prior to submitting an IRB application. For information regarding the use of animals in research, contact the IACUC administrator at iacuc@brandeis.edu.

51. CONDUCTING HUMAN SUBJECTS RESEARCH INVOLVING BIOMATTER

When human subjects research involves human blood, fluids, tissues, or cell lines; infectious agents; select agents; or rDNA, the principal investigator must get approval from the Institutional Biosafety Committee prior to submitting an IRB application. For information regarding the use of biomatter in research see the [IBC webpage](#).

52. CONDUCTING CLINICAL TRIALS

All Applicable Clinical Trials and all NIH funded clinical trials must be registered by the responsible party, typically the sponsor, on ClinicalTrials.gov within 21 days of enrolling the first study participant. Registration must include: a) descriptive information, b) recruitment information, c) location, and d) contact information.

Applicable Clinical Trials include:

- Device studies of health outcomes comparing an intervention with a device product against a control in human subjects
- Pediatric postmarketing surveillance of a device product
- Drug or biologic studies (other than phase 1) in human subjects designed to evaluate biomedical or health-related outcomes, including interventional and observational studies.

Small feasibility trials and larger clinical trials of prototype devices with a primary measure of feasibility rather than health outcomes and trials using only de-identified human specimens are not Applicable Clinical Trials.

Summary results information must be published within one year of the completion date of the clinical trial (date of final data collection for the primary outcome measure). Results data must include participant flow, demographic and baseline characteristics, primary and secondary outcomes, results of any scientifically appropriate statistical test, and adverse event information, as well as the full protocol and statistical analysis plan.

Noncompliance can result in an inability to publish in certain journals. ICJME journals require verification of registration and results reporting before accepting manuscripts for publication.

Federal penalties for noncompliance with this federal policy include civil or criminal judicial actions, as well as civil monetary fines of up to \$10,000 per day. In addition, noncompliance may be considered in future grant funding selection decisions.

What does it mean?

53. GLOSSARY OF TERMS

45 CFR 46 (the Code of Federal Regulations, Title 45 Public Welfare, Part 46 Protection of Human Subjects): First published in 1974, the Government policy for ensuring that the human subjects of behavioral and biomedical research receive the protections to which they are entitled and to minimize risks to them

Ad Hoc Disclosures: Disclosures of actual, potential, or apparent conflicts of interest made via modification request after the initial application has been submitted and within 30 days of acquiring the interest

Administrative Records: All related correspondence, initial and revised applications, principal investigator or student and faculty assurance, sample consent/information documents (including scripts), sample recruitment materials, study instruments, translation certifications, permissions/agreements (letters, DUAs, MOUs, MTAs, IAAs, IIAs, confidentiality agreements, etc.), international research addendums, statement of HIPAA protected health information use, application for waiver or modification of authorization for use or disclosure of PHHI, modification and continuation requests, progress reports, statements of significant new findings provided to subjects, reports of unanticipated problems, post approval monitoring findings, and current training (CITI, biosafety, etc.) certifications

Adverse Event: Any untoward or unfavorable occurrence (either physical or psychological) in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (see, as well, Serious Adverse Events and Unexpected Adverse Event)

Anonymous: Data are recorded such that no identifier whatsoever exists to link a subject's identity to that subject's response

Assent: Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research

Assurance: A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved

Assured Institution: An institution with an IRB working under a federalwide assurance (FWA) negotiated with the Office for Human Research Protections (OHRP) of the National Institutes of Health (NIH)

Authorized Institutional Official: An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in research

Belmont Report: A statement of basic ethical principles governing research involving human subjects used by the National Commission for the Protection of Human Subjects in 1978

Beneficence: Ethical principle to do no harm and protect subjects from harm by maximizing possible benefits and minimizing possible risks of harm

Benefit: A valued or desired outcome; an advantage

Cede Review: An agreement whereby one assured IRB relinquishes its oversight responsibilities to a second institution's assured IRB for collaborative human subjects research between investigators at both institutions

Children: Persons who have not attained the legal age for consent to treatment or procedures involved in the research, as determined under the applicable law of the jurisdiction in which the research will be conducted (18 in MA)

Clinical Trial: A prospective, biomedical or behavioral research study of human subjects that is designed to evaluate the effect of an intervention on the human subjects and evaluate a health-related biomedical or behavioral outcome

Coded Data: Data where identifying information (such as subject's name) has been replaced with a code and a key to decipher the code is available, which can link the identifying information to the data

Coercion: Overt or implicit threat of harm intentionally presented by one person to another in order to obtain compliance

Cognitively Impaired: Having either a psychiatric or developmental disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished (may include, as well, persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps)

Collaborative Institutional Training Initiative: A program that provides research ethics and compliance education to meet institutional, regulatory, and sponsor training requirements for investigators

Collaborative Research: Human subjects research conducted by an investigator at an institution with an assured IRB and an investigator not affiliated with this same institution

Common Rule: The Federal Policy for the Protection of Human Subjects published in 1991 and codified in separate regulations by 15 federal departments and agencies

Compensation: Payment in the form of money, gifts, services, or course credit given as remuneration for time and inconvenience of participation - not to be confused with a benefit

Competence: A legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on the information, and to make a choice

Confidential: Information that an individual has disclosed to the investigator with the expectation that it will not be divulged to others without permission

Conflict Management Plan: An agreement that sets out limits and restrictions on the investigator for the purpose of reducing or eliminating a conflict of interest that could directly and significantly affect the design, conduct, or reporting of institutional research

Conflict of Interest: A situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity

Consent: Permission for something to happen or agreement to do something

Consent Form: A form defining the elements of consent for research subjects, describing the research and what subjects' participation consists of if they choose to participate, as well as outlining their right to disengage from the research at any time

Continuing Noncompliance: Noncompliance that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research subjects or the validity of the research and suggest the potential for future noncompliance without intervention

Covered Entities: A HIPAA Privacy Rule designation for institutions, organizations, or persons who are 1) health plans, 2) health care clearinghouses, or 3) health care providers, and who electronically transmit transactional health information

Debriefing: Giving subjects previously undisclosed information about the research project following completion of their participation in research

Deception: Intentionally misleading subjects, giving subjects false information about the purpose of the research or omitting information about the purpose of the research

Declaration of Helsinki: A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries

De-identification: The process by which all personally identifiable information is severed from data

Economically Disadvantaged: Persons who struggle to provide basic necessities for themselves and their families or communities

Educationally Disadvantaged: Persons with educational deficits, learning disabilities, or cultural backgrounds that limit communication with a investigator

Enrolled Subjects: All subjects who have consented to participate in the study, including those that did not qualify after screening and those that dropped out after consent

Equitable: Fair or just; used in the context of the selection of subjects to indicate that the benefits and burdens of research are fairly distributed

Exclusion Criteria: Those characteristics that disqualify prospective subjects from participation in a study

Exempt Research: Research activities that involve no more than minimal risk to subjects, and which are exempt from the federal regulations on the protection of human subjects in research (note that the determination of exempt status is an administrative review process handled by the IRB staff)

Expedited Review: An IRB review procedure through which certain kinds of research, and changes to research, may be reviewed and approved without convening a meeting of the full IRB

Family Educational Rights and Privacy Act: A federal law that protects the privacy of student education records (20 USC § 1232g; 34 CFR Part 99)

Fetus: The product of conception from the time of implantation until delivery

Full Review: An IRB review procedure of research involving greater than minimal risk and requiring review by the fully convened IRB

Generalizable Knowledge: Data designed to apply to a population beyond the research subjects themselves and contribute to current academic understanding

Greater than Minimal Risk: The risk that the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or in the performance of routine physical or psychological examinations or tests

Guardian: An individual who is authorized under applicable state or local law to give permission on behalf of a child

HIPAA Privacy Rule: Health Insurance Portability and Accountability Act privacy regulation that protects the confidentiality of a person's PHI obtained from or through health care providers and organizations by giving the person the right to limit who may have access to it

Human Research Protection Program: The overarching program overseeing human subjects research, consisting of the IRB, the Institutional Official (IO), the Research Integrity team of the Office of Research Administration, and the Vice Provost for Research

Human Subject: A living individual about whom an investigator conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

Identifiable: The identity of the subject is or may readily be ascertained by the investigator or others, or associated with the information

Independent Investigator: A collaborating investigator who is not acting under the auspices of any institution with respect to their involvement in the research

Inclusion Criteria: Those characteristics that prospective subjects must have if they are to be included in a study

Individual Investigator Agreement: A formal written agreement in which an assured IRB agrees to serve as the IRB of record for collaborative human subjects research between an investigator at its institution and an independent or institutional investigator

Informed Consent: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research

Institutional Official: The university official responsible for ensuring the Human Research Protection Program has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official, and assumes the obligations of the institution's Assurance

Institutional Investigator: A collaborating investigator affiliated with an institution without an assured IRB

Institutional Review Board: A local administrative body established in response to the National Research Act of 1974 to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral research

Interaction: Communication or interpersonal contact between investigator and subject

Intervention: 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

IRB Authorization Agreement: A formal written agreement in which an assured IRB agrees to serve as the IRB of record for collaborative human subjects research between an investigator at its institution and a collaborating investigator at another institution with an assured IRB

IRB of Record: An agreement whereby one institution's assured IRB assumes oversight responsibilities of another institution's assured IRB, or an independent or institutional investigator

Joint Review: When the assured IRBs of two or more institutions with investigators participating in collaborative research retain oversight of the portion of a research project in which their investigator is engaged

Justice: Distributing the risks and potential benefits of research equally among those who may benefit from the research

Legally Authorized Representative: A person authorized either by statute or by court appointment to make decisions on behalf of another person

Master List: A document that lists the subjects' identifying information (e.g., name, address, phone number, social security number) along with their unique identifier (code), linking the two

Minimal Risk: Where the probability and magnitude of harm or discomfort anticipated in the proposed 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

Minor: Persons who have not attained the legal age for consent to treatments or procedures involved in research under applicable law of the jurisdiction in which the research will be conducted (in MA, <18 years of age)

Neonate: Newborn child

Noncompliance: Failure to fully comply with all laws and regulations governing human subject research activities, as well as the policies, procedures, or determinations, of the Brandeis University IRB, or its designee (see, as well, Serious Noncompliance, Non-serious Noncompliance, and Continuing Noncompliance)

Non-serious Noncompliance: Noncompliance that does not increase risk or decrease the benefits to research subjects, compromise subjects' rights or welfare, or affect the integrity of the research/data.

Nuremberg Code: A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects

Office for Human Research Protections: The Health and Human Services (HHS) office that oversees the regulation of research involving human research subjects

Participant: See Human Subject

Personally Identifiable Information: Any data that could potentially identify a specific individual

Pregnancy: The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus

Principal Investigators: The scientist or scholar with primary responsibility for the design and conduct of a research project

Prisoner: An individual involuntarily confined in a penal institution or other facility under statutes or commitment procedures

Private Information: 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

Prospectively Assigned: A pre-defined process (e.g., randomization) that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial

Protected Health Information (PHI): Any information about health status, provision of health care, or payment for health care that is created or collected by a "Covered Entity" (or a Business Associate of a Covered Entity), and can be linked to a specific individual

Quorum: The minimum number of committee members that must be present at a meeting to make the proceedings of that meeting valid

Recruitment: The process of advertising a study and making contact with potential participants (distinct from the process of informed consent)

Remuneration: Payment for participation in research

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

Research Data: Human subjects' data, documentation of subject eligibility, original signed and dated consent forms (or record of consent if verbal), master keys, and findings review logs, as well as ancillary materials such as administrative and financial records

Research Personnel: All non-PI/Student Researcher faculty, staff, students, and/or scholars participating on the research team

Respect for Persons: Treating individuals as autonomous agents and protecting persons with diminished autonomy

Review of Research: The concurrent oversight of research on a periodic basis by an IRB

Risk: The probability of harm or injury (physical, psychological, social, legal, or economic) occurring as a result of participation in a research study

Secondary research: Research using information or biospecimens for some other purpose after the primary (separate) research or clinical intervention used them

Sensitive Data: Data regarding such things as illegal activities, sexual attitudes, genetics, or religious beliefs, as well as data that could damage subjects' financial standing, employability, insurability, reputation, or be stigmatizing

Serious Adverse Events: Any adverse event that:

- Results in death
- Places the subject at immediate risk of death
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Results in congenital anomaly/birth defect
- Based upon appropriate medical judgment may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

Serious Noncompliance: Noncompliance that has the potential to increase risk to research subjects, compromise subjects' rights or welfare, or affect the integrity of the research/data

Student Researcher: The undergraduate or graduate student or postdoctoral scholar initiating the research under the supervision of the principal investigator

Subject: See Human Subject

Unanticipated Problem Involving Risks to Subjects or Others: An incident, experience, or outcome that meets all of the following criteria:

Unexpected (in terms of nature, severity, or frequency) given the following two criteria:

- The research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document
- The characteristics of the subject population being studied

Related or possibly related to participation in the research (where there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research)

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

Undue Influence: An offer of an excessive or inappropriate reward or other overture in order to obtain compliance

Unexpected Adverse Event: Occurring in one or more subjects participating in a research protocol, the nature, severity, or frequency of which is not consistent with either:

- The known or foreseeable risk of adverse events associated with the procedures involved in the research as described in either of the two following:

- The protocol-related documents, such as the IRB-approved research protocol, any applicable investigator brochure, and the current IRB-approved informed consent document
- Other relevant sources of information, such as product labeling and package inserts
- The expected natural progression of any underlying disease, disorder, or condition of the subject experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event

Vulnerable Population: Populations which are likely to be vulnerable to coercion or undue influence and require special consideration and protection, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons

Voluntarism: Free of coercion, duress, or undue inducement

54. LIST OF ACRONYMS AND INITIALISMS

AAHRPP: Association for the Accreditation of Human Subjects Research Protections Programs

AE: Adverse Event

CFR: Code of Federal Regulations

CIP: Certified IRB Professional

CITI: Collaborative Institutional Training Initiative

COC: Certificate of Confidentiality

COI: Conflict of Interest

DHHS: Department of Health and Human Services

DSMP: Data Safety and Monitoring Plan

DUA: Data Use Agreement

FCOI: Financial Conflict of Interest

FDA: Food and Drug Administration

FERPA: Family Educational Rights and Privacy Act

FWA: Federalwide Assurance

GCP: Good Clinical Practice

HHS: See DHHS

HIPAA: Health Insurance Portability and Accountability Act

HRPP: Human Research Protection Program

HSR: Human Subjects Research

IAA: IRB Authorization Agreement

IACUC: Institutional Animal Care and use Committee

IBC: Institutional Biosafety Committee

IC: Informed Consent

ICF: Informed Consent Form

IIA: Individual Investigator Agreement

IO: Institutional Official

IRB: Institutional Review Board

LAR: Legally Authorized Representative

LDS: Limited Data Set

MOU: Memorandum of Understanding

MTA: Material Transfer Agreement

NIH: National Institutes of Health

OHRP: Office of Human Research Protection

OIG: Office of the Inspector General

ORA: Office of Research Administration

ORI: Office of Research Integrity

PAM: Post-approval Monitoring

PHI: Protected Health Information

PHS: Public Health Service

PI: Principal Investigator

PII: Personally Identifiable Information

POC: Point of Contact

PRIM&R: Public Responsibility in Medicine & Research

QA: Quality Assurance

QC: Quality Control

QI: Quality Improvement

RCR: Responsible Conduct of Research

SACHRP: Secretary's Advisory Committee on Human Research Protection

SAE: Serious Adverse Event

SBER: Social, Behavioral, and Educational Research

SOP: Standard Operating Procedure