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There is pending regulatory change that will take effect on 19 July 2018. This module will be updated in July 2018 to reflect that change, unless there is a change to the implementation date of the regulation. You may also review the [CITI Program's Final Rule Resources](#) for information on the changes to the Common Rule. The CITI Program's Final Rule Resources will be updated accordingly throughout the year.

STUDENTS IN RESEARCH

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INTRODUCTION

This module is designed as a "one-stop shop" for students who may be involved in human subjects research as an investigator and/or a subject. It is intended for research studies that qualify as no greater than "minimal risk."

Degree requirements in undergraduate, master's, or doctoral programs often require students to conduct or assist in research projects that include human subjects. These projects, which provide students with an opportunity to learn various research techniques appropriate to their disciplines, must follow ethical principles and guidelines set forth in the federal regulations and institutional

policies for protecting human subjects. This module provides student investigators and student research assistants with a brief overview of the research regulations, the Institutional Review Board (IRB) review process, and ethical considerations in research involving human subjects.

In addition, students may be asked or "required" to participate as subjects in research projects. This module describes what students can expect when participating as research subjects, and describes their rights as research subjects.

Student researchers and student research subjects can benefit from the other Resources for Students section.

Learning Objectives

By the end of this module, you should be able to:

- Describe the historical development of regulations associated with the protection of human subjects
- Identify the required elements of informed consent
- Describe the different categories of exempt research
- Determine when research requires IRB review



HISTORY OF THE ETHICAL REGULATIONS

The history of the ethical regulations in human subjects research began in the 1940s with the Nuremberg Code. Since then, the U.S.

federal government has increased the awareness to protect the rights and welfare of human subjects by establishing regulatory codes and regulations. This section serves to provide a brief background on the history of the ethical regulations when human subjects are involved in research projects.

WHAT IS 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 to consent, freedom from coercion, no penalty for withdrawal, and comprehension of the risks and benefits involved.



WHAT IS THE DECLARATION OF HELSINKI?

In 1964, the World Medical Association established recommendations guiding 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 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
- Risks should not exceed benefits

WHAT IS THE FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS? (COMMON RULE)

In 1981, the Department of Health and Human Services (HHS) codified the Policy for the Protection of Human Subjects (45 CFR 46). Subpart A of these regulations, is also called the "Common Rule," provides for the basic foundation of the Institutional Review Boards. This Federal Policy has been codified by the federal agencies that conduct, support, or otherwise regulate human subjects research, hence the title "Common Rule." Additional subparts of 45 CFR 46 provide 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. Many federal agencies and departments have not adopted subparts B, C, and D. Therefore only Subpart A is known as the "Common Rule."

WHAT IS THE BELMONT REPORT?

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

RESPECT FOR PERSONS

"Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy." This states that the person must be capable of making an informed decision on whether or not to participate in a human subjects research project.

BENEFICENCE

"Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being." Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict

obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense:

1. Do not harm and
2. Maximize possible benefits and minimize possible harms.

JUSTICE

"Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of considering the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what aspects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis for which burdens and benefits should be distributed. These formulations are:



1. To each person an equal share.
2. To each person according to individual need.
3. To each person according to individual effort.
4. To each person according to societal contribution.
5. And to each person according to merit.

STUDENTS AS RESEARCHERS

When participating in or conducting human subjects research, student investigators and student research assistants must adhere to the guidelines and principles set forth by the U.S. federal regulations and institutional policies and procedures. This section of the module provides an overview of the information a student must know prior to conducting a research project.

WHAT IS AN IRB?

The IRB is an independent committee comprised of at least five members from relevant academic disciplines or experiences. At least one member must be not affiliated with the institution. The IRB must be diverse and must include at least one member whose primary concern is in a scientific area and one who is not a scientist. The members may include faculty, staff, students, as well as members from the local community. The IRB functions as a type of "human subjects advocate" whose role is to protect subjects participating in research. The IRB committee reviews research projects submitted by researchers (students, faculty, or staff). The

committee has the authority to approve, require changes to the study procedures, or disapprove proposed research projects. Officials at an institution may disapprove an IRB approved project but cannot approve a project that has been disapproved, suspended, or terminated by the IRB.

IRB members must have the necessary experience and expertise to evaluate proposed research projects. IRBs must be diverse in terms of race, gender, cultural backgrounds, and include members from the community.

The IRB is charged with reviewing all projects involving human subjects for compliance with institutional policies and state, local, and federal laws, as well as the ethical principles contained in the [*Belmont Report*](#) (that is, respect for persons, beneficence, and justice).

The IRB is part of a bigger system, the Human Research Protection Program (HRPP), in charge of the protection of research subjects. The HRPP may include the Office for the Protection of Research Subjects, the Office of Compliance, the Office of Contracts and Grants, and other Institutional officials and committees (for example, a community outreach program).

IRB APPROVAL REQUIRED

The IRB is charged with the responsibility of reviewing and overseeing human subjects research. The IRB review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, assuring adequate informed

consent, assessing and minimizing risks, and maintaining privacy and confidentiality. Human subjects research projects cannot be conducted without the approval of the IRB, or exemption by the individual or group identified by the organization or the IRB.

IRB approval is valid for one year or for a shorter interval determined by the IRB based on risks involved. If the research continues beyond a year, a continuing review application must be submitted to extend approval for the next year.

Note that certain projects may be required to be reviewed more frequently based on the risk involved in the study.

TYPES OF IRB REVIEW

Research projects are reviewed at three different levels: **exempt, expedited, and full board**. Minimal risk projects generally fall under the review categories of exempt or expedited review. For studies that are deemed more than minimal risk, a full/convened board review is required. An explanation of each type of review is found below. Student investigators should consult with the IRB/faculty advisor if they are unsure of which review applies to their study.

- **Exempt Review** - Exempt research is research with human subjects that generally involves no more than minimal risk. However, it is "exempt" from the provisions stated in 45 CFR 46, Subpart A (Common Rule). An exempt research project does not require ongoing review by the IRB, unless the project is amended in such a way that it no longer meets the exemption

criteria. However, institutional policy may have different requirements for obtaining consent as well as continuing review of exempted protocols. Student investigators should consult with their IRB regarding these matters. The IRB is required to determine if a research project falls under one of the following six exempt categories listed in the federal regulations (45 CFR 46.101(b)):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - a. Research on regular and special education instructional strategies.
 - b. Research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures (of adults), interview procedures (of adults) or observation of public behavior, unless:
 - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects. AND
 - b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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 (2) if:
 - a. The human subjects are elected or appointed public officials or candidates for public office.
 - b. Or the research is conducted for the Department of Justice under Federal statute 42 U.S.C. 3789g, or for the National Center for Education Statistics under Federal statute 20 U.S.C. 12213-1, which provide certain legal protections and requirements for confidentiality.
4. Research involving the collection or study of existing data, documents, records, pathological 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.
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:
 - a. Public benefit or service programs.
 - b. Procedures for obtaining benefits or services under those programs.
 - c. Possible changes in or alternatives to those programs or procedures. OR
 - d. Possible changes in methods or levels of payment for

benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if
 - a. Wholesome foods without additives are consumed or
 - b. 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 U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

- **Expedited Review** - If the research presents no more than minimal risk, the IRB may determine it qualifies for an expedited review. The expedited review covers the same elements as a full/convened committee review but can be conducted by the IRB chair or a designated experienced reviewer rather than the whole convened committee. There are nine expedited categories in the federal regulations (45 CFR 46.110):

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.
 - b. Research on medical devices for which
 - i. An investigational device exemption application (21 CFR

812) is not required.

- ii. Or, 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.
 - b. Or 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.
 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).

5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research 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)(4). This listing refers only to research that is not exempt.)

* Note: The following apply to the continuing review of research:

1. 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.
 - iii. And the research remains active only for long-term follow-up of subjects.
 - b. Or where no subjects have been enrolled and no additional risks have been identified.
 - c. Or where the remaining research activities are limited to data analysis.
2. 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.
- **Full Board (Convened) Review** - Studies that involve more than minimal risk require full board review at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present. While federal regulations do not specifically list categories that would fall under full board review, below are certain criteria that may require a study to have full board review:
1. Studies using vulnerable populations

2. Studies taking place internationally (particularly those with little or no provisions for protection of human subjects)
3. Studies where information may be disclosed that could require mandatory legal reporting (e.g., child/elder abuse, drugs, etc.)
4. Studies involving deception which raises the risk level of the subjects
5. Studies that fall under the jurisdiction of the Food and Drug Administration

Student research projects are generally reviewed the same as any other human subjects research conducted by faculty or staff. Student investigators, after consultation with their faculty advisor, who are planning on conducting a research project involving human subjects must obtain approval from their IRB. IRB approval must be given prior to any research activity/study procedures. There is no retroactive approval for data previously collected for the current study. **Failure to seek approval for thesis or dissertation research may invalidate the study and/or result in a delayed graduation.**

WHAT IS HUMAN SUBJECTS RESEARCH?

The IRB has been charged, by the federal regulations, with the responsibility of reviewing and monitoring *human subjects research*. Therefore, the first question with respect to IRB review of a project is a determination of whether the project fits the definition of human subjects research. In support of the Institution's mission to protect human subjects who are involved in research and the potential regulatory consequences of not obtaining IRB review and

approval, the student investigator should choose to err on the side of caution and consult the IRB when he/she is uncertain whether the study is human subjects research.

■ ASK, "IS IT RESEARCH?"

Federal regulations define **research** as "**a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge**" (45CFR46.102(d)). As described in the *Belmont Report* "...the term 'research' designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective."

"Research" generally does **not** include operational activities such as practice activities in medicine, psychology, social work, and public health (for example, routine outbreak investigations and disease monitoring) and studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies, or contracted-for services. It generally does not include journalism or political polls. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge.

■ ASK, "DOES IT INVOLVE HUMAN SUBJECTS?"

A **human subject** is defined by federal regulations as "**a living individual *ABOUT* whom an investigator (whether professional**

or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." (45 CFR 46.102(f)(1),(2))

Living individual - The specimen(s)/data/information must be collected from live subjects. Cadavers, autopsy specimens or specimens/information from subjects now deceased are not human subjects.

"About whom" - a human subject research project requires that the data received from the living individual is **about** the person.

Intervention includes physical/psychological procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes.

Interaction includes communication between the investigator and the subject. This includes face-to-face, mail, and phone interaction as well as any other mode of communication.

Identifiable private information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," (such as a public restroom) "and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record)" (45 CFR 46.102(f)(2)). **"Identifiable" means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual (ex: Social Security #).** Student

investigators should consult the IRB if they are unsure about certain issues such as identifiable cadaver materials needing review or certain state laws regarding human subjects.

Observational studies of public behavior (including television and public Internet chat rooms) do not involve human subjects as defined when there is no intervention or interaction with the subjects and the behavior is not private. Also, studies based on data collected for non-research purposes may not constitute human subjects research if individual identities are not available (for example, programmatic data such as service statistics, school attendance data, crime statistics, or election returns).

Studies based on data that are individually identifiable but are also publicly available may not constitute human subjects research. However, the term "publicly available" is intended to refer to record sets that are truly readily available to the broad public, such as census data. An investigator should not assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.

What follows are examples of types of studies that qualify as not human subjects research and those that are human subjects research. Student investigators may use this as guidance on whether a project is submitted as human subjects research or may receive the not human subjects determination. However, it is recommended that the student consult with the IRB and/or the faculty advisor on this matter.

STUDIES THAT ARE NOT HUMAN SUBJECTS RESEARCH:

- **Data collection** for internal departmental, school, or other institutional administrative purposes is not human subjects research. Examples: teaching evaluations, customer service surveys
- **Information-gathering interviews** where questions focus on things, products, or policies rather than about people or their thoughts regarding themselves are not human subjects research. Example: canvassing librarians about inter-library loan policies or rising journal costs
- **Course-related activities** designed specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment, but are **not** intended for use outside of the classroom may not be human subjects research. Students are advised to contact their local IRB as certain course-related activities may require IRB review. Example: instruction on research methods and techniques. *Note: The IRB is only required to review studies that meet the Federal definitions of engagement*, research, and human subject*
- **Biography or oral history** research involving a living individual that is not generalizable beyond that individual may not be considered human subjects research. Researchers are advised to contact their local IRB as these studies may be subject to local interpretation.
- **Research involving cadavers**, autopsy material or bio-specimens from deceased individuals is not human subjects research. *Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the IRB for further information*

- **Case histories** which are published and/or presented at national or regional meetings are often **not** considered research if the case is limited to a description of the clinical features and/or outcome of a single patient and do not contribute to generalizable knowledge. However, researchers are advised to contact their local IRB as these studies may be subject to local interpretation.
- **Publicly available data** do **not** require IRB review. Examples: census data, labor statistics. *Note: Investigators should contact the IRB if they are unsure if their data qualifies as "publicly available."*
- **Coded specimens and/or data sets** that were **not** collected for the currently proposed projects do not need IRB review as long as the investigator receiving the data/specimens cannot link the data/specimens back to individual subjects. If the data/specimen provider can ascertain the identity of the subjects (for example, subjects' names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. *Note: Investigators are not allowed to make this determination. These [projects](#) require verification from the IRB or the IRB liaison/designee.*
- **Non-Engagement* in Research** occurs when an institution's employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information, perform commercial services for the investigators, or inform prospective subjects about the availability of research. *Note: the examples above are not an all inclusive listing. Please see the following [website](#) for further information.*

* An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.

STUDIES THAT ARE HUMAN SUBJECTS RESEARCH:

- Studies that involve human subjects to test or develop devices, products, or materials that have been developed through research for human use.
- Studies that collect data through intervention or interaction with individuals. Examples of this type of research include the evaluation of teaching methods and programs, Internet surveys about alcohol consumption, studies that involve deception, research involving risky behaviors or attitudes, and open-ended interviews with minors about family values in a foreign country that contribute to generalizable knowledge. Data collection using non-identifiable information may be exempt. (Students are advised to discuss with the applicable IRB the process for determining exemptions.)
- Studies using private information that can be readily identified with individuals, even if the information was not collected specifically for the study in question.
- Studies that use bodily materials such as cells, blood, urine, tissues, organs, hair, or nail clippings, even if these were not collected for research purposes. However, such research may be considered exempt or Not Human Subjects Research if the



materials/data are coded and the investigator does not have access to the coding systems.

- Studies that intend to produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
- Studies that involve retrospective analysis of existing individually-identifiable private information.
- Studies that use human beings to evaluate environmental alterations, for example, weatherization options or habitat modifications

Research belonging to any of the above categories must comply with the Federal Regulations and the Institution's policies for the protection of human subjects.

*Please visit the [Office for Human Research Protections \(OHRP\) website](#) for the code of federal regulations.

WHAT ARE THE STEPS IN THE IRB PROCESS?

To obtain an IRB approval for a study, most student researchers have certain steps to follow:

1. *Student research preparation:*

The IRB application is completed under the guidance of the student's faculty advisor. The student's advisor is responsible for guiding the student investigator in the development of the research plan as well as the conduct of the research project. The

faculty advisor/committee will refine the project and once it is approved by the committee, they should indicate the expected level of review (exempt, expedited, or full board review). (Please note that the final determination of review category will be made by the IRB.) The advisor also assists students in a design to maximize the benefits and minimize the risks involved in the research, and assure the ethical conduct of the project. The Institution's IRB staff is also available to aid student applicants.

2. ***Departmental/Faculty review and approval:***

Depending on the Institution's policy, the department chair/faculty advisor must review and sign off on the application before it is submitted to the IRB for review. This signoff may address issues of scientific merit, availability of resources, institutional policies, or other issues at the department level.

3. ***Application submitted to IRB for review:***

The IRB staff may conduct the initial screening of an application to assist in the future review either for exemption or for further levels of review. The IRB grants the final approval. In some institutions, a designated reviewer/department or school may conduct a pre-review of the application before it is submitted to the IRB for review. If a study is exempt or does not qualify as human subjects research, a designee may determine this and no further approval is required. (The IRB/designee may provide a letter stating that the study qualified as exempt or as not human subject research.)

4. ***IRB review outcomes:***

The IRB will notify the researcher with one of the following

once the application has been reviewed:

- Approval - the application is complete, the risks to subjects are minimal/minimized, and the procedures are appropriate. The IRB gives approval for the research to be conducted.
- Approval with Contingencies/Stipulations - the application is complete but there are issues/changes that must be addressed before the project can begin. Once a satisfactory response to these contingencies is received and approved by the IRB, the review is complete.
- Deferred - applications that are found to have deficiencies (risk to subjects, unclear procedures, serious omissions, ethical issues, or major contingencies) will be deferred. The researcher is sent a memorandum listing the concerns that must be addressed for approval to proceed. The researcher's response is reviewed by the IRB and will be approved or deferred until all issues are addressed satisfactorily.
- Non-Approval - Applications that are found to have risks that outweigh the potential benefits to subjects and/or society will receive a non-approval and the research will not be allowed to be conducted. Institutional administrative officials may not override this decision.

5. ***Conduct of research and reporting:***

Once the application is approved, the researcher may begin recruiting subjects and conducting study procedures. However, the researcher must let the IRB know if any of the following occurs:

- Modifications and Amendments to the approved protocol

(changes to the original submitted study must be reviewed and approved by the IRB before they are implemented)

- Adverse Events/Effects and Unanticipated Problems involving risks to subjects or others (the IRB must be notified immediately if any undue harms result from the study)
- Complaints Regarding Human Subjects Research (the IRB must be notified immediately if any complaints, either from the subjects or the study staff, are made regarding the research study)
- Breach of Confidentiality (If any personal/confidential data has been inappropriately disclosed by any member of the study staff, the IRB must be notified immediately)

6. ***Status Report (Renewal or Closeout):***

Prior to the expiration of a study, the IRB will require submission of a status report to assess the study's progress or a final report when the study is completed. Either the student or the faculty advisor may submit the final report.

WHAT ARE SOME "OTHER CONSIDERATIONS" IN THE IRB SUBMISSION?

Student investigators need to be aware of some "other considerations" with regard to their human subjects research. Many of these terms will be useful to know when completing the IRB application as well as during the research process.

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.

If a student investigator intends to use or release to others (e.g., sponsors, other investigators, collaborators) any identifiable health information in connection with their research, he/she must indicate that in the IRB application.

- Protected health information (PHI) is health information transmitted or maintained in any form or medium that includes ALL of the three following characteristics:
 - identifies or could be used to identify an individual; and
 - is created or received by a healthcare provider, health plan, or healthcare clearinghouse; and
 - relates to the past, present, or future physical or mental health or condition of an individual; the provision of healthcare to an individual; or the past, present, or future payment for the provision of healthcare to an individual.
 - Examples include: name, social security number, telephone number, etc

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>

INFORMED CONSENT

Informed consent is the process of informing potential subjects about the key facts 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 may be required. (*See the [Code of Federal Regulations](#)). Students are advised to discuss research that may include such populations, as institution specific requirements may also exist. The IRB office as well as dissertation chairs or advisers may be helpful in providing information.

Consent documents must be clearly written and understandable to subjects. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine).

Scientific, technical, and medical terms must be plainly defined.

Depending on the study population, it is often recommended that the informed consent be written at the sixth to eighth grade reading level. Assent forms for minors and study recruitment materials must reflect the reading level of the minors. *The informed consent must be translated into the primary language of the subject if he/she is not fluent in English.

What elements should be included in an informed consent?

For human subjects to participate in a research study, they need to have enough information to give a truly voluntary informed consent. Information subjects must be given include:

- *Purpose* of the research
- *Procedures* involved in the research
- *Alternatives* available should a subject decide not to participate in the research
- *All foreseeable risks and discomforts* to the subject. *Note that these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- *Benefits* of the research to society and possibly to the individual human subject
- *Length of time* the subject is expected to participate
- *Payment* for participation (if applicable)
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency
- Statement that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive
- Subjects' *right to confidentiality and right to withdraw* from the study at any time without any consequences

There are two types of consent that may be required:

Consent - An adult capable of giving permission to participate in a study can provide consent. In most states, the subject must be 18 years of age and competent to make the decision to participate. Parents/legal guardians of minors can also provide consent to allow their children to participate in a study. Check with your local IRB for your state's requirement.

Assent - In most states if the subject is under 18 years of age, assent must be obtained. Assent is a child's affirmative agreement to participate in research. The assent form must include simple language written at the appropriate reading level of the youngest subject in the youth age range. An assent form may also be used if the subject is cognitively impaired. Researchers are advised to contact their local IRB regarding this matter.

PRIVACY/CONFIDENTIALITY

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

- **Privacy** can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- **Confidentiality** 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. Care should be taken to explain the mechanisms that have been devised to protect the privacy of the subjects, for example, the use of numbering or code or safely locked files in private offices. Furthermore, the investigator should describe who has access to the data and under what circumstances a code may be broken. Without appropriate safeguards, problems may arise with long-term retention of records. In special circumstances requiring additional safeguards to prevent potential criminal or civil prosecution of the participating human subject, the IRB may require the destruction of all data that can identify the subjects. 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 or destroyed.

A special situation arises for video or taped data and photographs since these media provide additional potential means for subject identification. Investigators must secure subject consent explicitly mentioning these practices. They should also explain plans for final disposition or destruction of such records.

RISK/BENEFIT

Risk

Risk is the probability of harm or injury (physical, psychological, social, or economic) occurring as the result of participation in a

research study. Both biomedical and social and behavioral research may entail some level of risk to a person's health, physical, psychological, or socioeconomic well being. Student researchers must consider the following risks when conducting their studies:

Risk Resulting from Study Questions/Surveys

In human subjects research, particularly social and behavioral projects, subjects may feel stress caused by the research questions or procedures. Perhaps questions raise painful memories or unresolved issues. Interviews of survivors of personal or state violence, for example, may be very stressful. Questions about at-risk behaviors may cause embarrassment, feelings of guilt, or 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.

Breach of Confidentiality

A breach of confidentiality is often the greatest risk to participants in social and behavioral human subjects research. Reputations or employment may be damaged or jeopardized if confidentiality is not maintained.



Information about subjects' activities may place them at risk of legal

action. For example, if a researcher asks parents how they discipline their children, information about child abuse may be obtained and must be reported. Similarly, if subjects divulge information about 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. Consent forms describing the kinds of questions the researcher will ask allow participants to choose whether they wish to divulge certain types of information or explore certain issues.

Benefits

Potential benefits for individual subjects may be easy to define in studies offering interventions for behavioral, psychological, or physical problems. However, research is often conducted as part of a faculty member or graduate student investigation into a specialized field of study. The research may provide no direct benefit to the subjects.

Furthermore, it may be many years before the results of the research are publicly known and made useful to society or to groups of people. Vague promises to benefit science or society are not

adequate descriptions of benefit in a consent form or a research application. When there is no direct benefit to subjects, they must be told what the researcher is trying to learn and why. (The only exception would be a study in which deception is a necessary, and IRB-approved, element of the design.)

Note that compensation to subjects is not considered a benefit in the risk/benefit analysis, nor is the fact that participants may find it rewarding to be helpful.

INTERNATIONAL STUDIES

Procedures normally followed outside the United States for research involving human subjects may differ from those set forth in federal regulations and institutional policies. These may result from differences in language, cultural and social history, and social mores. In addition, national policies such as the availability of national health insurance, philosophically different legal systems, and social policies may make U.S. forms and procedures inappropriate. In federally funded research, research activities in a foreign country may be approved if the ethical protections adhered to by a foreign institution are equivalent or greater to those in the U.S.

If protections are deemed equivalent, requests to review or waive some standard elements of U.S. approvals may be considered. However, protections afforded subjects must approximate those provided to subjects in the United States. The investigator is encouraged to contact the Chair of the appropriate IRB to discuss

these issues. Investigators will be required to obtain approval from an independent ethics committee (IEC), the IRB equivalent, for research done internationally for studies that are more than minimal risk. Many institutions outside of the United States have Ethics Committees who can review and approve the research. For studies that are minimal risk, the IRB equivalent to an approval letter or permission letter from the research site may be acceptable; however, it will be reviewed on a case-by-case basis. Students proposing to conduct research outside of the U.S. should also be aware that some countries may have more stringent regulations or policies associated with human subjects research.

International research studies must adhere to recognized ethics codes such as: 45 CFR 46, Nuremberg Code, The Declaration of Helsinki, and *The Belmont Report*. Consent and recruitment documents must be in the language that is readable and understandable by the subjects or the short form and translator method may be used. Additionally, the following issues should be addressed in the IRB application or be considered in the IRB discussion.

- Risks/Benefits to Subjects/Community
- Language Sensitivity
- Community spokesperson or tribal leaders
- Infrastructure development/availability
- Cultural sensitivities
- Justify Use of Population
- Genetics/Homogeneity/Validity of data to Other Populations

- Ethics Body Equivalent Approval (Research Ethics Review Board/IRB)
- Potential Coercion
- Paternalism
- "Helicopter" Research (data/sample collection & leaving site with no follow-up or benefit)
- Literacy Assessment



STUDENTS AS RESEARCH SUBJECTS

In an academic institutional setting, students play an integral role as subjects in certain research situations (for example, research dealing with teaching methods, curricula, and other areas related to the scholarship of teaching and learning). An underlying principle of the regulations governing the involvement of human subjects in research is that the subject's participation is voluntary and based upon full and accurate information.

Consistent with an overall concern that research subjects should not be coerced, student and faculty researchers should take particular care to avoid the unintentional or subliminal coercion that may occur when potential subjects are also students. For this reason, faculty researchers, in particular, must avoid involving their own students as research subjects. Faculty who wish to involve their own students as subjects should be able to provide a good scientific reason, rather than convenience, for selecting those students as research subjects. The research project should be relevant to the topic of the class, and participation should be part of the learning

experience for the students.

In instances where investigators can provide a good reason for involving their own students in their research, the IRB generally requires that someone other than the investigator (instructor) obtain informed consent and collect the data. When this is not possible, the IRB will consider other methods for obtaining consent and collecting data that would not reveal to the instructor whether or not a specific student participated in the research project until after final grades have been determined. The students should be informed of what these procedures are in the informed consent form. In addition, it is generally recommended that the investigator/professor provide a recruitment flyer or letter to a student pool, general student population, or both so that the student may be the one who initiates contact with the investigator/researcher.

If a student feels he/she has been coerced to participate in a study, he/she should immediately inform the institution's compliance office and/or the IRB.

EXTRA CREDIT (ALTERNATIVE FOR STUDENT SUBJECTS)

The IRB may approve projects that give extra credit to students who participate in a research project only when alternative means of obtaining equivalent extra credit with equivalent effort is made available to students who do not wish to volunteer as research subjects. The IRB carefully reviews the alternatives to ensure that students are not being coerced to participate. The informed consent

form should clearly state that there is an option to withdraw at any point without consequences (for example, extra credit should be given despite withdrawal).

STUDENT "SUBJECT POOLS"

"Subject pools" are often used where students enrolled in introductory courses are recruited by investigators from within the department/school for participation in research projects. The department/school may impose its own standards for the type of research that may be conducted in this setting and specify who may have access to such subjects and how access is obtained.

Investigators who recruit from "subject pools" are required to submit the research studies to the IRB for review and approval.

Beyond the considerations outlined above, academic units may impose their own additional constraints on using students as research subjects. The possibility of undue influence on students (grades or faculty pressure) must be addressed and avoided. The IRB may pay special attention to studies using student "subject pools."

WHAT SHOULD A STUDENT EXPECT AS A SUBJECT?

All students have certain rights as a research subject. These rights, such as the right to be free from any coercion, can be found below:

CONSENT FORM

In accordance with the principles of free and informed consent, privacy, and confidentiality, and in consideration of the vulnerable nature of students as research subjects, students have the right to a consent form that addresses key points of the study. Please refer to the *Important Terms/Parts of the IRB Application* section of this module under "What are the Steps in the IRB Process?"

■ RECRUITMENT OF SUBJECTS

Students have the right to be free from any coercion or bias that might result when a researcher is also evaluating them in a course. Therefore, the person recruiting the subjects should be someone other than an instructor of the students. This is to reduce any perception of coercion and to reduce the possibility of bias by the person evaluating the students resulting from knowing who is or isn't participating in the research project.

■ OBTAINING SUBJECTS' NAMES

Students have the right to privacy of personal information. Under the institution's privacy guidelines, the institution may not supply a researcher with the names of students for research purposes. Also, a researcher with knowledge of student names as a result of teaching or other institution-related activity may not be permitted to use that knowledge to generate a list of student names for research purposes. (There may be some exceptions - please check with the applicable IRB.) The researcher may create a written form describing the kind of subjects being recruited and why, which can be:

- Distributed in class (it would be important for the researcher to

be absent at the time of distribution to reduce any perception of coercion).

- Posted in a place where potential subjects will see it.
- Distributed via a class e-mail listserv (not using individual student names). If this option is employed, the use of the e-mail listserv should be "at arm's length." In other words, the listserv should either list students in the class of a third party or, if the listserv lists students in the researcher's own class, students should be directed to respond to a third party.

RESEARCH DURING CLASS TIME

Students have the right to have class time devoted to classroom activities appropriate to meeting the objectives for the scheduled course. Institutions discourage the use of class time for the investigator's research activities. If class time is to be used for research, the researcher must make a case to the IRB as to why the research is directly relevant to course content. A student can participate in the research activity without having his or her responses included in publishable data by withholding their consent or saying at the onset that their data may not be used.

HOW CAN COERCION BE AVOIDED?

Whenever possible, researchers should avoid involving their own students if another population of subjects is equally suited to the research question (e.g., another class section not taught by the researcher, recruitment by another instructor, or blinded/coded data collected by an associate so that subjects are not identified to the

instructor). Students should be given an opportunity to decline participation without jeopardy.

Unless the research question is directly related to class material, or the study process is being used as a teaching opportunity, such as in a research methods class, the use of class time to recruit subjects or class time used to complete study instruments is discouraged.

RESOURCES FOR STUDENT RESEARCHERS AND/OR STUDENT SUBJECTS

In an institutional setting, there are various resources that are available for student researchers and student subjects.

WHAT IS THE ROLE/EXPECTATION OF THE FACULTY ADVISOR?

Faculty advisors may be chosen by the student investigator or assigned to the student. Their role as the advisor is to guide students through the IRB process by discussing general principles of research ethics with the class/student prior to the initiation of any project involving human subjects.

Faculty members who supervise student research are responsible for the protection of human subjects and are required to:

1. Be familiar with the ethical and regulatory requirements of

human subjects research.

2. Determine whether projects require IRB review and assist students with the process. (If the project involves research in a non-US setting, then considerations of local regulations and customs must be understood and satisfied.)
3. Discuss research ethics with the students.
4. Advise students conducting international studies on understanding the local customs and ethics.
5. Monitor student projects, paying special attention to maintaining confidentiality, privacy, level of risk, voluntary participation and withdrawal, and informed consent.
6. Assure that any unexpected or adverse events are reported to the IRB.

*Responsibilities for faculty that uses students as subjects in research can be found in Section 3.

COMPLAINTS

Student researchers and student subjects must have access to reporting complaints regarding faculty when there are issues such as ethical concerns, coercion of student subjects, misguidance on research projects, or other issues that a student may find offensive or wrongful. Students can contact the appropriate department, the IRB office, the Office of Compliance, or the institution's ethics' office to report and address their concerns. More information can be found at [HHS Office of Research Integrity's website](#) (especially the section on mentoring).

WHAT IS THE ROLE OF THE IRB OFFICE?

The institution's IRB office, and its staff, can also be a valuable resource for student investigators. They can assist student in completing the human subjects application and understanding human subjects ethics, regulations, and the review process. They help the student comply with requirements and regulations to assure the protection of human subjects research and to help facilitate smooth completion of the research projects.

WHAT IS THE ROLE OF THE OFFICE OF COMPLIANCE?

In response to continuing scrutiny from government regulators and an increasingly complex statutory and regulatory environment, most institutions have an established institutional compliance program. The compliance program is a central office intended to enforce the institution's commitment to comply with all applicable laws and regulations, detect and correct compliance violations promptly and eliminate misconduct and other wrongdoing. The compliance office is also a resource for information on laws and regulations pertaining to human subjects research.

WHAT BIBLIOGRAPHIC RESOURCES ARE AVAILABLE FOR STUDENT RESEARCHERS?

There are many informational resources available on research with human subjects. Most Institutions have a website and their own

policies and procedures dedicated to research with human subjects. On these websites, the student investigator will find information about the Belmont Report, the human subjects research review process, and/or human subject educational opportunities. Institutions provide training throughout the year and the Institution's IRB can be contacted for more information.

Listed are a few internet websites for student investigators and student subjects on human subjects research:

- [HHS Office for Human Research Protections \(OHRP\)](#)
- [OHRP Regulations & Policy Library](#)
- [OHRP compliance references](#)
- [HHS Food and Drug Administration \(FDA\)](#)
- [FDA guidance documents](#)
- [FDA compliance references](#)
- [Engagement of Institutions in Human Subjects Research](#)
- [Coded Private Information or Biological Specimens](#)
- [University of Southern California Office for the Protection of Research Subjects website](#)
- [University of Minnesota Institutional Review Board website](#)
- [Vanderbilt University Institutional Review Board website](#)
- [University of Las Vegas Office for the Protection of Research Subjects website](#)
- [The Collaborative Institutional Training Initiative \(CITI\) Course in the Protection of Human Research Subjects](#)

[website](#) (Please check if your institution is a member of CITI.)

- [Public Responsibility in Medicine & Research \(PRIM&R\)](#)

COMMON TERMINOLOGY

MINIMAL RISK

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (Note that this definition of minimal risk does not apply to research involving prisoners, which has its own definition of what constitutes minimal risk).

PRIMARY VS. SECONDARY DATA

Primary data collection involves direct contact with, or observation of, one or more people for the purpose of collecting data about them.

Secondary data collection involves accessing information that has already been obtained about humans, either individually or in aggregate form. Secondary data which contains personal identifiers are subject to the requirements set forth under the institution's research policies. Secondary data, which do not contain personal identifiers, are exempt from these requirements. Secondary data -

whether they do or do not contain personal identifiers - may be used only when original consent allows the information to be used in this manner.

SUBJECT RECRUITMENT

Recruitment is the process by which potential subjects are informed about the study. Recruitment materials, such as fliers, email messages, newspaper ads, and phone calls, must be true, non-coercive, and must not highlight any potential monetary compensation. These materials must be approved by the IRB before they are implemented in the study.

IDENTIFIABLE PERSONAL INFORMATION

Identifiable personal information is any information that can allow researchers to ascertain the identity of the subject. Researchers must take caution in recording personal information and/or collecting certain types of data to ensure that the privacy and confidentiality of the subjects are maintained.

CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS

Coded means:

1. identifying information (such as name or social security number) that would enable the investigator to readily ascertain the

identity of the individual to whom the private information or biological specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and

2. a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

ENGAGEMENT OF INSTITUTIONS IN RESEARCH

An institution becomes "engaged" in human subjects research when its employees or agents

1. Intervene or interact with living individuals for research purposes
2. Or obtain individually identifiable private information for research purposes. Please see the federal guidance, *Engagement of Institutions in Human Subjects Research: OHRP Guidance (2008)*.

DECEPTION STUDIES

Deception is the intentional misleading of subjects or the withholding of full information about the nature of the study.

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, because it interferes with the ability of the subject to give informed consent. However, deception is arguably necessary for certain types

of behavioral research. Because humans act differently depending on circumstances, full knowledge by the subject might bias the results.

Subjects have the right to full disclosure as soon as possible. In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the completion of data collection. 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. This process is known as debriefing. Note that techniques of this type are contrary to the policy of full advanced disclosure in the informed consent process and document. *Deception techniques should be used with discretion and may only be employed with the approval of the IRB. Deception in some social and behavioral research where meeting the minimal risk provision is involved is often part of study designs in some fields of research.*

VULNERABLE POPULATIONS

Certain populations are considered to be vulnerable in human subjects research. People who cannot competently understand the information regarding a study and cannot give true consent. Such populations may include individuals with psychiatric, cognitive, or developmental disorders and substance abusers. It is critical that investigators evaluate whether subjects may be vulnerable and whether they are competent to consent.

While any individual who may fit the above category can be

considered vulnerable, federal regulations specifically define three groups of people: pregnant women, fetuses, and neonates (Subpart B), prisoners (Subpart C), and children (Subpart D).

- [*Pregnant women, fetuses, and neonates \(Subpart B\)*](#) Pregnant women, fetuses, and neonates are considered vulnerable because they may be at a greater risk than others. Special protections, however, are geared more toward medical research than social/behavioral research.
- [*Prisoners \(Subpart C\)*](#) Prisoners are considered to be vulnerable in that they may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision on whether or not to participate as subjects in research.
- [*Children \(Subpart D\)*](#) Children are considered vulnerable because they may not be able to completely understand the information presented about a study.



CONCLUSION

The purpose of this module was to assist both students researchers and student subjects with the IRB process. It included information that students in undergraduate, masters, or doctoral degree programs may encounter as investigators and/or subjects.

The information contained in this module provided general guidance in protecting human subjects as set forth by U.S. federal regulations and institutional policies. Students are advised to contact their own Institution's IRB for any additional policies and

procedures.

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