# Troy University Institutional Review Board Training Presentation Transcript

*Compiled and narrated by Bret Woods on behalf of the Troy IRB.* ***This transcript is for accessibility reference only****. See the IRB training presentation video for access to complete the IRB training requirements.*

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**Slide1:**
Welcome to the Troy University Institutional Review Board training presentation—narrated by me, Bret Woods. The following slides will present an overview of what you need to know about engaging in human-subject research through the University, as well as explore the history and scope of the review board and offer important information regarding the research approval application process.

**Slide 2:**
We should first establish how the Institutional Review Board—or IRB—defines research. According to the federal government, research is a systematic investigation designed to develop or contribute to generalizable knowledge. The primary way research studies contribute to a broader public is through publication. This means any research not intended for publication or similar public presentation would not be considered "research" according to the IRB.

For example, if there are students who are conducting research for class purposes and the instructor will be the only one viewing the research, it is not considered research officially—and does not have to be evaluated by the IRB.

However, pilot studies do count as research. This is because pilot study data is often used as generalizable knowledge in future publications and presentations. As such, the IRB evaluates studies that combine both systematic investigation with public contribution.

**Slide 3:**
What is a human subject? Again, we look to federal definitions and guidelines. A human subject is any living individual about whom an investigator collects data. So, human subject research is a systematic investigation that collects data from any living individual with the intent to publish or publicly present the information.

Note that for research involving the deceased, one would need to obtain consent from whomever has the record of the deceased.

**Slide 4:**
The primary function of the IRB is to make sure that the rights of human subjects are protected. The IRB oversees the research of all Troy faculty, students, and staff. Additionally, anyone employed by the University or enrolled as a student of the University while conducting any portion of a research study will require IRB approval before conducting their research.

There are three major concepts under scrutiny in any proposed research study: Autonomy, beneficence, and justice. These will be discussed later in this presentation in more detail. The main thing to keep in mind here is that the IRB must review and approve all research studies involving human subjects, across all the Troy campuses and affiliated sites.

**Slide 5:**
Researchers collaborating with people at other institutions will need to obtain IRB approval from all involved institutions. If the Troy researchers will not have access to the data collected in the research, Troy IRB approval will not be necessary. However, the researchers will still need to send the approved protocol from other institutions to the Troy IRB for records. If the Troy researcher is the principal investigator, then Troy IRB approval is required. In any event, researchers affiliated with Troy should complete the application process, and include any relevant approval protocol from other collaborator institutions.

**Slide 6:**
Institutional Review Boards were established to protect the rights of human subjects. It wasn't until the 1970s that the federal government set regulations concerning human-subject research because of research practices that were later called into question. There are many egregious examples of questionable and reprehensible research practices.

In working to improve the conditions of research studies in recent history, medical and behavioral scientists and legal scholars have considered many ethical questions, particularly about the use of deceptive practices, or about inadequate informed consent when working with human subjects.

The core consideration when conducting research with human subjects is informed consent—the right of research subjects to have enough information to be true volunteers and participants. Protecting vulnerable populations from harm and ensuring the voice of participants will be heard has become central to the institutional review process.

**Slide 7:**
Because of the past mistreatment of human subjects, the federal government established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission published the Belmont Report in 1979. The report discusses the general ethical principles and guidelines for conducting research with human participants. Everything we do as an IRB is based on the three main principles highlighted in the Belmont Report: respect for persons, beneficence, and justice.

These three principles contributed directly to the important research considerations of informed consent, risk-benefit analysis, and selection of participants. Let’s outline each of these principles.

**Slide 8:**
The first principle of the Belmont Report is “respect for persons.” We show respect to human subjects by giving them autonomy. Autonomy means participants need to agree whether they want to participate in the research study.

Note that having a captive audience, such as the students in an instructor's class, does not mean this group is an appropriate sample for study. Convenience samples of this sort are strongly discouraged, as participants in this context experience an implied expectation and may not feel like they could decline the study.

Special protection is given to people who might not have the capacity to make informed decisions by themselves. For example, this often applies to minors—individuals younger than 18 years old—as well as any individual whose capacity for decision making may be impaired.

**Slide 9:**
The application of the "respect for persons" concept is represented with informed-consent documents. There are three main parts of informed consent.

In general, informed consent means making sure that people are given enough information to make an informed decision on whether to participate in the study. Information should include why the study is being done, what its purpose is, and exactly what is going to happen to the participants during the study. Researchers need to be clear about the risks and benefits of participation in the study, and what they are going to do as researchers to make sure the participants' confidentiality is maintained throughout the study.

Another key component is comprehension. It is necessary that the participants of a study understand the language used in all informed-consent documents. Consent documents should be written to accommodate as much comprehension as possible—thus as a general convention, researchers should write their informed consent documents at a far lower reading level than would be expected for the participants in the study. For example, any informed consent documents intended for the general population must be written at an eighth-grade level or below. Any documents intended for college students must be written at no higher than a twelfth-grade reading level. Any documents intended for prisoners must be written at a third-grade level or below. And if the participants of a study do not speak English, we need to make sure the consent documents are written in a language that they understand, and at the appropriate level.

Comprehension is a crucial aspect of informed consent. Participants must be given every opportunity to understand the documents pertaining to the study and have the opportunity to ask any questions. Informed consent should be seen as an on-going process. Participants must feel that the process is transparent. They should be given whatever information they request to make an informed decision.

The final component of informed consent is a participant's voluntariness. Researchers must make it clear to participants that participation is not a requirement or an obligation. If individuals do not want to participate in a study—even if they have already given their consent—they should be made aware that they can withdraw from the study at any time without penalty. This can be tricky, especially when participants are given rewards or other incentives while participating in the study.

Rewards should not be so extreme that participants let their desire for the reward overcome a normal hesitance about participating in the study. This is a relative concept depending on the population and depending on the risk.

**Slide 10:**
Another application of the respect for persons concept deals with research on our own students or classmates. Instructors should always try to avoid research on their own students, especially current students. The teacher-student relationship involves a power differential so instructors should never require students to participate in their research projects.

In the event when students are subjects in a study, they must be given the chance not to participate. An instructor who offers extra credit for participation must offer equivalent alternative extra credit for nonparticipation. For example, if an instructor asks students to fill out a questionnaire that would take them 10 minutes to do so, the instructor cannot demand that students either do the questionnaire or write a three-page paper to get extra credit. The alternative extra credit assignment must take roughly 10 minutes to complete, as well. In addition, do not overload any one group of students with research studies. Any power dynamic or incentive that challenges a participant's autonomy undermines the concept of respect and consent.

**Slide 11:**
The second principle of the Belmont Report is Beneficence. Beneficence is a concept in research ethics which states that researchers should have the welfare of the participant as a primary goal of any research study. This is demonstrated by two obligations: First: do no harm, and second: maximize possible benefits while minimizing possible harms. Beneficence is best achieved through a careful attention to the research study's risks and benefits.

**Slide 12:**
An application of the principle of beneficence is whether the study's benefits outweigh the risks. Every principal investigator should consider this before submitting a study for approval. This is what the IRB will spend most of its time reviewing—evaluating the risks of the research and looking at how the researcher has minimized any risks of the study.

In general, the riskier the research is, the more benefits there should be. Note that the benefits of research are not restricted to apply to the individual participant. Benefits can be to society at large, to educational and academic literature, or to other further studies.

The breach of confidentiality is one of the main risks involved in research. Sometimes questions that seem innocuous on the surface could lead to economic harm, social embarrassment, or loss of reputation to the participant if the answers were known outside the research context. For example, a researcher may want to study student athletes and their gambling behavior. If the participants' answers became known to the

administration, the students could be expelled from the university. To minimize the risk to participants, researchers must strive to maintain participants' confidentiality.

If you do not need to ask a demographic question for purposes of your direct research study, don't ask. There is no reason to collect information on a participant's race or age or sex or classification or affiliation, and so on, just to have that information. Any use of demographic questions will need to be justified. Omitting unnecessary demographic questions also reduces the risk of a breach of confidentiality, because it becomes less likely a participant can be linked to their response(s). As an extension of beneficence, all benefits and risks must be specified and included in every IRB application.

**Slide 13:**
The third principle in the Belmont report is justice. Researchers should attempt to distribute the burden of research participation and the benefits that may result. Researchers should avoid unduly burdening one group for the benefit of another group. In the past this has happened with prison populations. Prisoners are a captive audience, and prisoners often agree to participate in research. However, many of the benefits that come from research will impact society while prisoners themselves may never benefit from a study's findings. This is a prime example of injustice in research.

Other populations who are vulnerable to coercion or undue pressure to participate in research include children, individuals with impaired decision-making capacity, and economically or educationally disadvantaged persons. The principle of justice is a key aspect of ensuring the protection of human subject research.

**Slide 14:**
Researchers must ensure that a particular group is not over-selected simply because they are readily available. Selecting a particular group just because they are easily accessible goes against the principle of justice. Leaving out a group just because it is more difficult to include them in the studies also goes against the principle of justice.

As an example, for many years in early medical research, new drugs were tested primarily on men for a number of limiting reasons including social bias and inequitable cultural norms. As a result, there has been a large gender gap in participation in clinical trials, and medical research has lacked data regarding the effects of certain drugs on the female body. Since 1993 medical researchers have been required to include women as well as men in their research and clinical trials.

**Slide 15:**
Research should take into account the participation of members of vulnerable populations so as not to exert undue influence or coercion during recruitment of research participants. *Vulnerable* is defined as "vulnerable to coercion and undue influence, in recognition that coercion or undue influence refers to the ability to make an informed decision about participating in research." This category includes "individuals with impaired decision-making capacity." Adhering to the principle of justice means that researchers must assess the vulnerability of human subjects participating in their research.

**Slide 16:**
Some studies may involve obvious physical risks, such as those that could occur from blood sample collection or from performing exercises—and these risks should be noted. However, some studies—particularly behavioral research studies—may have particular social and psychological risks that need to be considered and evaluated. The researcher must list all anticipated risks and include steps taken to ensure the safety of participants.

Social risks must also be taken into consideration and addressed. Social risks could include damage to reputation and employability. For example, a researcher may want to assess job satisfaction of teachers at a particular school. In this case, the researcher may think that there are no risks involved, but if a principal, administrator, or other teachers at the school saw the results of the survey and if the responses could be linked to a particular teacher, this may harm their employability and reputation. Such risk could also lead to unforeseen retaliation and damage a participant's career.
Risks like these can be minimized by providing the participants with a stamped, self-addressed envelope addressed to the researcher so that they could be mailed directly. Alternatively, the researcher may use an anonymous Internet survey that does not collect IP addresses. Anonymity and privacy can greatly help minimize social risks.

There may also be psychological risks in behavioral research. A key psychological risk is deception, which is sometimes necessary in research but needs to be justified in any research application. While reviewing applications, the IRB will look at whether deception is necessary, if the participants are told afterwards about the deception, and what possible harm deception might do to the individual.

People may learn or be reminded of unpleasant information while participating in a study. This might cause emotional distress. For example, research on abusive relationships could trigger unpleasant memories or experiences in participants. When appropriate, the informed consent document must state that the process may be unpleasant for the participant and include confidential psychological resources available to participants, in the event they experience problems during or after the study.

The IRB will review the data-collection process to make sure that appropriate provisions are included in the application and the study to protect the participants as much as possible.

**Slide 17:**
When we conduct research in an international setting, we have to abide by U.S. regulations, and country-specific regulations. First, the researcher must obtain approval from the relevant authority(ies) of the host country or countries. Even if on a Troy University site in a different country, and conducting research at that site, the researcher must also obtain permission from the host country or countries.

Each country has its own regulations concerning what needs to be done. The International Compilation of Human Research Standards provides guiding regulations in 130 countries, and from many international organizations.

According to Troy University IRB Policies and Procedures, 4.3.4 Research on Non-Native English Speakers: "If the research participants do not speak English fluently then the informed consent documents must be translated into their native language, and a cross-translation of this document must be submitted to the IRB." [Note: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html]

**Slide 18:**
The first step in the research approval process is to complete Troy's IRB certification. This includes watching this training presentation, followed by taking and passing the IRB Certification Quiz with at least an 80% accuracy. IRB certification is valid for three years from the date of completion.

After certification, complete the application form available on Troy's IRB web site, and complete all the additional materials that are needed, as specified on the web site. All applications must include the appropriate signatures before submission.

Approval applications must be submitted electronically to irb@troy.edu. The email must contain two attachments:

In the first attachment: Combine all application documents into one electronic document, either MS Word or PDF format. In the second attachment: include the study's informed Consent document/s in MS Word format.

Four weeks should be allowed for initial review of the application. After the application is reviewed initially, revisions may be needed.

**Slide 19:**
Troy's IRB has one application for all studies. Exempt, expedited, and full reviews are the three different types of reviews that research may fall under. The IRB Chair will determine what type of review is needed.

The application is on Troy's IRB web site.

The IRB meets the third Thursday of most months to review studies that require full board review. To be included in the IRB's agenda, applications must be submitted by the second Thursday of the month.

**Slide 20:**
IRB training certification for each investigator—and the supervisor of the study—must be included with every application. Each investigator and the supervisor of the study must also be sure to sign the final page of the application. Original signatures are required. The signature page must be scanned and re-inserted into the digital application. Informed consent documents must be included. This will be discussed in more detail later in the training.

Scripts for verbal assent must be included as well for participants like minors and those with impaired decision-making capacity. In addition to the parent's or legal guardian's informed consent, each participant's permission—referred to as the Verbal Assent—is required as well.

Include all research instruments such as interview guide, surveys, and any other documents given to or read to participants. If copyrighted materials are used, include a copy of the material and a description of compliance with copyright law. This may require a permission letter from the copyright holder. Copies of all finalized recruiting media, such as advertisements, flyers, brochures, and e-mails, must be included in the application.

**Slide 21:**
For a thesis, dissertation, or DNP capstone project, applicants must include the complete methodology section. If doing research internationally or in a non-Troy location, you must include a permission letter from that location.

Any sources of funding pertaining to the study must be disclosed in the application. For studies involving deception of participants, applicants must include debriefing material.

For research involving identifiable, sensitive information, researchers can apply for a certificate of confidentiality from the National Institutes of Health. The certificate prohibits disclosure in response to legal demands, such as a subpoena. The IRB may require you to get one of these certificates if your study potentially could be damaging to your participants.

**Slide 22:**
Most research studies require Informed Consent documents. In general, participants must sign this document to participate in the study. However, for some studies, a signed Informed Consent may not be required. For example, anonymous surveys necessitate unsigned Informed Consent documents. In such cases, researchers must include wording that participants understand the study and the consent they are giving. Participants can agree that advancing into the anonymous survey indicates they are consenting to participate.

Another exception to signed consent forms involves studying distinct cultural groups or communities in which signing forms is not the norm. Researchers can follow a similar protocol by stipulating that participants consent by advancing with the study. Note that researchers must be able to provide consent forms in the appropriate language and at the appropriate level of the participants in the study.

Participants must be given every opportunity to understand the purpose, procedures, risks, and benefits of the research study. And it must be made clear in the informed consent form that participants may withdraw their consent at any time without repercussions. To give individual consent, participants must have reached the age of majority for research subjects—which in Alabama is 18 years old. If the research participants are minors in their

region, researchers need to obtain both signed parental consent as well as the minor participant's verbal (or oral) assent. A minor cannot give legally-binding written permission, but they still have the right to refuse to participate in research.

Once the researcher obtains parental consent for participation, they must use age-appropriate language to ask whether the minor wants to participate. This verbal assent is usually a simplified version of the informed consent document signed by parents or legal guardians. Researchers must clearly convey the scope of the study and how participants will be involved. Then the participant should be asked whether they would like to participate in the project. The researcher must respect the minor participant's wishes not to participate, even if they have been already granted parental consent.

Once the Informed Consent documents are approved by the IRB, researchers will receive a notice on Troy letterhead with a noted approval date—and expiration date. Researchers are required to distribute only the *approved* Informed Consent document, word-for-word, to research participants.

**Slide 23:**
Informed consent is an on-going process and can be revoked at any time by participants without repercussions. All informed consent documents must be written at the participants' level of understanding, and researchers must use only IRB-approved Informed Consent Documents. Please refer to the Troy IRB website and follow the Informed Consent Checklist.

**Slide 24:**
After you submit your application, the IRB graduate assistant will check your submission for completeness. The graduate assistant of the IRB will inform applicants if something is missing from the application submission. In the event something is missing, the review process cannot go forward until the missing item is submitted. Only when the application is complete is it then passed to the chair of the IRB.

The chair decides which type of review is needed: exempt, expedited, or full. All three categories require IRB review. Generally, any research studies that are truly anonymous and that do not involve sensitive subjects can be exempt from IRB review. Other reviews may be deemed expedited, which means they will be sent to a small sub-committee of IRB members for evaluation. The sub-committee reviews and approves or denies the study on an as-needed basis.

Any study that collects personally identifying information and/or involves more than minimal risk to the participants will receive either expedited or full review. Studies that ask for sensitive information or that deal with children or other members of vulnerable populations usually go to a full review. Full reviews must be presented before the full IRB and are conducted during the board's monthly meetings on the third Thursday of each month.

After review, the principal investigator (PI) will be sent an e-mail with a list of revisions, approval, or reasons for denial. If revisions are required, the researchers may revise and resubmit the application. Once approval is granted, an approval letter will be e-mailed to the researchers. Some projects will need continuing review, especially those involving unanticipated risks or changes to the study.

If any unanticipated risks or changes occur during the study, researchers should contact the IRB immediately. Such changes might include alterations to a survey/questionnaire, changes in study populations, expansions of studies, *etc*. The chair will review any changes. If the chair deems that the changes are not substantial enough to affect the risk/benefit ratio, they can go ahead and approve the changes. If the changes will increase the risks or decrease the benefits of the research, then the full IRB must re-examine the study.

**Slide 25:**
Some key points about student research to keep in mind:

If the study is only for a class, and there is no possibility of the students' publishing the research, then it does not need to be reviewed by the IRB. Publication in this context means documenting the study in a form that is accessible to public view such as on the Internet, in a poster or a paper presentation, or in a journal or at a conference. If the study is truly only within the context of a class, then the instructor is solely responsible for ensuring that the rights of any human research participants are respected.
If there will be any possibility of presentation or publication, the study should be reviewed. For example, all thesis, dissertation, and DNP research must be reviewed.

Students conducting research must complete IRB training and certification, and a copy of the certificate must be included in their application. All correspondence that the IRB sends to students is also copied to the student's faculty supervisor.

**Slide 26:**
Faculty and staff members supervising student projects must sign the submitted IRB application. Doing so certifies that they are responsible for collaborating in the development of the project, reviewing the information included, overseeing the research, ensuring that the PI responsibilities are fulfilled, and checking the application for content, clarity, and methodology. All research must comply with Troy University IRB Policies and Procedures. If any research is submitted to the IRB that is unclear in its purpose or its methodology, it will be sent back both to the student and faculty supervisor for clarification before review can occur.

If the faculty or staff member plans to co-author the research study, the faculty or staff member's immediate supervisor must sign the form as well.

A brief note regarding thesis research: Our graduate school requires that in every master's thesis published, there is a "Human or Animal Subjects Review" form signed by the thesis chair *and* by the IRB chair, regardless of whether human subjects were involved. It is recommended that as soon as the student receives IRB approval for the research, they

should send the necessary copies of this form to the IRB chair for a signature. The student must submit as many copies of the form as they have thesis copies, and the forms must be submitted on the same bond paper on which the thesis will be printed.

**Slide 27:**
Some final notes. All data and informed consent documents should be retained for at least three years by the investigator after the scope of the study. Researchers should note where this data will be stored, the privacy of the data, and how the data will be disposed of in the time following the study.

When conducting research involving children, active consent is required. In the past, it was enough to send out permission forms informing parents that their child would be involved in a study unless they signed a form that noted their wish to be excluded. This is called ***passive consent***.

Currently, we require ***active consent*** which means if you do not have a signed permission slip from the parent who has reviewed the informed consent materials, then you cannot conduct research on children.

Active consent is necessary no matter what kind of research project. Even an anonymous survey cannot be given to a child without the parent's active, written consent. And remember, in addition to acquiring active consent from parents or guardians, verbal assent from minors is necessary.
Research in indigenous communities is subject to tribal law and must be conducted in accordance with those laws regardless of state or regional expectations.

If policy violations are discovered, the research must be halted immediately, and appropriate disciplinary actions will be taken as specified in the IRB Policies and Procedures handbook. New rules governing cooperative research go into effect 20 January 2020.

**Slide 28:**
If you need more information about the IRB or IRB policies, you can contact your college or site representative. Member directories are listed on the Troy website. Every college and every University site has an IRB representative. In some locations there are three representatives. Visit the IRB website for additional information.

Email questions to irb@troy.edu.

You can also call the IRB at 334-670-3112.

Thank you for completing this IRB training presentation. On behalf of the IRB and Troy University I would like to wish you well in your research projects and all your future endeavors.