

INTRODUCTION TO HUMAN SUBJECTS RESEARCH PROTECTION

A GUIDE FOR STUDENT RESEARCHERS

Acknowledgement

The Harvard University-Area IRB wishes to thank our colleagues at the University of California, Berkeley, the University of Michigan, the University of Southern California, and the Ohio State University for their willingness to share guidance materials developed for researchers at their own campuses, which served as the basis for this document.

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Introduction to Human Subjects Research Protection for Student Researchers

It is a privilege and not a right to conduct research with human subjects. Responsible conduct of research with human volunteers in social, behavioral, or biomedical research requires commitment to the rights and welfare of participants and to the professional standards of the researcher's academic discipline. This guide is designed to help student researchers at Harvard University understand their ethical obligations as a researcher, the federal regulations governing human subjects research, and the University's policies and procedures associated with the conduct of research whether or not the activities fall under the oversight of the Harvard University-Area Institutional Review Board (HUA-IRB), also known as the Committee on the Use of Human Subjects (CUHS).

KEY RESOURCES

The following key resources may be helpful to the student researcher:

Harvard University

- **Harvard University-Area IRB (Committee on the Use of Human Subjects)**

Richard A. and Susan F. Smith Campus Center

1350 Massachusetts Ave,

Suite 935

Cambridge, MA 02138

Phone: 617-496-2847

Email: cuhs@harvard.edu

Website: <http://cuhs.harvard.edu/>

The IRB website includes contact information for IRB staff; guidance materials, including informed consent templates; a schedule of formal training sessions as well as departmental hours; application submission dues dates; and the schedule of meetings of the full IRB.

- **Electronic Submission, Tracking, and Reporting (ESTR) system**

Website: <http://irb.harvard.edu>

ESTR is the IRB application tool for all human subjects research at Harvard University.

- **Undergraduate Research Training Program (URTP)**

The Undergraduate Research Training Program (URTP) is a comprehensive platform to create better prepared undergraduate researchers. The URTP is comprised of in-person training sessions offered several times throughout the academic calendar, a student-focused curriculum, and an online decision form that will assist students in determining whether their project requires IRB review. All undergraduate researchers who will be conducting research with human subjects (whether IRB review is required or not) must take part in the URTP. More information may be found here: <https://cuhs.harvard.edu/urtp-portal>

- **Training in the Ethical Conduct of Research**

Harvard policies require that all individuals who are involved in human subjects research complete training in the ethical conduct of research. This includes researchers and all study team members who have contact with human subjects or their identifiable data. Faculty sponsors of non-exempt research must also complete the training. More information may be found here:

<http://cuhs.harvard.edu/required-ethics-training>

- **Harvard Research Data Security Policy**

This policy is particularly focused on the protection of research data that are confidential by reason of applicable law and regulation, agreements covering the acquisition and use of the data, and University policies.

<http://vpr.harvard.edu/pages/harvard-research-data-security-policy>

Federal

- **US Department of Health and Human Services (HHS), Office of Human Research Protections (OHRP)**

OHRP is the federal agency that has regulatory oversight for research with human subjects. The OHRP website contains many useful resources related to the ethical conduct of research with human subjects and the regulations governing such research.

<http://www.hhs.gov/ohrp/about>

Chapter 1

Before You Begin

WHY DOES RESEARCH WITH HUMAN SUBJECTS REQUIRE REVIEW?

Harvard University is responsible for ensuring that the rights and welfare of research participants, or *human subjects*, are adequately protected in research conducted by its faculty, staff, and students. Federal laws require this protection, and in order for the University to fulfill its responsibility, all research involving human subjects as defined by the federal regulations must receive appropriate review and approval.

It is important to note that not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB. Please see Chapter 2 for an overview of what types of research require IRB review.

The federal regulatory framework governing human subjects research is found in the US Department of Health and Human Services *Policy for the Protection of Human Subjects* (45 CFR 46). See <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>. These regulations codify the key ethical principles found in the Belmont Report. See <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>. These principles are:

- Respect for persons
- Beneficence
- Justice

In essence, the Belmont Report tells us that for research to be ethical, subjects must choose to participate voluntarily after being fully informed about the research study (respect for persons), that the benefits of the research out-weigh the risks associated with the research (beneficence), and that the selection of subjects is equitable (justice).

Other federal regulations may also apply to the conduct of human subjects research at Harvard University. These are:

- Food and Drug Administration (FDA) (21 CFR 50; 56) regulations govern clinical research involving regulated drugs and medical devices. See <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=50> and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=5>.
- Health Insurance Portability and Accountability Act (HIPAA) (46 CFR 164 Subpart E) regulations cover research involving the use of Protected Health Information (PHI). See <http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/index.html>.

See Appendix I for more information on the ethical and regulatory framework governing the conduct of human subjects research.

WHAT IS AN INSTITUTIONAL REVIEW BOARD?

Institutional Review Boards (IRBs) were established by the federal government to protect the rights and welfare of human subjects participating in research. IRBs review human research activities to ensure that the University, affiliated institutions, and researchers are compliant with ethical standards, state and federal laws, and institutional policies governing human subjects research.

An IRB is an independent committee made up of at least five members from the academic disciplines for which it has oversight and at least one member who is not affiliated with the University. The membership comes primarily from the faculty, but also includes staff, students, and members of the local community. The membership must have the experience and expertise necessary to evaluate proposed research projects and must be diverse in terms of race, gender, and cultural backgrounds.

At Harvard University, human subjects research is reviewed by one of three IRBs. The Harvard University-Area IRB, the Committee on the Use of Human Subjects (CUHS), is the IRB for the Cambridge and Allston campuses.

All activities conducted by Harvard University faculty, staff, or students that involve research with human subjects as defined by the federal regulations are subject to IRB review or exemption (See Chapter 4). Researchers must be aware of their responsibility to seek IRB review. There are, however, some types of scholarly or scientific inquiry that involve interactions with people that do not require IRB review. Please see Chapter 2 for more information on studies that require IRB review and approval.

WHAT IS THE HARVARD UNIVERSITY-AREA IRB, THE COMMITTEE ON THE USE OF HUMAN SUBJECTS (CUHS)?

The Board

CUHS serves as the IRB for research conducted by researchers from the Cambridge and Allston campuses.

The Cambridge and Allston campuses are comprised of the Faculty of Arts and Sciences, as well as the following schools: John F. Kennedy School of Government, Harvard Graduate School of Education, Harvard Law School, Harvard Divinity School, Harvard Graduate School of Design, Radcliffe Institute for Advanced Study, Harvard School of Engineering and Applied Sciences, and the Harvard Business School.

The CUHS IRB is led by a Chair appointed by the Office of the Vice Provost for Research (OVPR). The IRB meets once per month.

The IRB Office

The IRB is supported by the IRB administrative staff. IRB staff members assist faculty, staff, and students seeking IRB approval; provide educational programming in support of the responsible conduct of research; and support the operations of the board. Most researcher interaction with the IRB is with the IRB administrative staff. The IRB staff manages the application workflow and communications between the researcher and the reviewers. In addition, qualified IRB staff members have authority to make specified application determinations, such as issuing exempt and not regulated decisions and approving expedited category research, modifications, and continuing

review applications.

In addition, the IRB staff provides the following services for faculty, staff, and students involved in human subjects research:

- assistance with general questions about human research review procedures;
- assistance with study-specific questions;
- coordination and delivery of educational programs;
- in-person consultation; and
- responses to researcher, community, and research participant questions and concerns.

Chapter 2

How do I know if I am conducting human subjects research?

Research projects meeting the regulatory definition of research with human subjects require review and approval by an IRB, or a determination that the research is exempt. Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research and may not require review by an IRB.

The questions that must be considered when determining whether IRB review and approval is required are 1) whether a project fits the regulatory definition of *research* (“regulated research”), and if so, 2) whether it involves *human subjects*.

Let’s first start with the definition of *research*. While an activity may be considered research, it is important to highlight that not all research meets the threshold of “regulated research” requiring IRB review. The federal regulations have a very specific definition of what is considered regulated research that requires IRB review.

IS IT RESEARCH?

The federal regulations define *research* as “a **systematic investigation**, including research development, testing, and evaluation, designed to develop or **contribute to generalizable knowledge**” (45 CFR 46.102(l)).

- A **systematic investigation** is a study or examination that involves a methodical procedure and plan, is theoretically grounded, specifies a focused and well-defined research problem or question, is informed by the empirical findings of others, is analytically robust, and provides a detailed and complete description of data collection methods.
- **Generalizable knowledge** is information expressed in theories, principles, and statements of relationships that can be widely applied. A plan to publish findings or present at a professional meeting generally, but not always, indicates an intention to contribute to generalizable knowledge.

Research generally does not include activities such as the practice of public health, medicine, counseling, or social work. Studies for internal management purposes such as program evaluation, quality assurance, or quality improvement are not research because the intent is not to draw conclusions beyond the activity or program being studied.

****A note about class/educational “research” activities** – Undergraduate class projects and research methods classes may involve data collection activities for training purposes that do not require IRB review and oversight because the intent is to teach methods, not to contribute to generalizable knowledge. *The goal of this educational exercise is to prepare the student for future research (i.e., research that will be conducted in their future academic career, such as during graduate school) that *will* meet the federal regulatory definition of research with human subjects, with the understanding that the current research activity most likely will not rise to the level of needing IRB review.* However, when the primary focus and initial intent of the class activities are to collect data to be used by students or other researchers beyond the classroom, thereby contributing to “generalizable knowledge,” IRB review may be needed.

****A note about student internships** – Students within many departments or schools of the University are involved in internships or practica. Some student practica/internships may include research activities that are designed to contribute to generalizable knowledge and, thus, involve research that requires IRB review.

DOES MY PROJECT INVOLVE HUMAN SUBJECTS?

If your activity meets the federal regulatory definition of research, the next step is to determine whether your research involves human subjects.

The federal regulations define a *human subject* as “a **living individual about whom** an investigator (whether professional or student) conducting research: (i) obtains **information or biospecimens through intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**” (45 CFR 46.102(e)(1)).

- **“Living individual”** refers to data (information or specimens) collected from living subjects. For example, research using data from the 1880 Census would not be human subjects research.
- **“About whom”** refers to the fact that the information collected must be personal information about an individual. For example, a survey that collects data about the activities of an organization is not human subjects research.
- **“Intervention”** includes physical procedures and manipulations of the subject or the subject's environment for research purposes. For example, taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention.
- **“Interaction”** refers to communication between the researcher and the subject. This includes face-to face, mail, internet and phone interactions, as well as other modes of communication.
- **“Individually identifiable”** means the identity of the subject is or may be readily ascertained by the researcher or others. Research with a de-identified data set is not research with human subjects because the data are not individually identifiable.
- **“Private information”** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

WHAT IF I AM NOT SURE IF MY PROJECT INVOLVES HUMAN SUBJECTS?

Harvard University has identified a number of project types that are “not research” and “not human subjects research” according to the federal regulations and, therefore, do not require review by the IRB:

Not Research

- case studies;
- class activities/research methods classes;
- journalism/documentary activities;
- quality assurance/quality improvement/program evaluation activities;
- oral history; and
- standard public health surveillance or prevention activities.

Not Human Subjects Research

- secondary analysis of publicly available data sets or other de-identified data sets that have been stripped of all identifiable information; and
- research on organizations.

DO I NEED TO SUBMIT AN APPLICATION IF MY PROJECT DOES NOT INVOLVE RESEARCH WITH HUMAN SUBJECTS?

If a formal determination is needed:

An IRB application is not required for most types of “not research” according to the federal regulations. If you would like a formal “not research” determination from the IRB, or if you are not sure if your project requires review, you can submit a brief application via ESTR, the web-based IRB application system. The IRB staff will issue a “not research” determination according to the federal regulations or will advise the researcher that the project does involve human subjects research and will recommend the submission of a standard application via ESTR.

Undergraduate Research Training Program:

The Undergraduate Research Training Program (URTP) is a comprehensive platform to create better prepared undergraduate researchers. The URTP is comprised of in-person training sessions offered several times throughout the academic calendar, a student-focused curriculum (the very one you are reading), and an online decision form that will assist students in determining whether their project requires IRB review (see previous description of the *Decision Form*). The URTP is required for all undergraduates conducting research with individuals, whether or not the activity rises to the level of requiring IRB review.

DECISION FORM

The Decision Form is an online form administered through Qualtrics that guides the researcher through the various regulatory and institutional requirements for research. Definitions and examples are provided with each question. A decision about whether the researcher needs IRB review is provided. Each form is also reviewed by an IRB regulatory expert to ensure that the form was completed accurately and the correct decision was provided.



I am planning on interviewing what might be considered a vulnerable population that will include sensitive questions. Is IRB review needed?

Inclusion of vulnerable populations, such as prisoners or children, is not a criterion of what requires IRB review. Nor is whether the research activity may involve risk. Whether IRB review is needed rests on the federal definition of research and whether the activity is “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.”

Even when IRB review is not needed, there may be institutional policies and procedures and professional ethics guidelines that would prevent such research from being undertaken. For example, Provostial Review is one such institutional policy and procedure that is in place for research activities that may be considered especially risky. Please see Appendix VI for more information on the Provostial Review process.

The research that I undertook as an undergraduate was not considered “regulated research” and IRB review was not required. I would now like to use that data for research that I am conducting as a graduate student. My new research is considered regulated research and has been reviewed by my institution’s IRB. Can I use my previously collected data?

There are many instances of when data that was initially collected for non-research purposes (e.g., student research) are later incorporated into new research studies. This is otherwise known as “secondary use of data not initially collected for research.” The phrase “not initially collected for research” means that the data was collected outside of regulated research requiring IRB review. Secondary use of this data in these circumstances is completely acceptable and permissible. However, depending on the identifiability of the data, IRB review may be needed.

I will be working on a faculty member’s research study that already has IRB review. Do I need to submit my own IRB application?

If the research study you will be working on is being conducted by the same institution you are affiliated with, you can be and will need to be added to the faculty member’s existing IRB protocol (e.g, a Harvard undergraduate joins a study led by a Harvard Faculty of Arts and Science faculty member).

However, if you will be part of a research study that is being conducted by another institution, your institution’s IRB may also need to conduct its own review. In some case, your institution’s IRB may also enter into a reliance agreement (also known as a “cede review”) with the other institution. By entering into this reliance agreement, one institution’s IRB will rely on the other institution’s IRB for review.

There are some additional considerations for reliance agreements: The researcher (here, the student) must be “engaged” in the research, the overall study must be non-exempt, and the other IRB must be willing to enter into a reliance agreement. The IRB uses the term “engagement” to describe type of involvement in a study. To be “engaged” means to be involved in activities that would engage their institution. Examples of activities that engage a researcher and their institution are consenting research subjects, interacting or intervening with human subjects, and analyzing private, identifiable data. Another consideration is whether the overall research is non-exempt, which means that the level of IRB review would either be via Expedited review or Convened IRB review. Finally, the other IRB must be willing to provide review for the relying IRB—It is important to note that not all IRBs will review for another IRB.

Chapter 3

Guidance on Designing your Human Subjects Research Application

In order to ensure that you are conducting ethical research regardless of whether your study meets the criteria for regulated human subjects research or not, there are some key points to take into consideration.

If you are an undergraduate researcher, the URTP offers an application template and information sheet template. You will find these resources in the online URTP portal.

Points to Consider for all research – whether or not IRB review is required

1. Participants

- a. Consider participant number and characteristics:
 - i. How many individuals will participate? You should list the maximum sample size; however, there are times when you may not be able to estimate this number. For example, you may be conducting an online survey which is open to the general public. In these instances, please indicate that you are not able to estimate the sample size and provide a brief explanation of why you are not able to.
 - ii. Will all participants be adults? If not, ensure that child assent and parent permission are obtained.
 - iii. Are there any specific selection criteria based on age, sex, race/ethnicity, participation in a program, etc.?
 - iv. Will you need to utilize or be helped by other institutions -- school, hospital, corporation, or other relevant organization? If so, obtain their permission.

2. Recruitment

- b. Consider how participants will be approached and recruited (e.g., posted flyer, script read by a researcher in person, email invitation, phone call, etc.)
- c. Consider how voluntary participation will be ensured:
 - i. Researchers should design their studies to minimize the risk of coercion or undue influence and always emphasize to potential participants that taking part in the project is voluntary. Offering reasonable compensation is entirely acceptable.
 - ii. Will participants be recruited by someone who might unduly influence them to participate? Can this be avoided? How can prospective participants be protected from feeling influenced or compelled to participate when they might not want to?
 - iii. Are participants offered any material inducement to participate? If participants are paid, what amount and when are they paid? Are gift cards or other forms of compensation to be offered? Is there partial payment for partial completion?
 - iv. Is there a risk that the compensation might be large enough to induce someone to participate when participation might be against their own best interests?

3. Vulnerable participants

- d. Vulnerable participants are individuals who are likely to be susceptible to coercion or undue influence (e.g., students, subordinates, patients). Vulnerable populations also include individuals who cannot give informed consent because of limited autonomy (e.g., children, cognitively impaired, prisoners).
- e. Restrictions and/or special considerations may also apply where other characteristics render populations vulnerable:
 - i. When recruiting children, both parents and their children must be involved in the recruitment process. Children are not eligible to participate in research without their parents' permission.
 - ii. Adults living in potentially coercive conditions – e.g., nursing home residents, half-way house residents.
 - iii. People who have experienced or now have:
 - 1. major injuries or acute or chronic disease;
 - 2. disabilities that interfere with the quality of their lives;
 - 3. homelessness;
 - 4. undocumented status; or
 - 5. stigmatized identity.

4. Procedures and activities

- f. Consider what participants will be asked to do, what will be done to them, or what information will be gathered:
 - i. How frequently and over what time period will interviews, tests, etc., be conducted? Will there be breaks?
 - ii. Where will research be conducted? If interviews will be conducted, how will interviewees be made comfortable? What privacy (if any) will be available?
 - iii. Are interviews to be audio or video recorded? This should be disclosed ahead of time to participants and their agreement obtained as part of the consent process.
 - iv. If recordings will be made, will these recordings be stored? Do you have plans for transcription? If you wish to have the option to use recordings in the future you should tell participants this and obtain their consent.
- g. Consider whether the study will involve either active deception or incomplete disclosure that is likely to significantly mislead participants.
- h. If so, what is the nature of the deception or incomplete disclosure? Is it likely to be significant to participants? If yes, is there another way to conduct the research that would not involve deception or incomplete disclosure, and, if so, why have you not chosen that alternative?
- i. What explanation for the deception or incomplete disclosure do you give to participants following their participation? Will participants be "debriefed" or receive information about the research project following its conclusion?

Please refer to Chapter 7: Special Considerations for more information on deception and incomplete disclosure.

5. Informed consent

- j. Participation in research must always be informed and voluntary (not coerced or unduly influenced). These conditions are met through a consent process.
- k. Points to consider:
 - i. How will you inform participants about your research and then obtain their consent (e.g., orally, in writing, in person, by phone, by email)?

- ii. Will you ask participants to sign a written document – a consent form?
- iii. Whether the consent process includes a signed consent form or not, you should give participants a document that repeats the explanation of the research, identifies you, and provides contact information.
- iv. Consent language should be as simple and straightforward as possible, and appropriate for the level of literacy, education, etc. of the participants.
- v. Will language translation/interpretation be needed? Is there any language barrier that could affect the consent process? If so, be sure to address this and, if needed, make plans for use of translators and translated documents.
- vi. Will recruitment and consent documents be translated into foreign languages? Children under 18 need to have their parents' permission in order to participate in research. In addition, they must themselves be asked to agree (“assent”) to participate.

6. Confidentiality

- I. Consider how confidentiality will be protected:
 - i. Will you use a key or code to identify participants? How will you securely store the information that links codes to identifying information (names, addresses, SSNs)?
 - ii. Will the research data be collected and stored in a manner to keep it separate from the information (names, etc.) that uniquely identify participants?
 - iii. For online studies, will IP addresses or other potentially identifying information be collected? What host site will be used (e.g., SurveyMonkey, iCommons, etc.)? Will those identifiers be removed from the data? If so, at what point, and if not, why must identifiers be retained?
 - iv. Where will data be stored, who has access, and how will it be secured?
 - v. Will research data be destroyed at the end of the study? If not, where and in what format and for how long will the data be stored? To what uses – research, public performance, archiving – might the data be put in future? Note: You should obtain participants' permission for possible future use of their data.
 - vi. If there is a key code connecting participants' data to their identity, when will the link be destroyed? (Include this information during consent process.)

7. Risks

- m. Think about possible risks of harm to participants that might result from:
 - i. the activities of the research –surveys, interviews, or activities you ask them to engage in; or
 - ii. inadvertent disclosure of the data you will collect about participants.
- n. Risks can be psychological or emotional (e.g., participants are asked to recall or describe unusually troubling aspects of life); legal (e.g., participants report their illegal statuses or activities); social (e.g., participants are asked to disclose a stigmatized identity, activity, or status like poor grades or HIV status and those data are inadvertently revealed); financial (participants are asked to invest their own money, or disclose private identity information such as social security numbers or private financial information and the research data are inadvertently revealed); and/or physical (activity involves strenuous activity, travel, ingestion of substances, etc.).
- o. Responsible research requires that risks be minimized, be reasonable in relation to any benefits that might occur, and be clearly communicated to research participants.
- p. Researchers should take measures to protect participant privacy (e.g., are questions tailored to the research problem only, so participants are not asked to provide unnecessary information?)

Risks no greater than those that research participants would encounter in their everyday lives are considered minimal risks. The following examples illustrate risks that are **potentially greater than minimal risk and strategies to reduce them**:

Revealing one's personal experiences of domestic violence would not be, for most people, a normal or everyday occurrence. Most people keep this information private. Revealing it could bring emotional risks (if in the recollection and recounting, painful feelings were aroused); social risks (if the information were revealed to others); and perhaps legal risks (if the individual were a perpetrator or if children were put at risk by the violence, even if the participant were not the perpetrator).

Appropriate risk-reduction strategies could include:

- a. carefully planning the interview ahead of time, and obtaining training and advice in techniques for emotionally sensitive and ethical interviewing;
- b. preparing a list of appropriate counseling resources to have ready for participants if needed;
- c. designing and rigorously adhering to methods to protect the confidentiality of data.
- d. Standard methods include passwords, encryption, and storing research data separately from a key-code linking personal identifiers (e.g., names) from id codes (e.g., numbers).

Discussing political organizing and one's political views in a corrupt and violent political environment might be a normal activity for activists, in that they talk to each other, but it still would not be routine for them to engage in such discussions with a researcher. The possible risks could be reputational (if their colleagues disapproved of them talking to a researcher, or if the data were inadvertently revealed outside the research); legal; and even physical (if disclosure might lead to physical reprisals).

Appropriate risk-reduction strategies could include:

- a. having a compelling and specific justification for questions that would elicit risk-inducing information and avoiding risk-generating questions;
- b. seeking training in techniques for ethical interviewing in politically sensitive contexts;
- c. designing and rigorously adhering to methods to protect the confidentiality of data, which probably would include avoiding identifiable information as far as possible, using encryption as well as passwords (for audio recordings as well as written data), and, destroying such information (e.g., by removing it from computers) as rapidly as possible. See the Harvard University Research Data Security policy for information on how to protect your data - <http://vpr.harvard.edu/pages/harvard-research-data-security-policy>

Running a few yards might be a normal physical activity, but running to the point of complete exhaustion would not be for most people; therefore, if it were a research activity, it would carry research risks beyond what is encountered in daily life.

Appropriate risk-reduction strategies could include:

- a. recruiting only conditioned athletes for whom running to exhaustion might be fairly routine; and/or
- b. requiring a medical exam ahead of time.

Chapter 4

IRB Review of Research with Human Subjects

What type of review is required for my project?

Projects that meet the definition of research with human subjects require documented IRB approval or a determination of exemption before starting any research activities, including pilot activities, advertising, or recruiting. All applications are submitted to the IRB for review via ESTR (<http://irb.harvard.edu>). Once submitted, applications undergo one of the following types of review:

- Exempt - Studies meeting one of eight specific exemption categories.
- Expedited - Studies involving no more than minimal risk are generally reviewed via expedited review.
- Full board - Studies that involve greater than minimal risk are reviewed by the full board. Studies with complicated research elements or involving vulnerable populations may also be reviewed by the full board.

What is minimal risk?

As defined by the regulations, “minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.” Types of risk include the potential for economic, legal, physical, psychological, or social harms. For social and behavioral research, the primary risks considered by the IRB include reputational, legal, or financial harms that might result from a breach of confidentiality or emotional/psychological distress or discomfort experienced by the subject in responding to research interactions or interventions.

EXEMPT REVIEW

What is exempt research?

Exempt research is research with human subjects; however, it is “exempt” from the IRB regulations only after initial review to determine if it meets the regulatory definition. To be exempt, a project must fall under one of eight exempt categories listed in the federal regulations (*45 CFR 46.104*). Exemptions are not usually granted for research involving prisoners as well as some types of research activities involving children.

Although research determined to be exempt is exempt to the federal regulations, Harvard University has certain requirements that one must follow when conducting exempt research.

If you will be interacting/intervening with subjects, and if feasible, an information sheet must be provided to the study subjects that includes the following elements:

- A description of the procedures: what questions will be asked, how long it will take, whether the information will be confidential;
- A statement that the activities involve research;

- A statement that participation is voluntary;
- Your name and contact information.

How is exempt research reviewed?

Exempt research requires submission of a standard IRB application. A designated IRB staff member reviews the completed application and associated materials to confirm that the research fits one of the exemption categories. If exempt, the IRB will issue an exemption determination letter via the ESTR system.

Exempt research projects are not subject to continuing IRB oversight, but researchers are expected to conduct exempt research in accordance with the ethical principles of the Belmont Report (see Appendix I, Ethical and Regulatory Framework) and the ethical codes of their professional discipline. IRB determinations for exempt projects do not expire. However, **if you plan a significant change to the exempt protocol that would exceed the scope of the exemption category, a modification must be submitted for IRB review and determination.**

EXPEDITED REVIEW

What is expedited review?

Federal regulations specify conditions under which research may be reviewed by the IRB using expedited review procedures. Expedited review is carried out by designated IRB members who may also be IRB staff. Expedited review is conducted on a rolling basis and is not subject to submission deadlines.

All human subjects research projects are subject to the same review criteria regardless of whether they are reviewed via an expedited or a full board review process (see Appendix II, Regulatory Elements of IRB). The same standard ESTR application and supporting materials (protocols, informed consent documents, recruitment materials, surveys, etc.) are submitted for either type of review.

Only research proposals that present **NO MORE THAN MINIMAL RISK** to participants qualify for review using expedited procedures. In addition, the research must fall within one of the nine categories of activities that qualify for expedited review (See Appendix V, Expedited Review Categories). The IRB will determine the appropriate expedited review category for your research.

The expedited review procedure may not be used for:

- research 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;
- classified research involving human subjects; and
- most research involving prisoners.

How is expedited research reviewed?

A designated IRB staff member conducts the review of each application and makes a determination about whether it meets the criteria for expedited review or will require review by the full board. The staff reviewer may return the application to the researcher for changes if the application and supporting materials are incomplete or unclear.

If the research qualifies for expedited review, the IRB staff completes the review based upon the criteria

described in Appendix II and issues a determination. The IRB staff communicates the outcome of the review via the ESTR system. The reviewer may approve the research, require modifications to the research before approval, or refer the submission to the full board for further review. (See Appendix III for a description of the types of determinations that the reviewer may issue for a proposal.)

FULL (CONVENED) REVIEW

What projects require review by the full (convened) board?

Projects that involve MORE THAN MINIMAL RISK or that do not fit into one of the specified expedited review categories must be reviewed by the full board at a convened meeting. Examples of other projects that may require review by the full board include:

- projects posing no more than minimal risk to participants but that involve vulnerable populations, sensitive topics, or complex research designs that would benefit from a review by the breadth of expertise represented at the full board. This includes studies that collect sensitive data that may require an NIH Certificate of Confidentiality (CoC) to protect subject data from compelled disclosure.
- projects referred to the full board by an expedited reviewer. For example, a reviewer may seek guidance from the full board in determining whether a study meets the regulatory definition of minimal risk or when the scientific question posed by the PI exceeds the expertise of the available expediting reviewers.
- research involving prisoners.

How is research reviewed by the full board?

A designated IRB staff member conducts the initial administrative review of each application identified as requiring full board review. The staff reviewer may return the application to the researcher for changes if the application and supporting materials are incomplete or unclear.

Once complete, the application is added to the agenda for the next available meeting of the IRB. A primary IRB reviewer and a secondary reviewer (if needed) are assigned to present the proposed research to the board at the convened meeting. All members receive a copy of the submission materials via ESTR. Consultants may also be invited to assist in the review of research where additional expertise is necessary. In some circumstances, the researcher may be asked to attend the board meeting to respond to the board's questions.

After the meeting, the board's decision will be communicated to researchers via ESTR. The board may vote to approve the research, determine that there are modifications required to secure approval, or defer action on the application if significant revisions are required. See Appendix III for a description of the types of determinations the IRB may issue for a study.

Researchers may not begin research activities until documentation of IRB approval is received via ESTR.

Chapter 5

What is Informed Consent?

Informed consent is the process of telling potential subjects about the key elements of a research study and what their participation will involve. The subjects in the study must participate willingly after having been adequately informed about the research. If the subjects are from a vulnerable population, such as prisoners or children, additional protections are required.

Consent documents must be clearly written and understandable to subjects. The informed consent document is an information tool, rather than a legal contract.

- Use non-technical language (comparable to the language in a newspaper or general circulation magazine), free from scientific, legal, or academic jargon.
- Be aware of the reading level of your subject population. In general, aim for an 8th grade reading level.
- Don't use the "first person" in the body of the consent (I understand, I agree, etc.), before you have actually explained the research. Use the "second person" to tell the subject about your project.
- Regulations preclude the use of exculpatory language that implies that the subject is waiving any legal rights by agreeing to participate.

ELEMENTS OF INFORMED CONSENT

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

The regulations further identify the following required elements of informed consent (*45 CFR 46.116*).

- a statement that the **activity is research** and describing **its purpose**;
- a description of **procedures** involved in the research, including a statement of the length of **time** the subject is expected to participate (for example, a one-hour survey, three one-hour interviews over the course of three months);
- a description of all reasonably **foreseeable risks** and discomforts to the subject (includes possible psychological, social, or economic harm, discomfort, or inconvenience, in addition to physical risks);
- a description of **benefits** of the research to the individual subject or to society in general;
- description of plans to protect the **confidentiality** of records identifying the subject (if appropriate);
- a disclosure of **alternative** procedures or treatment available should a subject decide not to participate in the research (rarely applies to social and behavioral research);
- for projects involving more than minimal risk to participants, an explanation regarding whether compensation or medical treatment is available if injury occurs (rarely applies to social and behavioral research);

- persons (**PI and Faculty Advisor**) to contact for answers to questions or in the event of a research-related injury or emergency;
- contact information for the **IRB** for answers to questions about the subject's rights as a research participant;
- statement that participation is **voluntary** and that refusal to participate or discontinuing participation will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive;
- statement regarding whether participant information or biospecimens will be used for future research studies upon removal of identifiers.

For projects involving *research with children*, researchers **must** obtain both the consent (permission) of one or both parent(s) as well as assent of the minor child depending on the design of the study. Projects involving participants who are cognitively impaired may require consent from a legally authorized representative (LAR).

Other optional elements **as appropriate** to the research project in part include:

- **payment** for participation (include information regarding payment if the subjects ends participation before completing the research);
- for surveys and interviews, a statement that the subject may **skip** any question they don't wish to answer, if possible.

See the IRB website at <http://cuhs.harvard.edu/> for informed consent templates, sample consent documents, and detailed guidance materials.

THE INFORMED CONSENT PROCESS

Informed consent is documented by the use of a written consent form that is signed by the subject or legally authorized representative. A copy of the consent document should be provided to the person signing it (*45 CFR 46.117*).

Regulations allow for some exceptions to the requirement for documented (signed) informed consent as well as allowing for waiving informed consent.

Waiver of Documentation of Informed Consent

According to *45 CFR 46.117*, an IRB may waive the requirement for the researcher to obtain a signed consent document if it finds either:

- That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, **OR**
- That the research presents **no more than minimal risk** of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, **OR**
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents **no more than minimal risk** of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

For projects on sensitive topics, use of a waiver of documentation may minimize the risk to participants by making it impossible to link them to the research project. Subjects are still provided with all of the information required for informed consent, either in written or oral form, but no signed consent document is obtained.

More commonly, the IRB waives the requirement for documented informed consent for minimal risk projects

such as those involving web-based or telephone surveys where obtaining a signed consent document might be impracticable. Again, subjects are still provided with the elements of informed consent through written material or an oral description.

Waiver of Informed Consent

In some circumstances, the IRB may approve a consent procedure that does not include or waives some or all of the elements of informed consent. In order to waive informed consent, the regulations (*45 CFR 46.116*) require that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 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;
- The research could not practicably (feasibly) be carried out without the waiver or alteration; **AND**
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The waiver of informed consent is primarily utilized in research involving the secondary analysis of existing identifiable datasets or with research involving deception (see Chapter 7 for more information).

Screening, Recruiting, and Determining Eligibility

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, **OR**
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Chapter 6

Researcher Responsibilities after IRB Approval

Approval of a research project by the IRB does not end a researcher's responsibilities with respect to reporting to the IRB. IRB review and approval must be obtained before any change to a research protocol or associated materials (consent, survey instruments, and recruitment materials) can be implemented, unless the project is exempt. For projects that involve more than minimal risk and in some study-specific special circumstances, the IRB must re-review the project and its progress prior to the expiration of its approval period, which is determined by the IRB and usually lasts one year. Finally, researchers have an obligation to report adverse events, unanticipated problems, or protocol deviations to the IRB as soon as they are aware of the problem.

MODIFICATIONS

A modification is a revision to an approved non-exempt research project. IRB review and approval are required before researchers implement a modification to a research protocol, except when necessary to eliminate immediate hazards to the subjects, which rarely applies to social and behavioral research. Any proposed change to a previously approved project must be submitted to the IRB as a modification via the ESTR system. For exempt projects, a modification is required ONLY if the study is revised in such a way that the exemption criteria no longer applies.

SCHEDULED CONTINUING REVIEW

The IRB conducts continuing review of research studies that involve more than minimal risk and in some study-specific special circumstances. An approval period generally last 12 months; however, the IRB may wish to review some studies with greater regularity depending on risk. The continuing review application must be submitted at least 4-6 weeks before the end of the approval period. Researchers will receive ESTR reminders prior to the expiration of the study approval. Also, IRB approval must be renewed as long as the researcher is actively analyzing the data collected as part of the project, unless the data set has been completely de-identified (including destruction of the key to coded identifiers).

Expiration of Approval Period - If the approval period for an active study has expired (or lapsed), all research-related procedures must stop, except where doing so would jeopardize the welfare of the human subjects. This means that no subjects may be enrolled in the research, no data may be collected, and data analysis must stop.

REPORTABLE NEW INFORMATION (RNI)

Adverse events are events that involve physical, social, economic, or psychological harm to subjects or others. Such adverse events may also indicate risks of harm to other subjects or to others. RNIs are unplanned or unexpected occurrences associated with the research, a significant subject complaint, a deviation from the approved research protocol, or a data security breach such as the theft of a laptop. An RNI is reported to the IRB via the RNI report in the ESTR system.

Please contact the IRB for guidance if one of these events occurs during your research.

WHAT DO I DO WHEN I HAVE COMPLETED MY STUDY?

By submitting a study closure, the researcher confirms that the study is finished and that there will be no further interaction with subjects or their data. Once the IRB receives and acknowledges the study closure, the study is closed in the ESTR system. Note: If the researcher wishes to enroll new subjects for the study, or otherwise engage human subjects in research after the study is closed, a new application must be submitted in ESTR. Therefore, a researcher should only close a study when they are no longer enrolling new subjects, using research interventions on existing subjects, collecting data (including follow-up data), or performing analysis of identified data as part of the approved study.

Chapter 7

Special Considerations

COLLABORATION WITH RESEARCHERS OUTSIDE HARVARD UNIVERSITY

Projects that involve collaboration with non-Harvard University researchers or non-Harvard University research sites that are “engaged” in the research may require additional external IRB approvals or inter-institutional agreements before a research project can receive final approval. An institution is engaged in research when its employees or agents intervene or interact with research subjects, including obtaining informed consent, or obtain individually identifiable private information for research purposes. See <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>.

DATA SECURITY

In social and behavioral research, breach of confidentiality is a serious risk posed to participants. Rigorous data security is a key element of protecting subject data from an accidental or malicious breach. Data security includes a plan to manage the physical documentation associated with the project, such as paper surveys, signed consent forms, or documents that contain contact information for subjects to ensure that those materials are not lost or accessed inadvertently by an unauthorized person. Increasingly important is the management of electronic data on desktops or servers as well as on mobile devices such as laptops and flash drives. See the Harvard University Research Data Security policy for information on how to protect your data: <http://vpr.harvard.edu/pages/harvard-research-data-security-policy>

INTERNATIONAL STUDIES

Research conducted outside the United States may create additional challenges for the student researcher and the IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants compared to the same research conducted within the U.S. Other countries and institutions within those countries may have Institutional Review Boards, Ethics Committees, or other research oversight bodies which require review of the research before it can be conducted in that country. Conversely, some may have no mechanism for ethics review of social and behavioral research. Except for research which is federally funded and the international site is engaged, the regulatory authority of the 2018 Rule does not cover research outside the U.S.; therefore, the IRB must ensure that equivalent protections for human subjects participating in research are in place.

In its review of your application, the IRB will consider the following information:

- description of where the research will be conducted (including geographic location and specific performance sites, where applicable). Note: In some areas, government–issue research visas are required;
- information about the local research context, including the current economic, cultural, political, or religious conditions of the area that may affect the conduct of the research, and a

description of the researcher's personal experience conducting research (or studying or residing) in the region;

- the language(s) in which consent will be sought from participants and the research will be conducted, as well as whether the researcher is fluent in this language or whether an interpreter will be required. If an interpreter will be used, it should be clear what limitations or risks, if any, this might present for participants, as well as how these potential problems will be overcome or minimized;
- a description of the informed consent process as appropriate for the culture;
- copies of translated study documents (recruitment materials, informed consent, study instruments);
- any benefits to the local community that will remain in the community once the research is complete;
- if compensation is being offered, a description of its appropriateness for the setting;
- procedures for data security and storage in the local setting and for transfer of data and/or specimens to Harvard University; and
- a copy of local IRB or equivalent ethics committee approval, where applicable. Depending on the location, this may take the form of a letter of approval from an IRB or research ethics committee, local university department sponsoring the research, institutional oversight committee, or an indigenous council. If the research is federally funded, check with the IRB for other regulatory requirements.

If you are traveling to an international setting for your research, submit your IRB application well in advance of your planned travel date. This is particularly crucial for projects that may involve more than minimal risk to participants that will require full board review. See the CUHS website (<http://cuhs.harvard.edu>) for meeting submission dates.

For those research studies that are determined to meet the criteria for expedited or full (convened) IRB review, it will also be necessary for the Office of the Vice Provost for Research (OVPR) to review the study. More information on this Provostial review may be found on the OVPR website <http://vpr.harvard.edu/pages/provost-criteria-review> as well as in Appendix VI: Provostial Review Process.

RESEARCH IN SCHOOLS

Research conducted in primary and secondary schools, colleges, and universities that receive U.S. Department of Education funds may be subject to additional federal regulation. Schools that grant access to researchers may also impose requirements, such as district approvals or informed consent processes that would not be required by the IRB.

The Family Educational Rights and Privacy Act (FERPA) (34 CFR Part 99)

<http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html>

FERPA applies to research involving student education records for any institution receiving U.S. Department of Education funding, meaning that it applies to most public and private K-12 schools as well as most public and private colleges and universities. Access to identifiable student records requires written permission from the parent (for minors) or from the adult student unless the research is being conducted by the researcher on behalf of the school.

The Protection of Pupil Rights Amendment (PPRA) (34 CFR Part 98)

<http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html>

The PPRA, created by the No Child Left Behind Act, applies to survey research conducted in elementary and secondary schools receiving funds under U.S. Department of Education programs. The provisions of the PPRA apply to surveys that involve specific sensitive survey topics. The PPRA includes requirements for parental

permission as well as for making survey questions available for parental review prior to administration.

SECONDARY DATA ANALYSIS PROJECTS

Projects that involve only the secondary analysis of data collected as part of a different research project do not require IRB review and approval if:

- the data set is publicly available; or
- the data set has been already de-identified, meaning that any data elements that could be used to identify an individual have been stripped.

Projects using Coded Private Information or Biological Specimens - If you will be using a data set provided by another researcher that has been coded for your use, your project may not require IRB oversight. *Coded* means that identifying information that would enable the researcher to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code) and a key (or cross-walk) to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Research using such a coded data set is not regulated by the IRB if the data were not collected for the proposed study and the researcher does not have access to the code linking to the identifiable information. More information regarding coded private information or biological specimens can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.

Please see Chapter 2 for more information on secondary use of data that was not initially collected for research.

DECEPTION AND INCOMPLETE DISCLOSURE STUDIES

Deception is the intentional *misleading* of a subject about the nature of the study. *Withholding* of full information is known as incomplete disclosure. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception increases ethical concerns and should be used with discretion because it interferes with the ability of the subject to give informed consent. The IRB recognizes that deception or incomplete disclosure may be necessary for certain types of behavioral research given that people act differently depending on circumstances and full knowledge by the subject might bias the results in some cases.

Special requirements for deception or incomplete disclosure projects:

Waiver of Informed Consent

Because participants are not provided with all the details of the proposed research at the time consent is obtained, deception projects must meet the criteria for waiver of informed consent including that the project poses no more than minimal risk to the subjects.

Debriefing

In most circumstances subjects have the right to full disclosure as soon as possible after participation in deception or incomplete disclosure research; a post-participation debriefing is usually required. The debriefing should disclose the full or true purpose of the research and allow the subject to indicate that their data not be used in the study. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects should not be exposed to undue stress or embarrassment and should have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected.

There may be circumstances when debriefing is not appropriate. This may be when disclosure of the information may cause more distress to subjects than if not disclosed or when disclosure may bias the scientific integrity of the study.

USE OF SUBJECT POOLS

Some academic units at the University operate student subject pools that grant academic credit for participation in research. While the IRB has oversight for the research conducted in these pools, the administration of the pools is governed by the academic units.

- **Psychology Study Pool**

The Department of Psychology administers the Study Pool, an online pool of current research studies for volunteer subject participation. The Study Pool serves to introduce students and members of the community to the process of psychological research and provide members of the department with subject participants for their research.

<http://studypool.psychology.fas.harvard.edu/>

- **Harvard Decision Science Laboratory**

The Decision Science Laboratory is an advanced research facility created to provide a critical resource to researchers from across Harvard University. The lab's objective is to create and support a community of scholars working in the many intersecting areas of Decision Science, and in so doing to establish Harvard as a leading institution at the forefront of research and writing in the field.

<http://decisionlab.harvard.edu/>

- **Harvard Business School Computer Lab for Experimental Research**

The Computer Lab for Experimental Research (CLER) studies human behavior and decision-making by inviting participants from across the Boston area.

<http://www.hbs.edu/behave/Pages/default.aspx>

Appendix I

Core Ethical Principles and Regulatory Framework Ethical Framework

Nuremberg Code

The history of the ethical regulations in human subjects research began in the 1940s with the Nuremberg Code. The Nuremberg Code was developed following the Nuremberg Military Tribunal which judged human experimentation conducted by the Nazis. The Code encompasses many of the basic principles governing the ethical conduct of human subjects research today. The Nuremberg Code states that “the voluntary consent of the human subject is absolutely essential” and it further explains the details implied by this requirement: capacity of participants to consent, participants’ rights to participate or not, freedom from coercion, no penalty for withdrawal, and comprehension of the risks and benefits involved.

Declaration of Helsinki

In 1964, the World Medical Association established recommendations to guide medical doctors in biomedical research involving human subjects. The Declaration governs international research ethics and defines rules for "research combined with clinical care" and "non-therapeutic research." The Declaration of Helsinki is the basis for Good Clinical Practices (GCP) used today.

Issues addressed in the Declaration of Helsinki include:

- research involving medical interventions with humans should be based on the results from laboratory and animal experimentation;
- research protocols should be reviewed by an independent committee prior to initiation;
- informed consent from research participants is necessary;
- research should be conducted by medically/scientifically qualified individuals; and
- risks should not exceed benefits.

The Belmont Report

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research created “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.” The Belmont Report sets forth the basic principles governing the ethical conduct of research involving human subjects. The Belmont Report encompasses three key principles: respect for persons (autonomy), beneficence, and justice.

Principle	Application
Respect for Persons	Respect for persons requires that protocols (including the informed consent process) be designed to promote personal capacity to consider alternatives, make choices, and act without undue influence or interference of others. The principle is reflected in requirements that legally effective informed consent be obtained, unless specific requirements for waiver of informed consent are met and appropriately documented; and that subjects with diminished capacity and others who are vulnerable to coercion or undue influence receive special protection or consideration.
Beneficence	Beneficence entails an obligation to protect individuals from harm. The principle can be expressed in two general rules: (1) do no harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. It is reflected in a requirement that principal investigators design and IRBs approve protocols only under circumstances where the benefits to the subjects and/or the importance of the knowledge to be gained justify the risks to the subjects sufficiently to warrant a decision to allow the subjects to accept those risks.
Justice	Justice requires fairness in distribution of burdens and benefits. The principle often is expressed in terms of treating persons of similar circumstances or characteristics similarly. It is reflected in the requirement that selection of subjects is equitable and is representative of the group that is intended to benefit from the research.

More information can be found at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

Regulatory Framework Governing Human Subjects Research

Since the release of the Belmont Report, the federal government has codified the protection of the rights and welfare of human subjects by establishing regulatory codes and regulations.

- Federal Policy for the Protection of Human Subjects (45 CFR 46)**
 In 1981, the Department of Health and Human Services codified the Policy for the Protection of Human Subject (45 CFR 46). These regulations, called the “Common Rule,” provided for the basic foundation of the Institutional Review Boards. This federal policy was updated most recently in January 2019, renamed the “New Rule” or “2018 Rule.” More information can be found at <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html>.
- U.S. Food and Drug Administration Regulations**
 The U.S. Food and Drug Administration, under the Department of Health and Human Services, also provides guidance for Institutional Review Boards. FDA regulations differ from the 2018 Rule in some ways as they are intended to regulate research involving drugs, devices, and biologics. See <http://irb.jhmi.edu/Guidelines/FDAvsOHRP.html>. More information can be found at <http://www.fda.gov/oc/ohrt/irbs/>.
- Health Insurance Portability and Accountability Act (HIPAA)/Privacy Rule**
 The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that generally prohibits health care providers (such as physicians or other health care practitioners, hospitals, nursing facilities, and clinics) from using or disclosing "protected health information" (PHI) without written authorization from the patient. The full text of the Privacy Rule can be found at the HIPAA privacy website of the Office for Civil Rights (OCR): <http://www.hhs.gov/ocr/hipaa>.

Appendix II

Regulatory Elements of IRB Review

When the IRB reviews a non-exempt research protocol, it must make eight specific regulatory determinations in order to grant approval. These determinations find their basis in the ethical principles of the Belmont Report and codified in the Common Rule: respect for persons, beneficence, and justice.

1. Risks to subjects are minimized

Minimal risk means that the probability and magnitude of harm and 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 examination or tests. Types of harm include economic, legal, physical, psychological, and social. Each type of harm may occur in social research either to participants or to people not directly involved in the research, such as family members.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any

Risks

In social and behavioral projects, primary risks to subjects tend to be related to psychological distress or harms resulting from a breach of confidentiality. Subjects may feel stress caused by the research questions or procedures. Questions raise painful memories or unresolved issues. Questions about at-risk behaviors may cause embarrassment, feelings of guilt, or result in legal liability when that behavior is generally illegal or socially unacceptable. Most psychological risks are minimal and transitory, but researchers must be aware of the potential for serious psychological harm.

A breach of confidentiality may be a significant risk to participants in social and behavioral research. If confidentiality of research data is not maintained, a participant might experience risks to reputation, employment, financial standing or insurance coverage. Information about subjects' activities may place them at risk of legal action. For example, if subjects divulge information about their participation in illegal or stigmatizing activities, any disclosure of that information could place the subjects at risk of significant harm.

The kind and level of risk is determined by context. For example, research regarding political activism in some countries may put subjects in serious jeopardy, while it would not in other countries.

In many cases, risk to privacy/confidentiality can be eliminated or reduced by careful procedures for ensuring confidentiality. Psychological support and referrals can be built into studies when emotional distress may be an outcome. The referrals can be made via an information card or debriefing sheet provided to the subject by the study team. Consent forms that describe the kinds of questions the researcher will ask allow participants to choose whether they wish to divulge certain types of information or participate in the study at all.

Benefits

Direct benefits for individual subjects may be present in studies offering interventions for behavioral, psychological, or physical problems. However, most social and behavioral research provides no direct benefit to subjects. Where the benefit is indirect, the potential risks and harms must be carefully evaluated. When there is no direct benefit to subjects, they must be told what the researcher is trying to learn and why. Compensation to subjects is not considered a benefit in the risk/benefit analysis, nor is the fact that participants may find volunteering for research to be interesting, educational or rewarding.

3. Selection of subjects is equitable

When evaluating the criteria used to select participants, the IRB focuses on whether a specific population is unfairly targeted or avoided. Fulfilling the goal of equitable selection does not preclude using demographic and other characteristics to justify differential selection of participants for legitimate research purposes.

The IRB applies special care in protecting individuals who may not be able to exercise their decision making capacity due to personal circumstances or environmental constraints. Examples of populations that might be considered vulnerable include prisoners, children, non-English speaking individuals, and people who are socially or economically disadvantaged. The IRB also applies special care when reviewing research that involves student-teacher and employee-employer relationships.

As part of evaluating the equitable selection of subjects, the IRB carefully reviews plans for participant recruitment and compensation.

4. Informed consent will be sought

Informed consent is the process of telling potential subjects about the key elements of a research study and what their participation will involve. The human subjects in the study must participate willingly, after having been adequately informed about the research. If the subjects are from a vulnerable population, such as prisoners or children, additional protections are required. See Chapter 5 for a discussion of the informed consent document and the required elements of informed consent.

In addition to the consent document, the IRB reviews the consenting process to ensure that a potential subject's decision to participate is voluntary and not subject to coercion or undue influence. For example, a consent process may be judged coercive when participants are subject to the formal or informal authority of others (e.g., prisoners, students, employees, or patients), when there are communication issues (e.g., non-English speaking individuals or low literacy rates among subjects), when there are capacity issues (individuals with mental illnesses), and when it is reasonable to believe that the incentives offered reduce the individual's capacity to make a reasoned, voluntary participation decision.

5. Informed consent will be appropriately documented, or, if requested, that the research meets the requirements for any waivers or alterations

Federal regulations require that informed consent be documented by the use of a written consent form approved by the IRB and signed by the participant. The IRB can waive this requirement in certain circumstances. See Chapter 5 for a discussion of the informed consent document and the required elements of informed consent.

The evaluation of this criterion is common in biomedical research, but rarely applies in social research except when direct interactions with subjects may produce harm.

7. Protection of subject privacy and data confidentiality

The protection of privacy and confidentiality are important issues in the protection of human research subjects. Protection of subject privacy and confidentiality are extensions of the principles of autonomy (respect for persons) and beneficence from the Belmont Report. Privacy and confidentiality are different concepts.

- Privacy is personal and can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- Confidentiality relates to data and pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

The researcher must describe plans to protect the subject's identity as well as the confidentiality of the research records and should include this information in the informed consent document. Care should be taken to explain the mechanisms that have been devised to protect the privacy of the subjects, for example, the use of numbers or codes as opposed to their name to protect their identity as well as the encryption of electronic data. Furthermore, the researcher should describe who has access to the data and under what circumstances a code may be broken in order to re-identify a subject. Subjects should be informed of whether the data collected will be retained, and if so, for what purpose, what period of time, or whether and when data will be de-identified and destroyed. Special care must be taken with video or audio taped data and photographs since these media may provide additional potential means for subject identification.

For projects that involve the collection of sensitive data, the IRB may recommend that the researcher obtain a Certificate of Confidentiality (CoC) from the National Institutes of Health. A CoC protects the researcher from being compelled to disclose data that could be used to identify a participant with a research project. Data are considered to be sensitive if disclosing the information could have adverse consequences for participants, such as posing civil or criminal liability or be damaging to their financial standing, employability, insurability or reputation. Examples of studies that might be considered sensitive include those collecting genetic information, information on illegal behaviors (such as substance abuse), or information on sexual behaviors or sexually transmitted diseases. The NIH may grant a CoC for any sensitive project, regardless of whether the project receives NIH funding. For more information, see the NIH Certificate of Confidentiality Kiosk <http://grants.nih.gov/grants/policy/coc/>.

It should be noted that CoC protects only against compelled disclosure. Appropriate data security measures should be implemented to protect against accidental or intentional breaches of confidentiality.

8. Protection of vulnerable subjects

In human subjects research, certain research populations are considered to be vulnerable and/or need additional protections. People who cannot competently understand the information regarding a study and cannot give true consent, such as individuals with psychiatric, cognitive or developmental disorders, and substance abusers, are considered vulnerable. A vulnerable population may include any group that is subject to undue influence or coercion. For example, an individual may feel compelled to participate in research because it is being conducted or supported by a teacher or employer. Research that specifically targets a vulnerable population will receive a higher level of scrutiny than projects that do not involve vulnerable populations.

While any individual who fits the above category can be considered vulnerable, federal regulations offer additional protections to three groups of people:

Prisoners are considered to be vulnerable in that their incarceration which could affect their ability to make a truly voluntary and non-coerced decision on whether or not to participate as subjects in research (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc>). Research projects involving prisoners as research subjects typically require review by the full IRB.

Pregnant women, fetuses, and neonates may be at a greater risk than others due to their physical status. Special regulatory protections, however, are geared toward medical research rather than social/behavioral research. (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb>)

Children are considered vulnerable because they may not be able to completely understand the information presented about a study. (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd>)

Appendix III

IRB Determinations

After completing its review of an application, the IRB will notify researchers of one of the following actions:

Approved – The IRB approves a research proposal when the application is complete and the IRB has determined that the study has met the regulatory criteria for approval. Once the approval determination is issued via ESTR, the research may be conducted according to approved procedures and parameters.

Modifications Required to Secure Approval – The IRB makes the determination of modifications required to secure approval when the proposal meets the regulatory criteria for approval but needs specified changes to the protocol, informed consent document(s), or other supporting materials prior to final approval. Such changes must require no more than the simple concurrence of the researcher. The researcher is notified of the study outcome via an ESTR **Modifications Required to Secure Approval** notice and is provided with detailed instructions regarding required changes to the application or study materials that must be completed before the application can receive final approval. Once all contingencies are met, the IRB will issue an approval notice via ESTR. For initial submissions, no research may be conducted until final approval is released by the IRB.

Action Deferred – The IRB full board may vote to defer action on an application when a significant action on the part of the researcher is required before the IRB can consider approval or disapproval of the research. Deferred applications are found to have major deficiencies, such as incomplete procedures and documentation, or major ethical issues, including unreasonable risk to subjects that make it impossible for the IRB to approve the research as proposed. The application is returned to the researcher via a **Deferred** notice within ESTR that details the issues that must be addressed in the application/materials before it can be reconsidered by the IRB. Upon revision of the application and resubmission to the IRB, the study will be rescheduled for review by the full IRB.

Disapproval – The IRB full board may vote to disapprove an application to conduct human subjects research when it determines that the study design does not provide, and is unlikely to be modified to provide, adequate protection to subjects. Disapproval of an application usually follows several attempts by the researcher in conjunction with the efforts of the IRB to modify the study design to afford protection to the subjects. This action can only be taken by the full board at a convened meeting. The researcher will be sent a rationale for the disapproval and may ask that the IRB reconsider the disapproval.

Appendix IV

Categories of Exempt Research

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

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

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

EXEMPTION #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:

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

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.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in

circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

EXEMPTION #4: Research involving the collection or study of data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

EXEMPTION #5: Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

EXEMPTION #6: Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

EXEMPTION #7: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research for which broad consent is required.

EXEMPTION #8: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use for which broad consent is required.

NOTE: The Harvard University Area IRB does not apply exempt categories 7 and 8 or the related regulatory provisions for broad consent.

Limited IRB review: If your research falls under exempt category two (i.e., survey and interview procedures) or exempt category three (i.e., benign behavioral intervention) and data that are collected are identifiable and sensitive, there must be a limited IRB review. A limited IRB review is a process by which the IRB (or IRB staff) ensure and document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. This follows the IRB's designation of a data security level according to the Harvard Research Data Security Policy.

Appendix V

Expedited Review Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [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: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

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

Appendix VI

Provostial Review Process

The Provostial Review is a review of research proposals conducted by the Provost's Office at Harvard University. The Provostial Review process is designed to review projects that pose management challenges and/or reputational risks beyond those routinely covered by the IRB or other review committees. The Provostial Review process also considers the question of whether the proposed research project is within the research and academic mission of the University, as opposed to advocacy or consultancy.

There are ten criteria that can trigger a Provostial Review. These criteria are described under the "Criteria and Procedures for Provost's Review of New Projects or Grants" on the Office of the Vice Provost for Research (OVPR) website: <http://vpr.harvard.edu/pages/provost-criteria-review>.

For undergraduate researchers, the most common criterion triggering a Provostial Review is #4: *"The project is international and involves human subjects research that requires IRB expedited or full review."*

The Provostial Review is undertaken by a team comprised of staff from OVPR, the Office of Sponsored Programs (OSP), and the Office of the Vice Provost for International Affairs. The Provostial Review team relies on the IRB to address human subject protection risks (e.g. risks-benefits to the participants, adequacy of consent forms, protection of privacy, etc.) and focuses its review on other risks. In general, the Provostial Review team reviews the same documents submitted to the IRB (e.g. the protocol, Informed Consents, and Questionnaires).

Therefore, the protocol should be complete and detailed, with a full explanation of the researcher's planned study design to assist with, and accelerate, both the IRB and the Provostial Review Process. The protocol should clearly describe the potential areas of risk in the planned project, and provide plans to mitigate those risks. The following provides a brief summary of the most common risks evaluated in the Provostial Review; researchers should carefully consider if their projects include any of these risks, and if so, provide details on their plans to manage those risk areas.

Note: *While the next sections will be focused on international research projects, the risks below are not limited to locations outside the U.S. Students planning projects in the United States should also consider these risks and how to mitigate them.*

1) Risk to the student

Harvard University undergraduates who wish to conduct international research must follow the Harvard College International Travel Policy (<https://www.globalsupport.harvard.edu/travel-tools/forms-policies/harvard-college>). This policy prohibits travel to high-risk regions, as defined by Harvard Global Support Services (GSS), and restricts travel to elevated-risk regions. A complete listing of GSS risk ratings can be found at <https://www.globalsupport.harvard.edu/travel-tools/risk-ratings>. Because these risk ratings are dependent on a number of factors, it is recommended that the website be consulted frequently to assess the risks in the region. When planning an international research project, undergraduate researchers should take the following steps:

- a) Check the GSS risk ratings site to determine if the region of interest is rated as high or elevated risk.

- i) If the region of interest is rated as high-risk, undergraduate researchers cannot conduct research there. The researcher must select another region for the project.
 - ii) If the region is rated as elevated-risk, the researcher should follow the steps described under “Restricted Travel” on the Harvard College International Travel Policy website. When submitting their protocol and related materials to IRB, the researcher should include their correspondence from GSS allowing them to conduct research in the region.
- b) When preparing the protocol, the researcher should describe how they plan to protect their safety while working internationally. These plans could include checking in with the local U.S. embassy, working with local universities or non-governmental organizations (NGOs) to help navigate the cultural norms, and/or arranging safe meeting places when conducting interviews with research participants.
 - c) Researchers should also provide details of their preparation for working in the area, including their fluency in the local language and any past travel or coursework that has helped them prepare for this project.

Example: A student plans to conduct a research project in a region designated as elevated-risk by GSS. In their initial protocol, the student does not include any details on their preparation for the travel; there is no mention of any local connections the student has made, no information on the familiarity of the student with the country, or how the student would choose a safe location for interviews. This lack of information raises concerns that the student has not sufficiently considered the potential risks in the region, and how they would protect themselves. The review will certainly yield a number of key questions that would, at the minimum, delay the approval of the project.

How to Fix: The protocol should provide details about the student’s efforts to prepare for this project, including discussions with GSS, contacting local NGOs, working with Harvard faculty who have experience in the region, and describing how they plan to setup a safe space for interviews. With this additional information, the Provostial Review team will be able to approve the work.

2) Reputational risks

The Provostial Review team assesses research projects not just on the subject of the research design, but also on the impact the project will have on the reputation of the participants, researchers, and the University. Generally, researchers should consider if anyone involved in the project, or the University itself, is at risk of reputational harm from the work. If there is a possibility of reputational risk, the researcher should explain why the risk is necessary, how they will mitigate that risk, and why other options for conducting the research are not feasible.

Example: A researcher’s planned project includes the use of deception to get responses from political officials, with no plans to debrief the officials before the results are published. The results of the work could attract media attention and could potentially embarrass the officials and hurt their reputation in the community.

How to Fix: The Provostial Review team would request that a debriefing email be sent to the participating officials once data collection was complete, explaining the research project and notifying them that the results would be published. Including such details would assist with expediting the review process.

3) Risk to populations involved

When conducting research in an international location, the researcher should carefully consider the cultural and social norms in the region of interest. Research conducted with marginalized populations, or projects that ask questions about socially-unacceptable or illegal behavior, could lead to negative consequences for the participants. In the research protocol, the researcher should explain how they will protect the participants, including plans to secure the data and to receive local IRB and/or community approvals in the region of interest.

Additionally, if the research will be conducted in any places of business or in educational facilities, etc., the researcher should provide a letter from the business owner or principal, etc., confirming that they have gotten permission to conduct the project on the premises.

Example: A research project includes plans to interview sex workers in Uganda. Soliciting to sell sex is illegal in Uganda, so the participants could face risks associated with their participation.

How to Fix: In the protocol, the Principal Investigator (PI) should note if past research work has been conducted among sex workers in Uganda, and provide plans to get approval from the local IRB and from community leaders in the area to conduct the research. A data security plan should also be provided, to ensure the participants' responses remain confidential.

4) Aligned with the mission of the University

Research conducted through Harvard University must fall within Harvard's mission as a research university. Harvard University does not engage in advocacy, and while individual Harvard researchers may well be advocates for various causes, including those informed by their research, the aim of an academic research project must be to answer a research question objectively. Objectivity is lost if the aim of a research project is to produce a particular result or achieve a pre-determined policy outcome.

Example: A project is proposed to provide a voice for homeless youth in San Francisco, with a stated goal of getting a youth homeless shelter funded based on the results of the project. This proposed project doesn't include a research question, a systematic investigation, or a plan to contribute to the body of research, but instead is planned solely to advocate for the population of interest.

How to Fix: The researcher could propose a project that examines the age distribution among the homeless population in San Francisco, with plans to interview homeless youth in the city. The results would be published in academic journals or presented at conferences. This project may lead to greater attention paid to the plight of homeless youth, but it is not the primary goal of the work.

5) Is it research?

Harvard University researchers receive funding and support from a variety of sources, both within and outside the University. Sometimes, researchers at Harvard are offered funding to complete a project on behalf of a government entity, NGO, or corporation. In those cases, the researcher must consider if the project is still research, or if they are working as consultants, providing services to the organization or government providing the funding. If the Provostial Review team determines that the proposal is for a consulting project, then the researcher will need to redraft their protocol to fit within the research mission of Harvard University. For more information, please see the Harvard University policy on consulting or related service agreements:

<http://osp.finance.harvard.edu/consulting-or-related-service-agreements>.

Example: A researcher at the Kennedy School of Government is provided funding by a foreign government to implement a new healthcare policy, with plans to provide a report back to the government funders on the success of the implementation.

How to Fix: The researcher could plan to systematically collect data regarding the implementation of the new policy and publish the results of that work in an academic journal. The results of this project could inform future work on how to best implement healthcare policies in the region of interest.

Resources:

- Office of the Vice Provost for Research (OVPR): <http://vpr.harvard.edu/>
 - Provost Review Criteria: <http://vpr.harvard.edu/pages/provost-criteria-review>

- OVPR Contact Information: <http://vpr.harvard.edu/people>
- Global Support Services (GSS): <https://www.globalsupport.harvard.edu/>
 - GSS Risk Ratings: <https://www.globalsupport.harvard.edu/travel-tools/risk-ratings>
 - Harvard College International Travel Policy: <https://www.globalsupport.harvard.edu/travel-tools/forms-policies/harvard-college>

Appendix VII

Useful Resources

Harvard University CUHS IRB

<http://cuhs.harvard.edu>

ESTR (Electronic Submission, Tracking, and Reporting) Support website

<http://estrsupport.fss.harvard.edu/>

Harvard Office for the Vice Provost of Research

<http://vpr.harvard.edu/>

Federal

Department of Health and Human Services (HHS) <http://www.hhs.gov>

Centers for Disease Control and Prevention (CDC) <http://www.cdc.gov>

Human Participant Protection in CDC Research <http://www.cdc.gov/od/science/regs/hrpp/>

National Institutes of Health (NIH) <http://grants.nih.gov/grants/policy/hs/index.htm>

Certificate of Confidentiality Kiosk <http://grants.nih.gov/grants/policy/coc/>

Office of Civil Rights (HIPAA policy) <http://www.hhs.gov/ocr/privacy/index.html>

Office of Human Research Protection (OHRP) <http://www.hhs.gov/ohrp/>

- Regulations <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- Decision Charts <http://www.hhs.gov/ohrp/policy/index.html#decision>
- Guidance and Policy <http://www.hhs.gov/ohrp/policy/>
- FAQs <http://www.hhs.gov/ohrp/faq.html>
- International Research Policies <http://www.hhs.gov/ohrp/international/index.html#NatIPol>

Food and Drug Administration (FDA) <http://www.fda.gov/>

Department of Education <http://www.ed.gov/>

- Human Subjects Research <http://www.ed.gov/about/offices/list/ocfo/humansub.html>
- Family Policy and Compliance Office (FERPA and PPRA)
<http://www.ed.gov/policy/gen/guid/fpco/index.html>

National Science Foundation <http://www.nsf.gov>

- FAQs on Interpreting the Common Rule for the Protection of Human Subjects for Social and Behavioral Research <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>

National Science and Technology Council Report on Expedited Review of Social and Behavioral Research Activities <http://www.ostp.gov/galleries/NSTC%20Reports/Expedited%20Review%20For%20Web.pdf>

Discipline-Specific Resources

American Anthropological Association (AAA) <http://www.aaanet.org>

American Educational Research Association (AERA) <http://www.aera.org>

American Psychological Association (APA) <http://www.apa.org>

American Public Health Association (APHA) <http://www.apha.org>

American Sociological Association (ASA) <http://www.asanet.org>

National Association of Social Workers <http://www.naswd.org/code.htm>