

Introduction to Human
Subjects Research
Protection:
A Guide for Student
Investigators

Acknowledgement

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Introduction to Human Subjects Research Protection for Student Investigators

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 investigator's academic discipline. This guide is designed to help student investigators 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 Institutional Review Board, the Committee on the Use of Human Subjects (CUHS).

Key Resources

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

Harvard University

- **Committee on the Use of Human Subjects**

1414 Massachusetts Ave,
2nd floor
Cambridge, MA 02138
Phone: 617- 496-2847
Email:

cuhs@fas.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.

- **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 investigators 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. The requirement may be satisfied by attending an undergraduate training session or by obtaining CITI or NIH certification online. 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 must receive appropriate review and approval.

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), also known as the “Common Rule.” See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>. These regulations codify the key ethical principles found in the Belmont Report. See <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>. 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=56>.
- 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 investigators 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 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 3). Student investigators and their faculty advisors 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. The CUHS staff can assist investigators with making project-specific determinations concerning the need for IRB approval.

What is the Committee on the Use of Human Subjects (CUHS)?

The Board

The CUHS serves as the IRB for research conducted by investigators from the Cambridge and Allston campuses, including the Faculty of Arts and Sciences.

FAS comprises [Harvard College](#) and the [Graduate School of Arts and Sciences](#), including undergraduate and graduate admissions; the [School of Engineering and Applied Sciences](#); and the [Division of Continuing Education](#), including the Extension and Summer Schools.

The CUHS IRB is lead by a Chair appointed by the Faculty of Arts and Sciences. The CUHS IRB meets once per month.

The CUHS IRB Office

The CUHS IRB is supported by the CUHS 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 CUHS IRB administrative staff. The IRB staff manages the application workflow and communications between the investigator 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 CUHS 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 at drop-in hours, an IRB program offering office hours once per week; and
- responses to researcher, community, and research participant questions and concerns.

Chapter 2 - Student/Faculty Responsibilities in Human Subjects Research

Students as PIs

At Harvard University, students may serve as principal investigators for their own research projects and are responsible for submitting the IRB application. **All research proposals from undergraduates, graduate students and post-doctoral fellows must include a faculty advisor as a member of the study team.** The IRB reviews and holds student research projects to the same standards as human subjects research conducted by faculty or staff. IRB approval or exemption must be obtained prior to initiating *any* research activity under IRB oversight. “Retroactive” IRB approval or exemption is not permitted under federal regulations and University policy. Failure to obtain IRB approval for research with human subjects may preclude the use of the previously collected data and could result in other institutional sanctions.

What are the responsibilities of the student investigator?

The student investigator, under the guidance of the faculty advisor, serves as the principal investigator for their research project and has primary responsibility for ethical conduct of the research. The student investigator is responsible for preparing the IRB application and for ensuring that the study adheres to relevant policies and regulations (institutional, state, federal and international – where applicable). Under the mentorship of the faculty advisor, the student investigator must:

- be familiar with the ethical and regulatory requirements for human subjects research and must complete required ethics training;
- submit an accurate and complete application to the IRB, allowing adequate time for review;
- obtain IRB approval prior to the initiation of research (including subject recruitment);
- conduct the research in accordance with the approved protocol;
- inform the IRB of all changes or additions to the previously approved study protocol;
- submit scheduled continuing review applications to the IRB, if required;
- manage research data carefully to ensure subject confidentiality;
- consult with the faculty advisor when problems are encountered; and
- report all unanticipated problems or serious adverse events involving risk to human subjects to the IRB as soon as possible.

What are the responsibilities of the faculty advisor?

The faculty advisor is an active mentor to the student researcher and shares the responsibility for the ethical conduct of the research with the student. The advisor is expected to discuss the general principles of research ethics prior to the initiation of any project involving human subjects, help students determine whether their project requires IRB review, and guide students through the IRB application process and also support the student in the conduct of the research after the project has attained IRB approval, if IRB approval is necessary.

All research proposals from undergraduates, graduate students and post-doctoral fellows must include a faculty advisor as a member of the study team whether or not IRB review and approval is required. More information about PI eligibility may be found here: <http://research.fas.harvard.edu/policies/principal-investigator-eligibility>

Faculty advisors must:

- be familiar with the ethical and regulatory requirements for human subjects research and must complete required ethics training;
- discuss research ethics with students, including the professional ethics of the discipline;
- help assess whether projects require IRB review and assist students with the IRB application process (if necessary), including timely submission of the application;

- assist students with designing a research project appropriate to the student's training and experience (**Note: Under Harvard University policy, research conducted by undergraduate investigators must be limited to projects that pose no more than minimal risk to human subjects**);
- instruct students on the use of good data security practices;
- counsel students conducting research in international settings on the importance of understanding local customs and regulations for subject and student safety and assist the student with establishing local relationships or local sponsorship for their research;
- monitor student projects, paying special attention to maintaining confidentiality, privacy, level of risk, informed consent process and voluntary participation and withdrawal of subjects;
- assure that the student reports unanticipated problems or serious adverse events to the IRB if their project has IRB approval; and
- assist students with issues regarding data ownership, publication authorship and other research conduct problems.

Chapter 3 – How do I know if I am conducting human subjects research?

Research projects meeting the regulatory definition of research with human subjects require either 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 first question that must be considered is whether a project fits the regulatory definition of *research*, and if so, whether it also involves *human subjects*.

Is it research?

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

- 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 activities** – 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. When the primary focus and initial intent of the class activities are designed to collect data to be used by students beyond the classroom, for example for scholarly publication or use for future research, it is the responsibility of the faculty advisor to assist students in determining whether obtaining IRB approval or exemption is required and if so, that this is done prior to the initiation of a human subjects research project.

****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. Contact the IRB for assistance with determining whether your internship activities require IRB oversight.

Does my project involve human subjects?

The federal regulations define a *human subject* as “a **living individual about whom** an investigator conducting research obtains (1) **data through intervention or interaction** with the individual or (2) **identifiable private information**” ([45 CFR 46.102\(f\)\(1\)\(2\)](#)).

- **“Living individual”** refers to data (information or specimens) collected from living subjects. For example, research using data from the 1980 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, 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 investigator 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 investigator 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’m not sure if my project involves research with human subjects?

The IRB staff can help you determine if your project involves research with 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?

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” according to the federal regulations determination or will advise the investigator that the project does involve human subjects research and will recommend the submission of an exempt or standard application type via ESTR.

Chapter 4 - 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.

Points to Consider

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
 - a. Consider how participants will be approached and recruited (e.g., posted flyer; script read by a researcher in person; email invitation; phone call, etc.)
 - b. 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 (*NOTE: Be sure to seek advice from your faculty advisor or the CUHS office before trying to recruit vulnerable participants.*)
 - a. 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).
 - b. CUHS strongly recommends that an undergraduate researcher doing an independent project should not enroll prisoners, pregnant women, or cognitively impaired individuals as target populations.
 - c. 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. Undergraduates planning research with the following potentially vulnerable populations should first set up a discussion with their faculty advisor and an advisor familiar with CUHS procedures and requirements.
- iii. Adults living in potentially coercive conditions – e.g., nursing home residents, half-way house residents.
- iv. 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

- a. 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? Recordings should be destroyed once no longer needed. If you wish to have the option to use recordings in the future you should tell participants this and obtain their consent.
- b. Consider whether the study will involve either active deception or incomplete disclosure that is likely to significantly mislead participants.
- c. 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?
- d. 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?
- e. An undergraduate researcher should not undertake an independent project involving human participants that includes deception or incomplete disclosure that is likely to be upsetting or in some other way harmful to the participants.

Please refer to Chapter 8: Special Considerations for more information on deception and incomplete disclosure.

5. Informed Consent

- a. Participation in research must always be informed and voluntary (not coerced or unduly influenced). These conditions are met through a consent process.
- b. 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

- a. 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

- a. 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.
- b. 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.).
- c. Responsible research requires that risks be minimized, be reasonable in relation to any benefits that might occur, and be clearly communicated to research participants.
- d. Undergraduate 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, and therefore if it were a research activity, 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 5 – 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 six 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 six exempt categories listed in the federal regulations (45 CFR 46.101(b)). Exemptions are not 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 an ESTR standard IRB application. A designated CUHS 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 approval for exempt projects does 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 CUHS IRB staff. Expedited review is conducted on a rolling basis and is not subject to submission deadlines. The CUHS IRB uses the expedited review procedure for most of the research subject to its oversight.

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 III, 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 IV, 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 investigator 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 III 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 in the research before approval, or refer the submission to the full board for further review. (See Appendix V for a description of the types of determinations that the reviewer may issue for a proposal.)

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

Full Board 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 will 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.

According to Harvard University policy, undergraduate researchers may not conduct research that poses greater than minimal risk to the subjects.

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 investigator 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 CUHS IRB. A primary IRB reviewer and a secondary reviewer (for new applications) 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 investigator 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 investigators 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 V for a description of the types of determinations the IRB may issue for a study.

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

Chapter 6 – 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

Regulations identify the following required elements of informed consent. See 45 CFR 46.116 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#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.

Other optional elements **as appropriate** to the research project 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.

For projects involving *research with children*, investigators **must** obtain both the consent (permission) of one or both of the 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).

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. See 45 CFR 46.117 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117>).

Regulations allow for some exceptions to the requirement for documented (signed) informed consent and may allow for waiving informed consent.

Waiver of Documentation of Informed Consent

According to 45 CFR 46.117, an IRB may waive the requirement for the investigator 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.

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 impractical. 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;
- 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 8 – Special Considerations for more information).

Chapter 7 - Investigator Responsibilities after IRB Approval

Approval of a research project by the IRB does not end an investigator'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. All non-exempt human subjects research projects continuing to interact with subjects or analyzing identifiable data must be re-reviewed by the IRB prior to the expiration of the approval period, as determined by the IRB. For projects that involve more than minimal risk or for some other special consideration, the IRB may require a more frequent review. Finally, investigators 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 research project. IRB review and approval is required before investigators 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. Contact the IRB staff if you have questions.

Scheduled Continuing Review

The IRB conducts continuing review of research studies continuing to involve human subjects according to the approval period issued. The continuing review application must be submitted at least 4-6 weeks before the end of your approval period. Investigators will receive ESTR reminders prior to the expiration of the study approval. Also, IRB approval must be renewed as long as the investigator 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, such as a lapse in IRB approval, a significant subject complaint, a deviation from the approved research protocol, or a data security breach such as the theft of a laptop. A 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 investigator wishes to enroll new subjects for the study, or otherwise engage human subjects in research after the study is closed, a new ESTR application must be submitted. Therefore, an investigator should only close a study when he/she is 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 8 - 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 insure 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 Common 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 investigator’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 investigator 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 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, as well as in colleges and universities, receiving 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 investigator that has been coded for your use, your project may not require IRB oversight. *Coded* means that identifying information that would enable the investigator 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 investigator 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>.

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. Because people act differently depending on circumstances, 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 of 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**

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 must have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected.

Please know that 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 both 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**

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. More information can be found at: <http://www.nihtraining.com/ohsr/site/guidelines/nuremberg.html>.

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 was revised in 1975, 1983, 1989, and 1996 and is the basis for Good Clinical Practices 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.

More information can be found at: <http://ohsr.od.nih.gov/guidelines/helsinki.html>.

The Belmont Report

In 1979, 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: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

Regulatory Framework Governing Human Subjects Research

Federal Regulations

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 (Common Rule) (45 C.F.R. 46)**
 In 1981, the Department of Health and Human Services codified the Policy for the Protection of Human Subject (45 C.F.R. 45). These regulations, called the “Common Rule,” provide for the basic foundation of the Institutional Review Boards. This federal policy has been adopted by the 18 federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title “Common Rule.” The Policy also provides specific protections to vulnerable populations such as pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D) involved in human subjects research. More information can be found at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>.
- U.S. Food and Drug Administration Regulations**
 The U.S. Food and Drug Administration, under the Department of Health and Human Services, also provide guidance for Institutional Review Boards. FDA regulations differ from the Common 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 “Privacy Rule (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 – Categories of Exempt Research

EXEMPTION #1 (45 CFR 46.101(b)(1)): Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

EXEMPTION #2 (45 CFR 46.101(b)(2)): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. **[Note: The use of Exemption #2 for research with children is limited to use of educational tests or public observation where the researcher does not interact with the children in any way.]**

EXEMPTION #3 (45 CFR 46.101(b)(3)): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

EXEMPTION #4 (45 CFR 46.101(b)(4)): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

EXEMPTION #5 (45 CFR 46.101(b)(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 (45 CFR 46.101(b)(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.

Appendix III - Regulatory Elements of IRB Review

When the IRB reviews a 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.

Regulatory Elements of IRB Review

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 investigators 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 the Code of Federal Regulations: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). See Chapter 6 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.

- **Waiver of Documentation of Informed Consent**

The IRB can waive the requirement for signed consent, referred to as documentation of informed consent, under two circumstances: 1) when the only link between a participant and the research is the consent form and the principal risk is potential harm resulting from a breach of confidentiality; or 2) the research presents not more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

The first waiver is often recommended by the IRB for sensitive projects where simply linking a participant to a research study might place a participant at risk (e.g., a study of domestic violence). The second waiver is routinely given for telephone or Internet surveys. The investigator is still obligated to offer the elements of informed consent to participants when a waiver of documentation is granted for either reason. This can be accomplished via an oral script or a written consent document.

- **Waiver of Informed Consent**

The IRB can also grant a waiver of elements of informed consent, or the entire informed consent process, in certain situations where the consent process might be culturally inappropriate, not possible given the nature of the research (impracticable), or where a full consent process might have an negative impact on the outcome of the research (deception studies). Where a waiver of informed consent is granted, the IRB must find that: 1) the research involves no more than minimal risk to the subjects; 2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably be carried out without the waiver or alteration; 4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation (such as debriefing document).

6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects

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 investigator 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 investigator 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 investigator obtain a Certificate of Confidentiality (CoC) from the National Institutes of Health. A CoC protects the

investigator 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. 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:

- **Pregnant women, fetuses, and neonates** are considered vulnerable because they 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>)
- **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.
- **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 IV – 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 V – IRB Determinations

After completing its review of an application, the IRB will notify investigators 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 investigator. The investigator 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 CUHS IRB full board may vote to defer action on an application when a significant action on the part of the investigator 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 investigator 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 CUHS 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 investigator, 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 investigator will be sent a rationale for the disapproval and may ask that the IRB reconsider the disapproval.

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 investigator 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 investigator 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>