Lawrence Technological University IRB Tutorial

This tutorial will help you and your research team to learn more about the development of codes and principles of research ethics, the informed consent process, selection and recruitment of research participants, protection of confidentiality of subjects, and regulation of research. You will also learn the basics of submitting LTU IRB protocols and what will be expected of you, as a researcher, after you have obtained LTU IRB approval.

This tutorial is certainly not exhaustive, and the LTU IRB promotes further education of researchers regarding the principles of research ethics. This tutorial has been compiled from several sources, and primarily contains material used by the Lawrence Tech IRB.

Reason for Training

In October 2000, the National Institute of Health (NIH) established a policy requiring education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.

To further demonstrate Lawrence Tech's commitment to the protection of human subjects, the LTU IRB's policies state that it will hold all research conducted at the institution to the same standards as federally funded research.

In conclusion, the LTU IRB requires completion of human subjects protections training for all investigators (internal or external) of a project.

The Importance of Research Ethics & Compliance

Societies and cultures around the world establish for themselves moral standards or rules (personal ethics) which define right or wrong conduct by members within the societies, and which establish punishments for those who violate those standards/rules. Those moral standards seek to ensure that people act in ethical ways in their interactions with others in society. Professional groups and organizations within a society also establish ethical principles which mandate practices and behavior of professionals when they act in an official capacity (e.g., business, legal, medical, and scientific research ethical practices). In contrast to personal ethics, which are generally written into legal codes, adherence to professional ethics is typically self-regulated within the professional organization.

As noted in the "History" section below, some individual researchers have valued the acquisition of scientific knowledge more highly than the protection of human subjects' rights and well-being. Significant harm to and death of subjects has occurred when scientists failed to adhere to basic moral standards/rules such as:

- Concern for the well-being of others
- Respect for the autonomy of others
- Trustworthiness & honesty
- Willing compliance with the law (with the exception of civil disobedience)
- Basic justice; being fair

- Refusing to take unfair advantage
- Benevolence: doing good

- Preventing harm

When professional organizations fail to adequately regulate the conduct of their members (through voluntary regulation), the Government generally steps in to enact involuntary (mandatory) regulations which must be followed, and if violated, the perpetrator risks legal action and criminal punishment or financial sanctions. Because of problems with research conducted in the past in the U.S., Congress has passed a variety of legislation intended to force professionals to adhere to personal and professional ethical principles which they should innately follow.

Lawrence Tech expects its faculty and student researchers who use human subjects in research to: (1) adhere to established personal (societal) ethical practices; (2) follow professional ethical principles established by their respective disciplines; (3) ensure full compliance with federal regulations governing protection of human subjects; and, (4) ensure full compliance with Lawrence Tech policies and procedures which address protection of human subjects. Failure to comply with those four points may result in loss of privileges to conduct research at the University, and could result in loss of federal funding, or withdrawal of federal permission to conduct research affecting all researchers at the institution.

History

Beginning of the Tuskegee Syphilis Study

The Tuskegee study of untreated syphilis in the Negro male began in Macon County, Alabama in 1932 and was conducted by the United States Public Health Service. The purpose of the study was to follow the progression of the disease untreated in hopes to demonstrate the need for establishing syphilis treatment programs.

This study consisted of more than 400 black men with syphilis as study participants. To begin with, the subjects were recruited into the study without informed consent. They were not informed of their disease nor were they informed that this research would not benefit them personally. These men were misled to believe that the spinal taps involved as a study procedure were “special free treatments.”

Although at the beginning of the study there was no intent to deny anyone treatment for a long period of time, when Penicillin, known as an effective treatment, became available after 1943, it was purposefully withheld from subjects. Findings of the study, including high death rates and occurrences of complications, even as early on as 1936, clearly indicated the severe progression of the disease.

Even so, researchers continued to keep the subjects enrolled in the study and uninformed of their diseases. In their defense, researchers claimed that, with the development of Penicillin, this research was “the last opportunity to study the progression of the untreated disease”, even though from 1891-1910, long-term studies of syphilis in 2000 untreated patients in Oslo, Norway were completed.

The announcement of the Nuremberg Code (discussed below) had no effect on the study. The study was exposed to the public through an article published in the New York Times and Washington Star in 1972. Although the study was never hidden and was previously discussed openly by the Centers for Disease Control and Prevention officials, the public reacted strongly to this exposure.

Nazi Experiments

During World War II, medical experiments were performed on thousands of unwilling concentration camp prisoners. These experiments were torturous and most often led to the death of these subjects. Examples of these studies include forcing concentration camp prisoners to endure high altitude decompression in order to determine the maximum safe altitude for German Air Force pilots, hypothermia research to determine survival time for soldiers parachuting into the cold water of the North Atlantic, and inflictions of gunshot and stabbing wounds or traumatic amputations to study different treatment effects.

Nuremburg Code

In 1946, 23 leading members of the German medical hierarchy involved with the Nazi experiments were indicted for their participation. In August 1947, all were found guilty. Sixteen were imprisoned and seven were sentenced to death for conducting "crimes against humanity." During this verdict, the judges included a section called "Permissible Medical Experiments", which became known as the Nuremberg Code.

The Nuremberg Code mandated protections for human subjects in medical and non-clinical experiments. The code established basic principles that must be observed in order to satisfy moral, ethical and legal concepts. The following list is an outline of these basic principles:

- Voluntary (informed) consent is essential
- Experiment to yield fruitful results for society, and not random or unnecessary
- Research to be based upon animal experimentation or knowledge of the disease or problem to ensure that the results justify the undertaking of the experiment
- Experiment conducted so as to avoid unnecessary physical and mental suffering and injury
- Experiment not conducted if possibility that death or disabling injury will occur
- Degree of risk not to exceed the humanitarian importance of the problem to be solved
- Proper preparations and facilities to protect the subject from remote possibility of injury, disability, or death
- Conducted only by scientifically qualified persons using highest degree of skill and care
- Subject at liberty to withdraw from the experiment at any time
- Scientist in charge must be prepared to terminate the experiment at any stage if continuation likely to result in injury, disability, or death to the subject

Radiation Experiments

From 1944 to 1974, the government sponsored thousands of radiation experiments. These studies were conducted to advance biomedical, national defense, or space exploration science. Some of these experiments involved prisoners and military personnel, at times unknowingly. If consent was obtained, it was found that the documents were difficult to comprehend and sometimes misleading. At times, consent documents overemphasized the benefits of the research and overstated the therapeutic potential. These consent documents often did not properly discuss the potential risks involved with participation, in particular psycho-social risks and financial costs that could be incurred.

Belmont Report

Due to the public's expression of concern resulting from public exposure of research abuses, such as the experiments previously discussed within this tutorial, Congress passed the National Research Act in 1974. The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which subsequently released the Ethical Principles and Guidelines for the Protection of Human Subjects of Research, also known as the Belmont Report, in 1979.

The Belmont Report is the basis for all current laws, regulations, and policies governing the use of human subjects. The three fundamental ethical principles of this report are respect for persons, beneficence and justice.

Respect for Persons
There are two basic moral requirements underlining this principle:

- To acknowledge autonomy (i.e., freedom to deliberate and make considered choices) of research participants
- To protect those with diminished autonomy. For example, immature children, geriatric/senile individuals, persons with diminished capacity from illness or mental disability, and persons with conditions that severely affect individual liberty (e.g., prisoners)

The extent of protection afforded to those with diminished autonomy depends on the risk of harm and likelihood of benefit of being involved with the research. In certain circumstances, extensive protection or exclusion is required. While other circumstances warrant only the assurance that involvement with the research is undertaken willingly, and that they are aware of possible adverse consequences.

One application of this principle is the consent process. Subjects must be given ample time to consider all of the information of a study they need before consenting to participate without pressure. Participants are free to withdraw participation at any time without penalty.

Beneficence
Beneficence is acts of kindness or charity that go beyond strict obligation. In the research content, those actions now become obligatory. There are two basic rules underlining this principle:

- Do no harm
- Maximize possible benefits and minimize possible harms

Thorough forethought in planning/designing the study is required to maximize benefits and reduce risks. The research must be designed to reduce risks to those necessary to achieve research objectives. When risks are significant, the researcher must adequately justify the risk to the IRB. Researchers must supply potential subjects with an adequate description of the risks and benefits within the consent process and consent document. It is essential that subjects are made fully aware of all potential risks and benefits. Being fully informed will allow subjects to choose whether participation is right for them (i.e., autonomy).

Researchers and the IRB are charged with analyzing the delicate balance of risk versus harm of a particular research study. When discussing beneficence, one must examine the risks and benefits potential to both the individual and society. Many times it is the individuals participating in the research who are exposed to the risks of the research; however, those individuals are rarely directly exposed to the benefits of the project.

The researchers and IRB must assess whether the risks that will be presented to the subjects are justified. It may be determined that the benefits to society at large outweigh the potential risks to individual participants. Anyway one looks at it, the benefits must outweigh the risks.

Risk: A combination of the probability of experiencing a harm and the severity of the envisioned harm
Benefit: Something of positive value related to health or welfare of the subject

The nature and scope of risks and benefits:

- Psychological
- Physical
- Legal
- Social
- Economic
- Dignity

Justice

Researchers and IRBs must ensure that the risks and benefits of research are distributed fairly. They must determine whether certain social classes or groups of people are not unjustly targeted for research, for example, because of ease of recruitment. The Belmont Report states that, "An injustice occurs when some benefits to which a person is entitled is denied without good reason or when some burden is imposed unduly."

Selection of Research Subjects

The principle of justice is applied during the selection of subjects. There lies a moral requirement for fair procedures and outcomes in the selection of research subjects.

There are two levels of justice in selection of subjects:

- Individual: don't offer potentially beneficial research to some individuals who are held in favor, and select only "undesirable" individuals for risky research.
- Social: draw a distinction between classes of subjects who ought and ought not to participate, based upon the ability of members of that class to bear burdens, and on the appropriateness of placing further burdens on already burdened persons.

There should be an order of selection of classes of subjects (e.g., adults before children).

Incarcerated or institutionalized subjects should be involved only when appropriate safeguards are met.

Injustice arises from social, racial, sexual, and cultural biases institutionalized in society. It is also injustice when vulnerable subjects (e.g., racial minorities, the economically disadvantaged, the very sick, and the institutionalized) are used because of their vulnerability and manipulability or for sake of convenience.

When determining the population of research, researchers must not target a specific gender or ethnicity unless it is appropriately justified.

Vulnerable Populations

Researchers must also provide compelling justification for the use of vulnerable populations within research. Individuals within vulnerable populations may have limited autonomy. In other words, they may not be able to provide sufficient informed consent. This may be because they cannot fully understand the research or are within a coercive environment.

Examples of vulnerable populations:

- Children
- Cognitively impaired
- Comatose patients
- Prisoners
- Pregnant women & fetuses (clinical studies)
- Students
- Employees
- Terminally ill

Children

"Children" are persons who have not attained the legal age for consent (18 years of age in most states), and thus cannot legally provide "consent" to treatments or procedures involved in research. In some instances, the child may be considered an "emancipated minor" as defined by applicable law in the jurisdiction where the research will be conducted, and may in that case provide legal consent.

"Assent" means a child's affirmative agreement to participate in research. It is an act signifying understanding (recognizing that the minor has not reached full legal age). Mere failure to object by the child should not, absent affirmative agreement, be construed as assent.
The assent process, while not legally binding, should involve taking the time to explain to a child, at whatever age they can begin to understand, what is going on in the proposed study, why the study is being done, what will be done to them, and that if they object, the research will be terminated, and they will not be punished or scolded. As children develop, they should gradually become the primary guardians of personal health and the primary partners in medical decision-making, assuming responsibility from their parents. Just as is the case with informed consent, the emphasis on obtaining assent should be on the interactive process in which information and values are shared and joint decisions are made.

"Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research. For most research studies, parents must provide their permission (parental consent) to allow their child to participate in the research study. [NOTE: Unless waived, it is required that a signed Parental Permission (Consent) form be on file for each participating minor. "Passive" consent, i.e., sending the child home with a form which states "please let us know if you don't want your child to participate", and then in the absence of a response (failure to object) from the parent, construing this to mean agreement that the child can participate, is not allowable.]

Cognitively Impaired

The predominant ethical concern in research involving individuals with psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), cognitive disorder, or developmental disorders (e.g., mental retardation), or who are substance abusers is that their disorders (affecting cognitive or emotional functions) may compromise/diminish their capacity for judgment and understanding ofthe information presented and their ability to make a reasoned decision about participation. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

Many individuals with disabilities affecting their reasoning powers may be residents of institutions responsible

for their total care and treatment. The impact of institutionalization may further compromise their ability to exercise free choice (voluntariness). (These concerns apply both to voluntary patients and those committed involuntarily.) The eagerness for release may induce an institutionalized person, especially one who is involuntarily confined, to participate in research out of a desire to appear "rational" and "cooperative" to those who will make decisions about his or her release. Persons who are institutionalized, particularly if disabled, should not be chosen for studies that bear no relation to their situation just because it would be convenient for the researcher.

As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the matter of being a research volunteer, and quite capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

Persons formally adjudged incompetent have a court-appointed guardian who must be consulted and consent on their behalf. Officials of the institution in which incompetent patients reside (even if they are the patient's legal guardians) are not generally considered appropriate, since their supervisory duties may give rise to conflicting interests and loyalties. Family members or others financially responsible for the patient may also be subject to conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances.

Students

The problem with student participation in research conducted at the university is the possibility that their agreement to participate will not be freely given. Students may volunteer to participate out of a belief that doing so will place them in good favor with faculty (e.g., that participating will result in receiving better grades, recommendations, employment, or the like), or that failure to participate will negatively affect their relationship with the investigator or faculty generally (i.e., by seeming "uncooperative," not part of the scientific community). A way to protect against coercion is to require that faculty-investigators advertise for subjects generally (e.g., through notices posted in the school or department) rather than recruit individual students directly.

Requiring participation in research for course credit (or extra credit) is also controversial, though common in the social and behavioral sciences. As with any research involving a potentially vulnerable subject population, IRBs must pay special attention to the potential for coercion or undue influence and consider ways in which the possibility of exploitation can be reduced or eliminated.

Another concern raised by the involvement of students as subjects is confidentiality. As with research involving human subjects generally, the Lawrence Tech IRB is aware that research involving the collection of data on sensitive subjects such as mental health, sexual activity, or the use of illicit drugs or alcohol presents risks to subjects of which they should be made aware and from which they should be protected, to the greatest extent possible. The close environment of the university amplifies this problem.

If a research project includes the need to access student records (i.e., SAT or GRE scores, or student GPA), a separate signed consent/permission form must be obtained from the student subject and submitted to the Registrar's office.

Employees
The issues with respect to employees as research subjects are essentially identical to those involving students as research subjects: coercion or undue influence, and confidentiality. Employee research programs raise the possibility that the decision will affect performance evaluations or job advancement.

Recruitment of Research Subjects

Recruitment begins with the advertisement of the study and/or the invitation into the study. The IRB must review and approve all forms of advertising and recruitment, including invitation letters/e-mails, telephone or in-class recruitment scripts, flyers, and radio/television/internet advertisements.

Advertising Do's . . .
- Supply adequate information about the study
- Use simple language
- Provide contact information
- Obtain approval to post ads, if necessary
- Be careful of subtle coercion
- State the inclusion/exclusion criteria
- Briefly describe the study procedures & location
- State that it is research

Advertising Don'ts . . .
- DO NOT overemphasize compensation
- DO NOT offer "free care"
- DO NOT claim that the study is superior to alternatives
- DO NOT use coercive language

Consent Process & Document

Under the principle of respect for persons, subjects, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them.

There are three elements to the informed consent process:
1. Information
2. Comprehension
3. Voluntariness

Information
Subjects must be given adequate information to properly make an informed decision regarding participation. At a minimum, federal regulations require the following information to be included in the consent process and consent document:
- Brief description of the research procedures, including length of procedures
- Statement that the study involves research

- Purpose of the research
- Risks and anticipated benefits
- Alternative procedures (if therapy – clinical/surgical treatment involved)
- Description of confidentiality/anonymity provided
- Explanation of compensation provided, if any
- Statement indicating that subject is free to withdraw at any time from the research project without penalty
- Statement that questions can be asked, and names and addresses/telephone numbers of PI and IRB Chair provided

The LTU IRB has additional requirements that must be contained within a consent form. Visit our website at https://www.ltu.edu/sponsored-research/irb for consent templates that will help you ensure that all required elements are included.

Comprehension

Subjects must be able to adequately understand the project, his/her role, and the risks involved. As the risks become more serious, the obligation to ensure subject comprehension greatly increases.

Timing

To achieve understanding, potential subjects should not be presented information all at once or only at the last minute. People need time to think about whether or not they want to participate. They may wish to discuss the decision with family, close friends, or religious advisors. They should not feel rushed or coerced. They need time, especially if the information is disturbing or particularly complex, to digest the information and come to terms with it. Researchers should be prepared to give adequate time to the subjects for review – one day, a week, or more, depending upon the level of risk and complexity of the subject's involvement in the research. During lengthy studies, the researcher must also "maintain" consent. This may be accomplished by checking with the subject throughout the study to accomplish the following:

- To ensure that the subject still has a full understanding of the study
- To answer any questions that may have developed after the initial consent process
- To address issues of discomfort, confusion, or to have the subject decline continued participation
- To gather the opinion of the subject as of how the study is going or if he/she has any recommendations for the improvement of the study
- To discuss the remainder of the study procedures to remind the subject where he/she is at in the study process

Consent Process: Ensuring Comprehension

The informed consent process is different from the consent form. It involves meeting with a potential subject, finding out whether he or she is capable of giving consent, and discussing the purpose, risks, and benefits of participation. The consent form formalizes the agreement to participate and should be designed to document the process. Obtaining informed consent is not just giving a prospective subject a consent form and getting it signed. If consent by the subject involves their being truly informed, the subjects must genuinely understand the study; hence, researchers should strive to convey information to subjects, not merely disclose it to them. Subjects should be able to say what they are consenting to (i.e., be able to describe the project and their involvement in their own terminology).

Barriers to Comprehension

- Disorganized descriptive materials
- Rapid presentation with too little time for questions
- Subject's intelligence, rationality, maturity, culture, and language
- Illiteracy
- "Incompetency" – infants, young children, mentally disabled or comatose patients

Voluntariness

Voluntary recruitment involves the free-will choice of individuals in conditions free of extreme urgency, with little time to ponder choices and undue influence / coercion. Recruitment not free of these conditions invalidates any consent that may be given.

Undue influence / coercion =

- To offer excessive, unwarranted, inappropriate, or improper rewards or overtures to obtain consent
- To manipulate a person's choice through the controlling influence of a close relative or friend
- To threaten withdrawal of a service to which the person is otherwise entitled

Documenting Subjects' Consent

If feasible, researchers are advised and may be required to obtain signed consent from each participant prior to their participation. Written, signed consent should be sought unless there are compelling reasons for the IRB to grant a partial or full waiver of consent. Signed consent forms must be stored securely by the research team and be retained for a minimum of three years following the completion of the research project.

Obtaining a Waiver of Informed Consent from the IRB

If necessary and adequately justified, researchers may request a waiver for the requirement to obtain informed consent from subjects. In other words, subjects are unaware that they are participating in the research. Obtaining this waiver is sometimes necessary in order to conduct research.

Obtaining a Waiver of Signed Consent from the IRB

Many socio-behavioral research projects qualify for a waiver of the requirement for the researcher to obtain signed consent documents from subjects. If this waiver is approved, researchers must ensure that subjects are fully consented to participate in the study. In other words, the research project and all of its elements are fully disclosed to subjects in order for subjects to make an informed decision about participating; however, the researchers do not need to obtain each subject's signature on the consent form. If seeking a waiver of signed consent, the IRB highly recommends and may require that the investigator provide subjects with a written statement regarding the research. This is typically called an information sheet. The information sheet provides subjects with much of the same information required in a consent document; however, signatures are not obtained from subjects.

Both of the waivers discussed above may be requested for either some or all of the study's procedures involving human subjects. If the waiver does not cover all study procedures involving human subjects, a consent form or the informed consent (depending on the type of waiver sought) may be required to cover the additional study procedures.

Paying Research Subjects

Paying individuals to participate in research has been a controversial issue within the IRB community for many years; however, there are few regulatory guidelines to address this issue.

Compensation must not be large enough to be considered coercive. Researchers and the IRB must consider the subject pool's socioeconomics while reviewing protocols involving payment for research participation. Unfortunately, there are no set standards for what amount if considered coercive. Considerations for compensation will be made on an individual (per study) basis by the IRB.

Institutional Review Boards are charged with the responsibility to review both the amount and method of payment to ensure that neither are coercive or present undue influence to participate or to continue participation.

If a study includes a large amount of compensation, depending upon the socioeconomics and study procedures expected from participants, the IRB may require that the researchers delay informing participants of the compensation until after the subject completes study procedures. This will help to ensure that subjects are participating because of voluntariness instead of compensation (i.e., undue influence).

Compensation should be prorated based on duration of study participation. Payment must not be contingent on the participant completing the study procedures. In other words, even if the subject decides to withdraw from the study, he/she must be compensated, at least partially, based on what study procedures he/she has completed.

Protecting Confidentiality & Anonymity

Researchers need to be creative to ensure that the utmost confidentiality or anonymity is provided to their research participants.

Do not collect identifying information from participants unless it is absolutely necessary to the research. If identifying information is collected, keep this information separate from subjects' responses (e.g., responses to questionnaires/interviews, biological specimens, lab information, etc.). To do so, use a study code/ID to link identifying information to study responses. Keep the document linking study ID with identifying information in a separate locked area and limit access to head researchers. Identifying information:

- Names
- Addresses
- Employers' names or addresses
- Relatives' names or addresses
- Dates (e.g., birthdate, date of death)
- Phone/fax numbers
- Email addresses
- Social Security Number
- Member account numbers
- Voiceprints
- Fingerprints
- Full face photos & comparable images

Who Regulates Your Research?

The Department of Health and Human Service's (DHHS) Office for Human Research Protections (OHRP) is responsible for the implementation of the US Code of Federal Regulations related to human subjects and the requirement of the establishment or use of an IRB for projects receiving federal funds.

Per Lawrence Tech's policies all research at Lawrence Tech that includes the use of human subjects and/or private information about humans must comply with all of the regulations in the Code of Federal Regulations (CFR) at 45 CFR 46.

OHRP ensures regulatory compliance in the protection of human subjects and requires that Lawrence Tech, an institution receiving federal funding for research, provide written assurance documenting how it will comply with requirements for the protection of human subjects.

Lawrence Tech Institutional Review Board (IRB) for the Protection of Human Subjects

Responsibilities:

- Provides local assurance of compliance
- Reviews and approves, disapproves or requires modifications of protocols
- Conducts annual re-evaluation of ongoing protocols
- Ensures that Principal Investigators and staff are appropriately trained
- Reports noncompliance to Institutional Official and OHRP

Lawrence Tech IRB Submissions, What You Need to Know

Please visit the Lawrence Tech IRB website at https://www.ltu.edu/sponsored-research/irb for information regarding:

- How to complete an application
- To find IRB application forms
- To learn more about the Lawrence Tech IRB
- For help developing your study procedures and forms, for example, your consent form
- Overview of & links to federal regulations

LTU IRB Approval, When is it Required?

Click here for the flow chart to use as an aid to determine when LTU IRB approval is required. Researchers must seek and obtain LTU IRB approval BEFORE conducting any research type activities involving human subjects, including informal recruitment.

Type of Review Categories

A. Exempt Research Review

- Exempt human subject research projects may be reviewed by the IRB Chair, or designee, and do not require full Board review.
- Obtaining written, signed consent from research participants is not required by federal regulations; however, obtaining consent is always required, and certain departments (e.g., psychology) or the IRB may require written consent even for exempt research.

- The IRB holds the authority to recommend or require modifications to submitted IRB materials in the interest of protecting human subjects.
- Modifications to the research protocol must be approved by the IRB prior to implementation (except where necessary to eliminate apparent immediate hazards to subjects) to ensure the research continues to meet Exempt status.
- It is the researchers' responsibility to report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
- There is occasional confusion about research that is "exempt." Some individuals have mistakenly assumed that "exempt research" does not need IRB review. However, "exempt" means that it falls within a narrowly defined category of research needing administrative review by the IRB Chair, or designee, rather than full board review.
- Once approved, involved researchers are notified of the Exempt approval via an official IRB approval letter sent via e-mail. IRB approval will be granted for up to three years. The IRB approval expiration date will be specified in the approval letter. Continuing review is required for re-approval if the research is to continue beyond the expiration date.

What Qualifies for Exempt Review?

To qualify for Exempt Review, the research must meet all of the following criteria:

- Must not involve pregnant women, prisoners or mentally impaired persons;
- Must not include survey research with minors unless involving standard educational activities (e.g., educational tests) within the particular education system;
- Must not include observation of a minor's public behavior unless there is no researcher interaction;
- Must not involve video or audio recording of subjects without their consent; and
- Must be in one or more of the categories for exempt research described in the next section.

Categories for Exempt Review

- Click here for the full DHHS description of exempt categories presented in section 46.104.

Category 1

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

Examples:

- Evaluating the use of accepted or revised standardized tests
- Testing or comparing a curriculum or lesson
- A program evaluation of pharmacy continuing education

Category 2

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

1. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR
2. Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR
3. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. (See "WORKSHEET: Limited IRB Review (HRP-319).")

Examples:

- Surveying teachers, nurses, or doctors about a technique or an outcome
- Interviewing managers about a management style or best practice
- Conducting a focus group about an experience or an opinion of a community program

Category 3

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

1. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; OR
2. Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR
3. The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. (See "WORKSHEET: Limited IRB Review (HRP-319).")

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

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

Example:

- Healthy adult subjects are asked to take part in two two-hour-long assessments of memory, attention and information processing speed before and after 1 hour of cognitive enhancement exercise using specially designed computer software. The procedures are conducted during a single visit, and subjects are encouraged to take breaks when desired.

Category 4

Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

1. The identifiable private information or identifiable biospecimens are publicly available; OR
2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR
3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); OR
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Note: Exemption Category 4 only applies to the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials typically will be publicly available materials, medical records, or existing repositories of clinical specimens. No contact between investigator and subject is allowed. If an investigator wants to collect information/specimens directly from research subjects, then another IRB review path will be required. Exemption Category 4(iii) only applies to the use of data (when HIPAA applies) and **not to** biospecimens.

Example:

- A researcher is given two datasets that contain private, identifiable information. The researcher uses the identifiers to merge the two datasets but strips the resulting (merged) data of identifiers immediately

after the merge and before conducting data analysis. The resulting data used for the analysis is completely de-identified with no link to identifiers.

Category 5

Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine: public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

Category 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 Dept. of Agriculture

B. Expedited Research Review

- An expedited review procedure consists of a review of research involving human subjects by the IRB Chairperson or by one or more experienced reviewers designated by the Chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.
- IRB approval will be granted for a determined length of time not to exceed one year. The IRB approval expiration date will be specified in the approval letter. Continuing review is required for re-approval if the research is to continue beyond the expiration date.
- Unless waived by the IRB, signed consent must be obtained from all subjects prior to their involvement in the research.
- The IRB holds the authority to recommend or require modifications to submitted IRB materials at any time.
- Modifications to or additions/deletions of human subject research-related documents (including the research protocol) must be approved by the IRB prior to implementation (except where necessary to eliminate apparent immediate hazards to subjects).
- It is the researchers' responsibility to report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
- Once approved, involved researchers are notified of the Expedited approval via an official IRB approval letter sent via e-mail.

What Qualified for Expedited Review?

To qualify for Expedited Review, the research must meet all of the following criteria:

- Be of minimal risk to the subjects;
- *Minimal risk* means that the probability and magnitude of the 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.
- Must not involve pregnant women, prisoners or mentally impaired persons;
- Involve only procedures listed in one or more of the following categories:

Categories for Expedited Review

- Clinical studies of (a) drugs for which an investigational new drug application 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), or (b) medical devices for which an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 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 (Note: amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than two time 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 (Note: amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than two times per week).
- 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); and (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 removal 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.
- 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, electroretinoraphy, 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.
- 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).
- Collection of data from voice, video, digital, or image recordings made for research purposes.
- 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, social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

C. Full IRB Review

- A project that involves greater than minimal risk (see definition, below) requires approval by an IRB panel, the Board, composed of members qualified to review research in that field. The Board typically meets once per month.
- IRB approval will be granted for a determined length of time not to exceed one year. The IRB approval expiration date will be specified in the approval letter.
- Continuing review is required for re-approval if the research is to continue beyond the expiration date. The continuing review request must be reviewed by the Full IRB at its monthly meeting unless one of the following applies: 1) the research is permanently closed to the enrollment of new subjects; all subjects have completed all research related interventions; and the research remains active only for long-term follow-up of subjects; or 2) where no subjects have been enrolled and no additional risks have been identified; or 3) where the remaining research activities are limited to data analysis; or 4) continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories for expedited approval 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.
- Unless waived by the IRB, signed consent must be obtained from all subjects prior to their involvement in the research.
- The IRB holds the authority to recommend or require modifications to submitted IRB materials at any time.
- Modifications to or additions/deletions of human subject research-related documents (including the research protocol) must be approved by the IRB prior to implementation (except where necessary to eliminate apparent immediate hazards to subjects).
- It is the researchers' responsibility to report promptly to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.
- The Board's decision to contingently approve, table, or disapprove a protocol will be communicated to the investigators via e-mail, which will specify the reasons for the decision and proposed actions/revisions, as applicable.
- Once approved, involved researchers are notified of the Full IRB approval via an official approval letter sent via e-mail.

Categories for Full Review

Research that requires full committee review may include one or more of the following:

- Prisoners
- Pregnant Women
- Fetuses
- Human in Vitro Fertilization
- Mentally Disabled Persons

- Microwaves or X-Rays
- General Anesthesia or Sedation
- Research that poses greater than minimal risks to subjects (unless qualifying for Exempt review)
- Vulnerable Populations: Individuals whose willingness to volunteer in a study or clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces (i.e., ROTC or Corps of Cadets), and persons kept in prison or detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.
- This list is not exhaustive. The final decision as to whether an application is reviewed by the Board at a convened meeting is that of the IRB Chair and/or Board.

A **human subject** is a living individual about whom a researcher obtains either: 1) data through intervention with the individual; or (2) identifiable private information.

Research is defined as a systematic investigation, including research and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102d). This is generally interpreted to mean that if the results of the work are meant to be published or disseminated to an unrestricted audience, it is considered as regulated human subjects research. However, the benchmark/goal of 'publishing' is not a part of the federal code. If an activity follows a deliberate plan whose purpose is to develop or contribute to generalizable knowledge, such as an exploratory study or the collection of data to test a hypothesis, it is research.

In addition, LTU IRB approval must be obtained for all senior theses and dissertation research even if there is no intention to publish or disseminate the results. IRB approval is no longer required for class projects.

Application for IRB Approval

The LTU IRB Application for Approval to Conduct Research With Human Participants can be found here: https://www.ltu.edu/sponsored-research/irb

New Study
Before beginning your research involving human subjects, you need to obtain IRB approval. The IRB must review and approve all study documents pertaining to human subjects, including but not limited to: 1) advertisements & invitation letters, 2) survey instruments, including questionnaires & interview scripts, 3) consent document(s), and 4) the Research Protocol (which is an application form found on our website at the above link).

Amendment Request
Researchers must report all changes of study procedures, study personnel, or changes to study forms (e.g., questionnaires, interview questions, invitation letters, etc.) to the IRB BEFORE implementing the change. Send an email to irb@ltu.edu

Basically, if there is a change to any of the documents originally submitted to the IRB, or if there is an addition of a study document, the IRB needs to be informed.

Continuing Review Request (Also called re-approval)
Studies are approved for a specified period of time (three years for exempt research, and one year for expedited and full board research). Your IRB approval letter will contain your study's expiration date. It is essential that you request and obtain IRB re-approval to your study before it expires if you plan to continue the study past the expiration date. If you close your study (i.e., data analysis is complete at Lawrence Tech and all activities involving human subjects are complete), report this to the IRB via e-mail at irb@ltu.edu

The IRB office will prompt you to re-approve your study or report it as closed within two months of your study's expiration date; however, it is ultimately the responsibility of you, the Principal Investigator to re-approve the study or report the study as closed in a timely fashion.

Adverse Event Reports

Adverse Events are new findings or unexpected problems whose nature, severity, and frequency are not described in the information provided to the IRB or to study participants. Examples include unexpected complications experienced by a subject, missteps in the documentation of consent, or breaches of confidentiality. It can represent a new symptom experienced by a study subject or an exacerbation or worsening of an existing condition.

Any problems involving the conduct of the study or subject participation (including recruitment, consent, screening and termination) should be reported immediately in an email to irb@ltu.edu. For example, if a subject complains about any aspect of his or her treatment as a study subject, this should be reported and the subject should be referred to the IRB Chair for assistance.

Approved Applications

All correspondence from the IRB office is through email. Once an application is approved by the IRB, all investigators listed on the application will receive an official approval letter via email. Retain this official approval letter. The Graduate Department will request a copy of this letter prior to graduation.

Continued Compliance

Compliance does not end with initial IRB approval. To continue compliance, researchers have the following responsibilities:

- To conduct the study according to the protocol / IRB application
- Report to the IRB any deviations from the protocol / IRB application
- Report to the IRB any proposed changes to the originally approved IRB submission
- Report to the IRB any adverse events
- Unless waived by the IRB, obtain informed consent from each individual participant before conducting any study procedures with that particular participant

- Unless waived by the IRB, document consent by obtaining signatures of involved participants on the consent form
- Maintain signed consent documents for three years
- Report progress of approved research to the IRB in the manner prescribed by the IRB at the time of approval
- Monitor the rights and welfare of participants throughout the study

(Please continue to "The Training Module" on the following page)

TRAINING MODULE

Acknowledgements: The LTU IRB gratefully acknowledges Serge F. Hein, Ph.D., 316 East Eggleston Hall (0302), Educational Leadership and Policy Studies, Virginia Polytechnic Institute and State University, Blacksburg, Virginia, USA 24061 (e-mail: shein@vt.edu or phone: (540) 231-9713).

Threats to Ethical Decision Making During Research

by Serge F. Hein, Ph.D.
Educational Leadership and Policy Studies
Virginia Polytechnic Institute and State University

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This module focuses on a variety of important factors that can undermine researchers' ability to make sound ethical decisions during the research process. Some of these factors may be obvious to you, but other factors can be more subtle and can operate tacitly during research. The general aim of this module is to expose you to a variety of significant threats to ethical decision making and, equally important, to encourage you to develop an orientation of mindfulness and ongoing reflection about potential ethical threats to your own research. The treatment of threats to ethical decision making that is presented in this module, however, is not meant to be exhaustive. Other challenges to ethical decision making can exist during research, and it is important to be vigilant in monitoring for them.

As you progress through this module, you will find that a lack of knowledge of a particular aspect of the United States Code of Federal Regulations (CFR) at 45 CFR 46 (protection of human subjects) or the Belmont Report (referred to in the remainder of the module as the federal regulations governing the use of human subjects) is only one among many factors that can lead to poor ethical decision making. In many instances, researchers are likely familiar with various aspects of these federal regulations, but other factors undermine their ability to make ethical decisions.

Before you begin this module, several other points should also be emphasized:

- Although each threat to ethical decision making is discussed separately in this module, it should be noted that these threats are not necessarily mutually exclusive. That is, several threats can operate simultaneously in any research situation and can contribute to poor ethical decision making. For example, a researcher's lack of knowledge of a particular aspect of the federal regulations governing the use of human subjects and a high workload can both contribute to an unsound ethical decision (e.g., a researcher may be uncertain about a particular ethical issue but feel overwhelmed by his or her current workload and, ultimately, fail to become more informed about the issue).
- Threats to ethical decision making can also influence one another. For example, a high workload and high stress can undermine a researcher's ability to be sufficiently reflective.
- Ethical behavior, as it relates to the relationships that the researcher establishes during research, is not limited solely to interactions with participants. It also encompasses the researcher's treatment of research assistants, transcribers, Institutional Review Board (IRB) administrative staff, and anyone else who is involved in some way in the research process. It is therefore important for the researcher to pay adequate attention to the nature of his or her interactions, whether direct or indirect, with all individuals who are involved in the research.
- Eight major threats to ethical decision making are discussed in this module. Following a

description of each threat, information is provided about specific ways in which the threat can appear during research. Suggestions for addressing the threat are also provided.

1) Inadequate Knowledge of Federal Regulations or How They Apply to Your Research

One of the most obvious threats to sound ethical decision making is a lack of awareness, or a lack of adequate understanding, of a particular aspect of the federal regulations governing the use of human subjects. Even when the content of these federal regulations is understood, gaps in understanding can arise due to a failure to apply an aspect of the regulations adequately to one's own research circumstances. In some instances, a researcher may fail to see the relevance of a specific portion of the federal regulations for a particular aspect of his or her research. When ethical issues or practices are overlooked by researchers, they can include the following:

- Any changes to an IRB-approved research protocol, regardless of magnitude, require IRB approval.
- When soliciting participation for a study, the researcher should normally not exceed two follow-up reminders. Exceeding two reminders can constitute a form of harassment.
- When a person has declined to participate in a study, the researcher needs to cease immediately any further recruitment of that person. No additional attempts to persuade the person to participate can occur.
- All of the information contained in the consent form needs to be communicated to the participant using language that she or he can understand (i.e., "lay language" needs to be used). Informed consent should be understood as a process, rather than as a form that needs signing. Thus, in addition to being viewed as a legal document, the consent form should be viewed as a "teaching tool" that informs participants about the research.
- The participant must be given the opportunity to read the consent form in its entirety and to ask questions and discuss the study.
- All data and other information that is collected from participants needs to be stored in a locked place when not being used. Any computer on which primary data are stored needs to be password protected and have an up-to-date firewall and virus protection. Also, the use of encryption is strongly encouraged.
- Documents that contain information about participants' identities need to be stored in a separate place than other information that is collected from participants.
- Dual relationships (i.e., where you are functioning in one or more roles beyond your role as researcher) need to be avoided when they involve your own clients or supervisees.
- When other types of dual relationships exist, such as those involving your own advisees or students, extra care needs to be taken to make clear that the person is free to decline to participate in the study and that such a decision will not carry negative consequences.
- The researcher needs to ensure the ethical conduct of all other research personnel who are under her or his supervision or control.
- When offering student participants extra credit as compensation for participating in a study, equal alternatives for earning the extra credit need to be provided and advertised.
- The researcher must avoid coercing individuals to participate in the study. Coerced participation can result from offering excessive or otherwise inappropriate compensation, exaggerating the study's benefits, or downplaying the study's risks.
- All on-line survey research must make use of a secure on-line site, which involves using Secure Sockets Layer (SSL) encryption. In other words, the link that participants use to access the on-line survey needs to begin with "https" rather than "http".

What You Can Do:

- Take the time to familiarize yourself with all aspects of the federal regulations governing the use of human subjects. In terms of safeguarding the well-being of participants, maintaining your professional reputation, and avoiding legal or other difficulties that can result from engaging in unethical behavior, doing so is time well spent.

- If you are unsure about an ethical issue, contact the IRB. The IRB administrative staff is there to help you. A second strategy is to discuss the ethical issue with one or more knowledgeable colleagues.

2) Making Inadequate Use of the IRB Administrative Office

Another threat to sound ethical decision making arises from inadequate use of the IRB administrative staff. This can occur in a variety of ways:

- A researcher may have a limited understanding of the IRB's role in research or the resources that the IRB administrative staff can provide to researchers. As a result, a valuable source of information that could inform a research decision is overlooked, possibly resulting in a poor ethical decision.
- Due to a lack of time or other constraints, a researcher may, ultimately, have little contact with the IRB. As a result, a valuable source of information that could inform a research decision is not used, possibly resulting in a poor ethical decision.
- A researcher may be fearful of discussing ethical issues with the IRB. This fear may be compounded by the common misconception that only "bad" people behave unethically. In such a case, the researcher may deal with his or her concerns about being labeled or stigmatized by deciding not to contact the IRB. Keep in mind that people make mistakes. Being ethical does not mean that a researcher never makes ethical mistakes: What it does mean is that a researcher takes steps to address an ethical mistake as soon as possible after becoming aware of its existence. Acting promptly, and working openly with the IRB and Post-Approval Monitoring, to address an ethical issue will help to minimize harm to participants or to others who are involved in the research.
- A researcher may view IRB approval as a "hurdle" or "obstacle" to be overcome prior to conducting the research. He or she may also pay "lip service" to specific IRB requirements, rather than viewing the IRB review process as providing valuable and impartial feedback that results in a stronger, more ethically sound study that will satisfy all applicable federal regulations governing the use of human subjects.

What You Can Do:

- Take the time to learn about the scope of the IRB's responsibilities and the various resources that it provides to you as a researcher.
- Rather than viewing the IRB administrative staff as simply the people who approve your research, view them as people who are committed to providing you with expert, ongoing guidance for all ethical issues that are relevant to your research.
- When you are uncertain about an ethical issue, don't hesitate to contact the IRB administrative staff. You will find them to be a friendly and valuable source of impartial information.
- If you have made an ethical mistake, don't be afraid to contact the IRB. Again, they are there to help you. Their approach to addressing such issues is a nonjudgmental one, focusing instead on finding the most effective strategy to address the issue and minimize harm to participants or to others.

3) Lack of Time, High Workload, and Stress

A lack of time, high workload, or high stress level can all contribute to a researcher's inability to think clearly or thoroughly enough about an ethical issue. Researchers often have a wide range of responsibilities and tasks that need to be attended to at any given time, and time is therefore limited. Time pressures, work overload, or high stress can result in a variety of undesirable outcomes, such as "shallower" processing of information, overlooking important information, minimizing potential risks, or a general expediency in getting research or other tasks completed. As a result, poor ethical decisions can be made that fail to safeguard the rights and welfare of participants, among other consequences. Lack of

time, work overload, or high stress can lead to a variety of undesirable outcomes that include the following:

- The researcher may (a) lack the time to provide junior research team members or research assistants with adequate training in ethical research practices or (b) assume that they already possess such knowledge.
- The researcher may fail to check initially with junior research team members or research assistants (or other research team members who are familiar with these individuals) to determine their level of understanding of various ethical research practices.
- If the researcher has provided initial training for junior research team members or research assistants, a lack of time, a high workload, or high stress may result in a failure to follow up with them (a) to ensure that they have retained what they learned during their initial ethical training, (b) to ensure that their initial ethical training has been adequate to allow them to deal effectively with all ethical issues that have arisen during the course of the research, and (c) to check to see if they have any questions or concerns about ethical issues that have emerged during the course of the research. In this regard, it is valuable to review all training information with research assistants and junior research team members who have little prior research experience. It should also be emphasized here that it is normally the responsibility of senior researchers to instruct junior researchers, through both direct means and the example that they provide, in the knowledge and skills required to be an ethical researcher. Keep in mind that all members of a research team have the capacity to influence one another, but the behavior of senior researchers is often watched closely and emulated by junior researchers.
- Due to a lack of time or high stress, the consent process with participants may be rushed or otherwise compromised (e.g., all aspects of informed consent have not been discussed with the participant prior to having her or him read the consent form). As a result, a truly informed consent has not been obtained.
- The researcher may forget to revisit issues of consent with participants when the conditions of the research have changed. Keep in mind that informed consent is an ongoing process.
- During the course of research, a lack of time or high stress may cause the researcher to demonstrate an inadequate level of respect for participants and their time (e.g., the participant may feel rushed or unimportant).
- The researcher may fail to obtain IRB approval before implementing changes that have been made to an IRB-approved research protocol.
- The researcher may forget to keep primary data secure when they are not being used.
- The researcher may fail to report unanticipated problems or participant complaints to the IRB.
- The researcher may forget to destroy primary data at the time specified in the IRB-approved research protocol.
- The researcher may forget about one or more promises that were made to participants or to research sites.

What You Can Do:

- Monitor your overall stress level regularly. If you find that it is too high, take steps to reduce it, and consider adopting one or more stress management strategies.
- Monitor your workload regularly. If you find that you have more work than you can cope with, take steps to reduce it and/or to reduce future commitments to new work. Over-committing to work activities can lead to high stress, decreased productivity, lower work quality, and burnout.
- If you are experiencing time pressures, a high workload, or high stress, make a conscious effort to slow down and give ethical issues the careful attention that they deserve. The welfare of your participants depends on it. Also consider that the personal repercussions of poor ethical decisions can themselves be very stressful and time consuming to deal with.

4) <u>Forgetting Important Information over Time</u>

In the absence of factors such as time pressures, a high workload, or high stress, a researcher may, over time, simply forget important information about a research study. Aspects of an IRB-approved research protocol (e.g., the appropriate timeline for destroying primary data) may be forgotten, particularly if the

research spans several years or has been formally closed with the IRB Office. Forgetting information about the research protocol can occur in a variety of ways. Some examples include the following:

- Over time, the researcher may forget aspects of the IRB-approved research protocol to be followed and conduct the study in ways that deviate from what was approved.
- Over time, particularly if multiple amendments have been made to an IRB-approved research protocol, the researcher may forget aspects of one or more amendments and conduct the study in ways that deviate from those approved amendments.
- Over time, the researcher may forget promises that she or he has made to participants or to a research site, such as providing copies of journal articles that have resulted from the research, providing a written report of the research findings, or making a presentation to people at the research site.
- Over time, the researcher may forget the specific timeline specified in the IRB-approved research protocol and study documents for retaining primary data and participant information. As a result, these materials may be retained for longer than was originally approved. Failure to destroy these materials at the stipulated time increases the risk that they will be revealed accidentally, thereby posing a risk to participants.
- For the above (and other) instances of forgetting important research protocol-related information, keep in mind that the IRB makes use of several mechanisms to ensure compliance with federal regulations governing the use of human subjects. These include the annual research protocol approval process and random post-approval monitoring of researchers.

What You Can Do:

- Keep all IRB-approved research protocols and amendments in one place where you can find them easily and review them regularly.
- Maintain a log book or file of important dates for research activities such as destroying primary data for each IRB-approved study.
- Maintain a log book or file of commitments that you have made to participants or sites for each IRB-approved study.

5) <u>Inadequate Reflection</u>

Another threat to effective ethical decision making can arise from the researcher's failure to engage in an adequate level of reflection about specific ethical issues, the research protocol, or the potential impact of the research protocol on participants or other individuals. Researcher reflectivity can also involve efforts to "place yourself in the participant's shoes." In other words, the researcher asks: How would I want to be treated if I was a participant in this study? Poor ethical decisions can sometimes result from failing to adequately consider how participants will experience a particular aspect of the study. It can be seen that this facet of reflectivity can involve the researcher's empathic capacity. Researcher reflectivity also includes a recognition of the important role that power plays in all research involving participants (i.e., research involves asymmetrical power relationships, in which the researcher holds significantly more power than participants) and the ways in which power shapes the researcher-participant relationship.

A fundamental way in which researchers can increase their level of reflectivity is to cultivate an attitude of constant questioning about the research process. This involves engaging in continual self-questioning about ethical issues that can arise at various stages of the research and about the adequacy of decisions and actions that are taken. It is also important to extend this attitude of constant questioning to include the

decisions and actions of other research team members.

Inadequate researcher reflectivity can occur in a variety of ways. Some examples include the following:

- The researcher may fail to adequately consider the degree to which the language that he or she is using during the informed consent process is understandable to participants.
- A researcher has decided that mailing gift certificates to participants (for participating in a study) will not be feasible. Instead, he instructs participants to pick up their gift certificate from a graduate assistant who works for the researcher but who is not a member of the research team. Although the graduate assistant has no prior knowledge of the study or the participants, her interaction with any of the participants (e.g., a participant referring to the study in some way) could result in a violation of participant confidentiality.
- The researcher may fail to consider whether participants (or people who are solicited to participate in a study) will be left with negative experiences as a result of either their involvement in the research or their contact with the researcher. For example, in soliciting participation for a study, the researcher may not see the harm in sending participants four follow-up reminders. Participants, however, may consider a third or fourth reminder irritating or may view it as a form of harassment.
- The researcher may fail to adequately consider the long-term consequences for participants of taking part in the study. In other words, are there any lasting harmful effects on participants of being involved in the study? For example, in conducting a study of a vulnerable group that may not want to be more socially visible (e.g., drug abusers), the researcher needs to consider carefully how the study's findings may change the participants' lives. More specifically, disseminating the findings may change public policy in ways that make the participants' lives more difficult (e.g., providing law enforcement with more effective strategies for apprehending drug abusers). Such an outcome could be construed as causing harm to the participants. Although long-term risks and benefits are often difficult to assess, doing so is nevertheless essential.

What You Can Do:

- Develop an attitude of constant questioning during all stages of research.
- Ask yourself the question: How would I want to be treated if I was a participant in this study? Or consider how people who are quite different from you would react to being in the study: How would a friend, relative, or someone else experience participation in this study?
- Ask yourself the questions: How does the power imbalance that is inherent in research shape the nature of my relationships with participants? How might the power that I hold as researcher influence the verbal and nonverbal behavior that I observe in participants?
- Consult with another research team member, a knowledgeable colleague, or IRB administrative staff whenever reflection on a particular issue results in concerns or doubts about the proper course of action to be taken.

6) <u>Inadequate Moral Reasoning</u>

Inappropriate ethical decisions can also result from the researcher's use of inadequate moral reasoning. Using adequate moral reasoning is a critical component of effective ethical judgments. Thus, it is important to monitor and evaluate your level of moral reasoning during various stages of research, as well as monitor and evaluate the moral reasoning of other research team members and research assistants.

A research example involving two different levels of moral reasoning about the course of action to be taken by a researcher is presented below, for illustrative purposes. It can be seen that the level of moral reasoning used in each case also influences the justification that is provided for the proposed action.

- In preparing for data collection, which is scheduled to begin the following week, a researcher finds that he needs to make several changes to the IRB-approved research protocol. The

responses below illustrate two distinctly different levels of moral reasoning, the first of which is inadequate for arriving at an ethical decision about the appropriate course of action to be taken.

Low Level of Moral Reasoning: "I'm not going to bother submitting an amendment to the IRB. These changes to the research protocol are very small. It's not a big deal. Plus, the IRB will never find out about it anyway."

High Level of Moral Reasoning: "I'm going to submit an amendment as soon as I can because it's important that the IRB approve these changes to the research protocol before I start my data collection. Federal regulations governing the use of human subjects require that I obtain IRB approval before making any changes to the research protocol, regardless of how small those changes are. The IRB may see something that I haven't seen, as far as harm that could come to the participants because of these changes to the protocol. Plus, not getting IRB approval for these changes wouldn't fit with how I view myself as a researcher or as a person."

What You Can Do:

- Monitor and evaluate the level of moral reasoning that you engage in during all phases of the research process.
- Consult with other research team members, a knowledgeable colleague, or the IRB administrative staff about your reasoning process, particularly if you have doubts or concerns about its adequacy.
- Monitor and evaluate the moral reasoning of other research team members and research assistants and discuss deficiencies when they arise. Such discussions should also make clear what an adequate level of moral reasoning would involve, including the decision that would result.
- In assessing the level of moral reasoning that you or other research team members engage in, keep in mind that the IRB uses several mechanisms to ensure compliance with federal regulations governing the use of human subjects. These include the annual research protocol approval process and random post-approval monitoring of researchers.

7) Competing Priorities

The existence of competing priorities for the researcher can also pose a serious threat to ethical decision making. For example, investments of time, money, and other resources in research, or the researcher's own professional aspirations, all have the potential to undermine ethical decision making. In some instances, the desire to collect much-needed data can result in participants' rights being ignored or otherwise violated. The researcher may reason, "My decision doesn't cause any *real* harm to the participants. Besides, these data are important to my career." Thus, even when a researcher is aware of the appropriate ethical decision to be made, other priorities (e.g., professional or personal needs) can allow unethical behavior to occur. It can also be seen that this threat to ethical decision making can overlap with the previous threat (i.e., inadequate moral reasoning).

Researcher priorities can compete with, and take precedence over, ethical decision making in a variety of ways. Some examples include the following:

- Due to concerns about obtaining an adequate sample size for a study, a researcher may intentionally or unintentionally harass individuals into participating in the study (e.g., sending out five reminder e-mails to students to solicit their participation in an on-line survey) or otherwise coerce them into participating (e.g., using strong, persuasive language during face-to-face interactions, with the aim of minimizing the person's ability to decline to participate).
- A research coordinator in a multi-site study, who receives an incentive for each participant who is recruited, may coerce individuals into participating or recruit individuals who do not meet all of the criteria for participation in the study.

- If the researcher is pressed for time during the data collection, she or he may reduce the amount of time spent during the consent process (e.g., rushing through important information or failing to provide the participant with an opportunity to read the contents of the consent form or to ask questions). In this situation, it is unlikely that the researcher has obtained a truly informed consent from participants.
- A researcher may intentionally or unintentionally use verbal and/or nonverbal forms of behavior to prompt a participant to respond to a research procedure in a way that will yield the desired research results.
- A researcher may consider another research team member's behavior or decision about a particular research issue to be unethical but may avoid addressing it due to a fear of negative personal consequences (e.g., angering a fellow research team member, "burning a bridge" with a valued colleague).

What You Can Do:

- If you find yourself being tempted to allow other priorities to override ethical considerations, consider the potential negative consequences to you of doing so, which can be both professional and personal.
- The professional costs of behaving unethically can be high, including litigation, sanctions from a funding agency, difficulties with your employer, difficulties obtaining IRB approval for future research, and loss of professional status (e.g., loss of respect from colleagues and students, which may be highly resistant to change over time).
- Also consider how one researcher's unethical behavior can place an entire university at risk. Failure to comply with federal regulations that govern the use of human subjects can lead to a federal government audit, which can result in (a) suspension of all research activity at the university and (b) suspension of all federal government research funding to the university until the ethical issues involved have been resolved. A third risk to the university is the possible loss of prestige or other damage to its public image.

8) Problems Associated with Team-Based Research

Team-based research can pose additional threats to ethical decision making. These threats can take a variety of forms, including miscommunication or a lack of communication between team members, differing levels of understanding about specific ethical issues, and differing priorities about ethical issues. Each of these threats is discussed separately below.

Miscommunication or a lack of communication between research team members can sometimes result from the unique interaction of the individuals who comprise the research team (e.g., two team members may have dramatically different communication styles). In other instances, however, time pressures, overload, or stress that is experienced by one or more team members can also result in communication problems. In either of these situations, team members may fail to communicate important information to other team members (e.g., forgetting to discuss information during a team meeting, forgetting to e-mail information to another team member) or they may communicate incomplete or otherwise inadequate information (e.g., discussing information too briefly, not communicating information clearly enough, failing to check for understanding). Some examples of this threat include the following:

- Before he leaves the office for the day, a researcher forgets to tell other research team members that he has been working with some primary data that are stored in a filing cabinet. He assumes that other team members will also need to use the data that day, and he therefore leaves the filing cabinet unlocked. The other team members do not use the data, and the filing cabinet remains unlocked until the following day.
- Several research team members are responsible for the data collection phase of a study that focuses on the topic of student substance abuse. The study involves two phases, in which participants complete a survey questionnaire and participate in a focus group interview. At the

end of the survey questionnaire, participants are asked to indicate their willingness to participate in a focus group interview. Prior to collecting data, the above team members discussed the coordination of their work only briefly. One of the team members, who is responsible for collecting the survey questionnaire data, is slow to inform the other team member that some of the participants have declined to participate in the focus group portion of the study. When the latter team member does not hear from her colleague, she assumes that all of the participants have agreed to participate in the second phase of the study. She e-mails all of the participants who completed the survey questionnaire, and most of the participants who declined to participate in a focus group interview react negatively to receiving the e-mail. They view the e-mail as unwanted, and some of them experience a high level of distress. Several of them file formal complaints with the IRB.

When research team members differ in their level of understanding of ethical principles, and the relevance and application of those principles to specific issues that arise during the research, ethical decision making can also be undermined. When one or more team members are unaware of, or inadequately informed about, an ethical issue, it is important for other team members to address the issue and provide the necessary information. Issues of power, however, can complicate or undermine this critical educative process. Specifically, the existence of a power differential between individual team members can influence whether a team member feels comfortable addressing an ethical issue or pursuing it until it is resolved satisfactorily. He or she may avoid doing so because of self consciousness or a fear of possible repercussions (e.g., creating tension within the research team, damaging a relationship with a colleague, alienating oneself from other team members who side with the colleague). There may also be pressure exerted on one or more team members to conform to another team member's preferences. The issue of a power imbalance within the research team may be particularly problematic for junior research team members, who normally hold less power in such relationships.

Even when no communication problems exist and all research team members are knowledgeable about ethical principles and specific ethical issues that arise during the course of the research, they may differ in the priority that they assign to addressing those ethical issues in an adequate way. Thus, disagreement can arise in deciding how specific ethical issues should be addressed. One team member may view her or his own approach to dealing with an ethical issue as "good enough," whereas another team member may consider the approach to be inadequate, incomplete, or otherwise unethical. Such differences in perspective can result from a variety of factors, including work style, values, and formal training, among others. Because these differences are based on assumptions and beliefs that are often tacit and deeply held rather than based on knowledge of ethical principles, they have the potential to become highly charged. As a result, they may have a greater capacity to generate disagreement or conflict than the other two threats that have been discussed in this section. Much like the previous threat, team member differences in the importance attached to dealing with an ethical issue adequately can be more difficult for junior research team members to address. Some examples of this threat include the following:

- In developing a research protocol, a more senior research team member states, "I think that we should keep the IRB protocol as general as possible. By not getting into some of the specifics, we'll get the protocol finished sooner, and we can avoid having to submit amendments later on, when we are doing the study." A junior team member, who places a high priority on developing detailed and thorough research protocols, views the suggested approach as unethical but feels uncomfortable disagreeing with a senior colleague. He therefore says nothing.
- In developing a research protocol, a senior research team member states, "I think that we should keep the IRB proposal as general as possible. By not getting into some of the specifics, we'll get the proposal finished sooner, and we can avoid having to submit amendments later on, when we are doing the study." A junior team member, who places a high priority on developing detailed and thorough research protocols, mentions tactfully (but somewhat tentatively) that developing a more detailed research protocol would be valuable and that it would provide a better basis for the IRB to assess the adequacy of the research and minimize any problems that could arise during the

research. The senior team member responds by saying, “I don’t think that that will be necessary. Besides, I have a lot of experience submitting IRB proposals, and I’ve always done it this way. There have never been any problems. Plus, we’re all very busy people.” The junior team member reluctantly decides not to pursue the issue any further.

- A week before initiating the data collection phase of a study, a research team member realizes that a relatively small change will need to be made to the conditions that are experienced by participants in the treatment group. He brings the issue to the attention of another team member who responds, “Don’t worry about it. It’s such a small change, and it’s consistent with everything else that we are asking the participants to do. There’s no need to submit an amendment. Plus, we’re really pressed for time right now.” The first team member responds by emphasizing how it is important to obtain IRB approval for any changes to a research protocol, regardless of their size, and stating his commitment to doing so. He also offers to complete the form that is required for the amendment. The form is submitted the following day, and the amendment receives IRB approval well before the data collection is scheduled to begin.

What You Can Do:

- Recognize that other team members’ communication styles may differ from your own, and take the time to understand other communication styles.
- Monitor your own communications to other team members to ensure that the information is adequate. Ensure that lines of communication remain open at all times.
- When communicating important information, follow up to ensure that the recipient has truly understood you. Never assume complete understanding.
- Monitor your stress level and workload. Consider keeping a written record of research activities that need to be done, rather than committing them to memory.
- In situations where multiple research team members work in one location, consider developing a system (e.g., a logbook) that can be used to record important events and leave messages for other team members.
- In situations where you feel that a higher ethical standard is called for, or another research team member has inadequate knowledge of an ethical principle or issue, it is important to communicate your concerns to other team members and to avoid acquiescing to another team member’s position. Acquiescence can carry significant costs, both professionally and legally, for the entire research team.
- In trying to persuade other team members of your view, present the information in an open, tactful, and nonjudgmental way. View the situation as an opportunity to have an open discussion about the issue.
- More generally, it is important to cultivate a team culture in which research team members feel comfortable evaluating, questioning, and openly discussing one another’s assumptions, views and suggestions.
- If you believe that it will be difficult to persuade a particular research team member of your position on an ethical issue, consider sharing your position and your concerns with another team member and having that person broach the topic for you. This strategy can sometimes be effective in overcoming resistance to alternative perspectives.
- Avoid becoming defensive if other team members are initially unreceptive to your position. In such situations, it is also important to restate your commitment to the ethical position that you have taken.
- Emphasizing the potential ethical and legal repercussions (e.g., litigation, loss of research privileges, loss of respect from colleagues and others) of an unsound approach to dealing with an ethical issue is often a highly effective way of persuading other team members to reject the approach.
- As an early research team activity, consider having all team members agree to the appointment of a knowledgeable outsider who can serve as a mediator if an ethical issue arises that cannot be resolved by the research team. A second strategy would be to agree to obtain an opinion from IRB administrative staff if an unresolvable ethical issue emerges.

- If extended discussion is unsuccessful in resolving the ethical issue, other team members are unwilling to appoint a mediator or to consult IRB administrative staff about the issue, and you believe your position to be the only ethical one, your obligations as an ethical researcher would be to remove yourself from the research team and to notify IRB administrative staff about the situation.

Conclusion

In this module, eight major threats to ethical decision making have been discussed. This list, however, is not exhaustive. Other factors can also undermine your ability to make ethical decisions, and you should therefore be vigilant in monitoring for them. Threats can appear during any stage of the research process, and they can manifest themselves in a wide variety of ways. In this module, it has been possible to provide only a relatively small number of examples of concrete ways in which threats appear during research. For this reason, it is important to maintain an attitude of constant questioning during all aspects of the research process and, more generally, to engage in an adequate level of reflection about specific ethical issues, the research protocol, and the potential impact of the protocol on participants or other individuals (see Threat #5: Inadequate Moral Reasoning). As discussed earlier, it is also critical to extend an attitude of constant questioning to the decisions and other behavior of other research team members. Maintaining a high level of reflectivity and an ongoing awareness of the major threats discussed in this module will provide you with a solid basis for making sound ethical decisions during the course of the research that you undertake.