Overview of the IRB Process Transcription

Slide 1

The following presentation provides an overview of the process by which researchers who intend to conduct research with human subjects receive approval from IUP. All research using human subjects that is conducted at IUP must be approved by the Institutional Review Board for the Protection of Human Subjects, also known as the IRB. As of the creation of this presentation, Dr. Jennifer Roberts from the Criminology and Criminal Justice Department serves as the chair of the IRB. Dr. Timothy Runge, from the Educational and School Psychology Department, serves as the Expedited Reviewer for the IRB.

We will begin this review with a general overview of *why* IRBs exist in the first place. Next, we will discuss the types of reviews conducted on human subjects research proposals. We then review the online portal through which all human subjects research proposals are submitted at IUP. We conclude with some helpful hints about how to prepare a human subjects research proposal that meets many of the requirements for approval.

Slide 2

Very briefly: Why do we even have research ethics? If you know anything about human history, and more specifically United States' history, our country had a fairly poor track record of conducting human subjects research up until the 1960s. Many of the reasons oversight of human subjects research is needed and why IRBs exist are the result of the atrocities that happened during WWII with Nazi Germany, the Holocaust, and the genocide of Jews and others viewed by the Nazis as inferior. In our own country, the Tuskegee experiments conducted from 1932 to 1972 occurred when the U.S. Public Health Service purposefully injected individuals with syphilis, and then watched them get sicker and sicker, until they died. The intent of these experiments was to study the natural progression of untreated syphilis. Sadly, these experiments were conducted largely on poor African-American men who were told they were receiving free health care from the U.S. government. There are other examples of unethical treatment of individuals in scientific experiments, but these are some of the more notable examples.

Because of these atrocities against human subjects, internationally and nationally, we now have some rules about how we engage in research that involves human subjects. Ultimately, having a set of rules and oversight of all research conducted with human subjects is just, frankly, the right thing to do.

Additionally, every organization that receives federal money, including most institutions of higher education like IUP, are required to follow these rules when engaging in research that uses human subjects. Therefore, it is the responsibility of the IRB to make sure that everybody who's conducting research with human subjects is following these rules. Consequently, the IRB provides a level of assurance to the federal government that all IUP researchers are following the rules. If IUP is caught violating these federal rules, the entire institution could be sanctioned by the federal government including the complete closure of all human subjects research across the campus.

As a result, IUP must regularly attest to the federal government that all human subjects research sponsored by the institution adheres to the federal guidelines. This *federal-wide assurance* is the attestation of IUP's compliance. The IUP IRB is the supervising body to assure that all human subjects research meets federal requirements.

We also believe that the review of all human subjects research by the IRB strengthens the quality of a research project. While the IRB does not typically weigh in on the exact research question or methodology employed to answer that research question, sometimes the IRB will make recommendations that increase the protections of human subjects while also improving the methodological rigor of the study. Therefore, it is possible that the IRB can provide additional support to improve the quality of your study.

Slide 3

The first question you have to consider when designing your research project is to determine whether or not the data you want to collect are actually considered research data according to the federal and IUP definition. This may seem like a strange question, but you first have to ask yourself: Is the activity that I want to do even considered research? The reason this question is important is because the IRB is federally-required to review and approval all research that involves human subjects. The federal government actually defines *research* very specifically. If the activity is categorized as research, then the IRB must review and approve it. If the activity is not categorized as research, then the IRB does not need to review it. Importantly, the categorization of whether a project is research or not rests with the IRB, not the principal investigator. When in doubt, contact the IRB for its decision.

So fundamentally, you need to ask yourself this question: Is the activity I want to do considered research by the federal government and IUP? The way you answer this broad question is by responding to three related questions:

1. Is the activity a systematic investigation? Meaning, do you have a very specific set of research questions? A thesis or dissertation, for example, likely has at least one research question. Most empirical inquiries have at least one research question. Relatedly, is the research question being answered by a methodology that will procure data to answer that research question? If you have a research question and a methodology that will be employed to answer that research question, it is very likely that you are about to engage in systematic evaluation.

2. The second question you have to ask yourself is: Is the information you would like to gather intended to be shared to produce generalizable knowledge? By this we mean, what is the audience with which you want to share results from this work? A wider audience, in most cases, typically means more than just your thesis or dissertation committee or students in a particular IUP class you might be taking. If you are going to share results with professional colleagues, if you are going to attempt to get your results published, if you are going to share results with your mom or your dad, or if you are going to go to a conference and present results, then all of those would be examples of sharing results with a wider audience to produce generalizable knowledge. Research is any activity that has the intent of producing generalizable knowledge that is shared with a wider audience.

If you intend on producing generalizable knowledge, then your activity likely would be considered research.

3. The third question seems very obvious: Are you collecting data from people? If you are collecting data about road signs, but not people, then your activity would not be considered human subjects research. However, if you want to collect any data from people, then your project might be considered human subjects research.

If you answer yes to these three questions, then what you are about to do is considered "human subjects research" according to the federal government and IUP. If you answer yes to these three questions, then you will need to submit a research proposal to the IUP IRB for its review and approval **before** you engage in any subject recruitment or data collection. The IUP IRB must review and approve your research project before you can begin subject recruitment.

Slide 4

The information that you provide to the IRB is submitted to the Chair of the IRB. The Chair performs a quick review of the proposal to determine what type of review it receives. Notably, the IRB determines what level of review is conducted on a proposed research project. In turn, the type of review conducted typically dictates how many IRB members review the research proposal and the time it typically takes the IRB to complete its review. More on these latter two issues in a bit.

Importantly, the researcher does NOT make the determination as to what type of review is conducted. While hopefully obvious, the reason the IRB makes that determination and not the researcher is because the researcher may be biased in their appraisal.

Therefore, let's summarize these three types of review: Full Board, Expedited, and Exempt.

Slide 5

The first type of review that can be conducted on a research project is termed a Full Board review. Quite honestly, few research projects generated by researchers at IUP are categorized as needing a review by the full committee of the IRB. A full board review occurs when the research subjects are likely to be exposed to a level of risk that is greater than what they would typically experience in a given day. This term *minimal risk* is a subjective statement. But more than minimal risk typically means you want to collect data from members of a protected population or you are asking your research subjects about intrusive, stressful, or potentially traumatic events. Let us first consider the former: members of a protected population.

Some research that proposes to gather data from protected populations could be categorized as more than minimal risk and thus reviewed by the full committee of the IRB. Such protected populations include minors under the age of 18, individuals who are incarcerated, pregnant women, fetuses, individuals with mental health challenges, and individuals who are economically or educationally distressed. Notably, for all of these protected populations, it is the intersection of their protected population status *and* the content of the research topic that determines whether the project is categorized as needing a full board review. For example, asking women who are pregnant about their preferences of clothing would not be considered

more than minimal risk because the women's pregnancy is not directly related to nor potentially harmful when you are asking about their clothing preferences. But if you are asking women who are pregnant to perform some vigorous exercises, the exercises could potentially put the mother-to-be or fetus in jeopardy, so a full board review would be warranted. Similarly, asking 3rd graders their thoughts on a specific lesson plan intended to teach the different phases of the moon would not be considered more than minimal risk to the school children. Asking 3rd graders, however, whether they ever have been bullied and how they dealt with being bullied would likely be more than minimal risk and thus reviewed by the full committee of the IRB.

I hope these illustrations help you understand that simply attempting to collect data from a protected population does not automatically make the research project one that must be reviewed by the entire IRB committee. But rather, a full board review is conducted when the specific nature of the subjects' protected population status is a central feature or aspect of the study.

Aside from the additional review afforded to research projects that attempt to gather data from protected populations, the nature of the research itself – regardless of your subjects' characteristics – might warrant a full review by the IRB committee. These are studies in which the content under investigation is personally intrusive, stressful, or potentially traumatic. For example, a study of people's criminal, or illegal, behavior would likely require a review by the full committee of the IRB. Asking extremely intrusive, personal questions about topics such as sex or drug use likely would be viewed as more than minimal risk, resulting in a review by the full committee of the IRB. Studies that ask participants to reflect on painful or traumatic life experiences might also be categorized as requiring full board review. Finally, a research design that intentionally deceives subjects would also likely be categorized as requiring review by the full committee of the IRB. These all would likely require review by the full committee of the IRB.

As a reminder, before we move to the next level of review, the categorization of the type of review is made solely by the IRB, not by the researcher. But it is important for researchers to know *why* and *how* their research projects are categorized for review.

Slide 6

The remaining two types of reviews are far more likely to occur at IUP given the types of research being conducted at our institution. Again, a reminder that the IRB determines the level of review, not the researcher.

An expedited review means there is no or little risk to the human subjects. We estimate that at least 95% of the research projects at IUP are reviewed this way. An expedited review means that the research project does not involve any protected populations and / or the nature of the empirical inquiry is rather benign. That is, the data to be collected are not of a sensitive or personal nature. Subjects are asked to report on every day experiences. Moreover, research projects that do not intentionally withhold information from the subjects in an effort to deceive them from the true purpose of the project might be reviewed in an expedited manner.

An exempt study is one that, just like an expedited review, involves research activities that do not put the subjects at any heightened risk. Often, but not always, these projects typically utilize

data that are anonymous, so the researcher is not able to identify the source of the data. Exempt studies oftentimes include data that we refer to as archival, meaning somebody else collected the data and now the researcher is requesting to access those de-identified data.

Because both expedited and exempt reviews involve little to no risk to subjects, they do not have to be reviewed by the entire IRB committee. In fact, expedited and exempt reviews are completed by just one member of the IRB, often either the Chair or the designated Expedited Reviewer.

Slide 7

We use the term *protocol* to indicate the information that is submitted to the IRB for its review. The protocol is the complete description of the purpose of the research project, all subject recruitment and data collection efforts, the process for obtaining informed consent, and how the privacy afforded to subjects will be guaranteed.

IUP uses a secure, online portal for IRB protocol submissions and the entire review process. This system is called IRBManager. The link to log into IRBManager using your IUP single sign-on credentials, as well as a few How to Guides, are indicated on this slide. A note to student researchers: student researchers must have a faculty advisor to mentor them through the entire IRB process. Within IRBManager, student researchers submit their protocol to their faculty advisor. The faculty advisor reviews the research protocol and mentors the student researcher until the research protocol is ready for submission to the IRB for its review. When that occurs, the student researcher submits the finalized research protocol to the faculty advisor who, in turn, submits it to the IRB.

Once you and your research team – including your faculty mentor if you are a student – have submitted your research protocol to the IRB, you will receive an automatically-generated email to your IUP account from IRBManager indicating that your protocol was received. Within 2-4 business days, you will receive another email from IRBManager indicating what level of review your project was assigned. If your research protocol is assigned for a Full Board review, that email will also indicate the date of the next Full Board meeting. In the case of expedited or exempt studies, you will hear directly from the IRB member who was assigned to conduct that review.

As can be seen on the table at the bottom of this slide, the type of review conducted on your research project dictates the length of time you will need to wait until your project is reviewed. If your project is designated for full board review, then the date on which your protocol was officially submitted to the IRB will dictate the IRB meeting at which your project will be reviewed. Please visit the IRB website to see a complete list of dates that protocols must be submitted to IRBManager to make the agenda for the next meeting of the complete IRB committee. Projects designated as expedited and exempt reviews will be reviewed on an ongoing basis, as they are submitted to the IRB. Consequently, these expedited and exempt reviews are typically completed and provided to the researcher within 7-10 business days.

Please note that these timelines are *estimates* and do not include the amount of time it takes you and your research collaborators – including faculty advisors – to review and finalize a research

protocol. It is very likely that researchers collaborating with others or students under the mentorship of a faculty member will require multiple drafts of a research protocol before it is finally submitted to the IRB for its review.

It is also important to inform you that there is a very high likelihood that your research protocol will need to be revised once or twice before it is finally approved. It is actually fairly unusual for a researcher to have a research protocol approved on its first submission. Usually researchers have at least one revision, simply because there is so much that has to be carefully detailed in a protocol that it is very easy to miss something. Therefore, we encourage all researchers to factor in extra time to receive IRB approval given this process typically takes longer than most researchers initially believe.

Slide 8

As was stated earlier, you will receive an email notification from the IRBManager system to your IUP email account indicating that your research protocol was received. Within a few business days, you will receive a second email indicating what category of review your study was designated: whether it was designated for a full board review, expedited review, or exempt review. Next steps will be detailed in that second email.

Please know that all communications with the IRB, IRBManager, and in any aspect of your research project must be conducted using your IUP email account. You are not permitted to communicate or conduct your study using a non-IUP email account. The reasons for this are because IUP must have complete oversight of all research that is conducted under its federal-wide assurance, including monitoring of email communications.

Finally, while it should go without saying, it is important that researchers understand that they cannot commence with any research activity – including recruiting subjects – until they have received official approval from the IUP IRB. Failure to adhere to this requirement would be a gross violation of research ethics.

Slide 9

If your research project is designated as requiring a review by full committee of the IRB, you will be invited to the next IRB Meeting. The date, time, and location will be provided to you. We strongly encourage researchers and their collaborators, including faculty advisors, to attend these meetings as they are often quite fruitful in clarifying issues or concerns that members of the IRB have. Further, researchers who attend these meetings typically experience a much more efficient approval process because they attended the meetings and were able to respond to IRB members' questions.

If researchers are not able to physically attend the meeting, we can accommodate them via conference call or some other conference technology like Zoom. Please make us aware of your needs, and we are happy to make those accommodations.

Attending a full board meeting is not intended to feel like an interrogation. Rather, it is an opportunity for the IRB members to ask questions, seek clarifications, offer advice, and generally become more informed of your proposed research project. Basically, the IRB just wants to find

out more about your study. IRB members will ask questions, and researchers are invited to ask questions of the IRB. At the conclusion of the meeting, the researcher is excused so the IRB committee can discuss in executive session. An official decision is communicated to the researcher within 4-5 business days.

Slide 10

Let's just imagine for a moment that your research project was approved by the IRB. Congratulations! You are now permitted to recruit subjects and collect data. But let's also imagine that once you receive IRB approval, you realize you need to make a change to your recruitment or data collection methods.

If you determine that a change to your already-approved methodology is necessary, you must first receive approval for these changes before you can implement them. Basically, the IRB must review and approve all changes before you can deviate from your approved methodology.

There is a form on IRBManager to formally request a change in a research protocol that has already been approved. The form is pretty simple. It's called a *Request for Change in IRB Protocol*. Like all other forms related to the IRB approval process, this *Request for Change in IRB Protocol* is found within the online, IRBManager system.

Researchers fill this form out and append any new research materials and the existing informed consent. These reviews are typically completed within a week, although if the proposed changes increase the level of risk to the subjects, the request for change may need to be reviewed by the full committee of the IRB at its next monthly meeting. Most requests for change, however, are rather simple, do not increase the level of risk to subjects, and can be reviewed within a week.

Slide 11

That was a brief summary of the IRB review process. While there are many details and processes that occur within the overarching IRB review process, you now have a general idea of how human subjects research is reviewed and approved at IUP.

We now turn our remaining attention to the task of creating an IRB protocol that is clear, well-organized, fully describes the entire research project, and results in a project that is approved. This is no small task and one that often slows down the research enterprise because researchers fail to submit strong research protocols to the IRB. The next set of slides are intended to position you as the researcher to have a successful and efficient experience with the IRB.

Frankly, authoring a strong research protocol should not be a mystery. Therefore, in the remaining slides, we attempt to demystify the process by telling you exactly what you need to consider and carefully describe in your research protocol. Bottom line: if you remember nothing else from this review, remember this one piece of advice: carefully follow the instructions that are provided in the IRBManager system. If you read the directions and follow them, your IRB review and approval process will be much smoother and will be completed much more quickly than if you elect to ignore or do not attend to the instructions within IRBManager.

Slide 12

Everything you submit to the IRB for review is completed using a secure, web-based system called IRBManager. The link to log-into IRBManager is listed here. There are a few How To Guides regarding IRBManager posted on that website, including how to log in, how to create a new research protocol, and how to designate research collaborators and faculty advisors within IRBManager.

When you are ready to log into IRBManager, you sign on using the same credentials you use to log in to your email or any computer on campus. Please then follow the instructions in those How to Guides to create your research protocol and, as applicable, assign collaborators and faculty advisors.

Slide 13

Here are some general tips on how to write a clear, comprehensive research protocol that will result in a more efficient and pleasant experience receiving IRB approval. First and foremost: Please follow the instructions that are embedded directly into the IRBManager system. The instructions are in red text on the right-hand side. Being able to carefully attend to all the details listed in the instructions for each text field will position you well for a more efficient approval.

Many of the first text fields in IRBManager are just demographic information: your name, and, as applicable, names and contact information of your collaborating colleagues and faculty advisor. For your estimated project start date, provide your best estimate of when you will start, taking into account the length of time needed to receive IRB approval. Importantly, you cannot start recruiting subjects or collecting data until you get approved anyway, so indicate a start time for the project that seems reasonable. When you put in your estimated project end date, please read the directions. The directions clearly indicate that approval cannot be for more than one year. So, indicate an estimated project end date that is no longer than 365 days from the project start date.

Next, you start completing information that is very specific to your recruitment and data collection processes. For example, provide details on the purpose of your study. Provide a short background to the study. You will describe how subjects are recruited, including appending the recruitment tools such as emails or flyers for IRB review and approval. Then you will detail all the research activities that subjects will complete, and you will append all research materials such as survey or interview questions or other data collection tools. The informed consent document is appended as are any site approvals as necessary.

Some researchers prefer to complete the description of all these details within Microsoft Word or some other application and then copy / paste that narrative into IRBManager. You can certainly do that. Note that when you paste into IRBManager, sometimes the formatting of the text is compromised. Things that are italicized or bolded may not appear as such in IRBManager. Do not worry so much about formatting within IRBManager. Focus your energy on writing a well-organized, thorough, and articulate protocol.

Other researchers, however prefer to enter all the information directly into IRBManager. Please note that you can save your information by clicking "Save" and return to your protocol within IRBManager at a later point in time.

A final general note about writing a good protocol within IRBManager: Remember that the IRB reviewers most likely do not know your discipline at all. Using acronyms without first identifying the acronym will confuse the reviewer. Using jargon or discipline-specific language without careful explanation will result in an unfavorable review. Please make sure you are mindful of the fact that the reviewer does not know your discipline. Assume that the person who is reviewing your research protocol does not have any experiences to which they can relate to your research area. Therefore, make your research protocol very clear to someone who does not have any discipline-specific knowledge. Pretend that you are explaining your study to your parents or your grandparents or your significant other. Do not leave it up to our imagination as to what you are trying to do because the reviewer may not assume correctly and request revisions to your protocol.

Slide 14

The next section of the research protocol in IRBManager is the method of subject selection, otherwise known as the recruitment process. This is where you describe how are you going to get subjects to agree to participate in your study. Tell us exactly how are going to recruit subjects. Complete this section by carefully following all the instructions embedded within IRBManager.

Be careful of the relationship you may have with potential subjects and whether potential subjects might feel coerced, or compelled, to participate in your study. If you have a supervisory or hierarchical relationship with potential subjects, you will need to develop a recruitment strategy that provides potential subjects a way of declining to participate with a sense of ease that you will not punish them for their declination. This situation happens in some research conducted at IUP when researchers want to recruit students in a class that they are teaching. The students in that class may feel compelled to participate to curry favor with, or appeal to, the instructor. This scenario is a perfect opportunity for coercion to adversely affect the voluntary nature of the subject's decision to either participate or not. Therefore, recruitment strategies that mitigate this potential for students in a class to feel coerced to participate in their instructor's research must be described in this section.

If you are using recruitment materials, like an email, a flyer, an advertisement, or a social media post to recruit subjects, the IRB must review and approve those recruitment materials. The recruiting materials must minimally contain the following content: Briefly state the purpose of the study. Tell potential subjects what they will be asked to do. Provide your name and your IUP contact information as well as your advisor's IUP contact information, if applicable. Finally, please include the statement that is in all capital letters at the bottom of this slide. Do not rewrite or modify that statement in any way. Just include it verbatim in your recruitment materials. That statement is commonly referred to as our boilerplate statement and must be included on all recruitment documents.

A note related to electronic communication with potential subjects and those who consent to participate in your study. All email communications throughout the entire research project must

be completed using your IUP email account. This is because IUP provides oversight of your entire research project, and therefore must be able to access your email if necessary. IUP does not have ownership over your personal Google or Yahoo account, so we do not allow you to use your personal or non-work or non-IUP emails in any activity related to your research project.

Slide 15

The next large section of the research protocol in IRBManager is the Methods and Procedures Applied to Human Subjects. Essentially you must describe very carefully and thoroughly what your consenting subjects will do from the moment they provide consent to the moment they have completed all research activities.

The first important note about the content you include in this section is: Please carefully and fully follow the embedded directions within IRBManager. Remember that we don't know your discipline. Please detail exactly what your research subjects are doing from the moment they agree to participate until the last time you interact with them. If there are gaps in the steps of your research methods, we are going to be confused and will request revisions to clarify missing details.

While describing the steps of the research subjects' participation, be mindful of any risk that they might experience. If there is the potential for research subjects to be at risk – of physical, psychological, or emotional harm – then describe what steps or precautions you will take to either prevent or mitigate that risk. These preventions or mitigating efforts must be included in your Methods and Procedures Applied to Human Subjects section.

This matter of risk is at the heart of why IRBs exist in the first place. It is our job as the IRB to ensure that all potential risks are identified and either prevented or mitigated. That is the #1 priority of the IRB. Therefore, we ask that researchers be mindful of potential risks and plan out their methodology to address these risks.

Please append all research materials that you use, such as survey and interview questions, testing materials, print materials the subjects will use, and demographic questions. Provide clear citations or references to the appendices within the Methods and Procedures Applied to Human Subjects. Many researchers find it easiest to number or letter their appendices and specifically indicate those numbered or lettered appendices within the Methods and Procedures Applied to Human Subjects section.

In summary, the IRB must review and approve all tools used to collect data from your human subjects. Please include those in your research protocol.

A few additional details to consider and include in your research protocol when using a common research methodology employed at IUP: focus groups. A focus group is when you have more than one person in a room who is responding to questions or prompts from the researcher. If you use a focus group, please append a script that is read by the person who is facilitating the focus group detailing the *ground rules* of that focus group. The ground rules of a focus group should include statements that you cannot guarantee that everybody will keep the conversation confidential. You can *request* that focus group participants keep the conversation to only those in

the focus group, but you cannot monitor what focus group attendees tell others outside the focus group. This all relates to the limits of guaranteeing the confidentiality of focus group conversation. Details like this should be included in the focus group script that is submitted for review to the IRB.

Slide 16

After the section on Methods and Procedures Applied to Human Subjects is a section on the privacy afforded to the research subjects. Once again, please follow the instructions embedded within IRBManager. Beyond that, please note: privacy and confidentiality are not the same. Privacy is a term that represents the degree of access people outside of your research team have to the identities of your research subjects. In other words, privacy refers to the extent to which you can disclose the identity of research subjects.

There are three different levels of privacy and they are each listed very clearly right there for you. The level of privacy is dependent on the amount and quality of data provided by the research subjects.

Anonymous means that you as the researcher have no way of identifying the person who provided those data. For example, research subjects that complete a survey without providing any sort of identifying information such as names or birthdates would be considered to be *anonymous*.

A *confidential* research subject is someone who provides data that you, as the researcher, can attribute to an individual, but you promise not to share their identity with anybody outside of the research team. An example might be someone who completes a recorded interview or a focus group. You absolutely know their identity and can match their responses to their identity. But, given they are confidential research subjects, you will not disclose their identity to anyone outside of the research team unless legally required to do so.

The third level of privacy, which is the least protective, is *no expectation of privacy*. This level of privacy means that anyone outside of your research team could reasonably identify the source of the data, so the research subject has no expectation that his / her identity will remain private. In these situations, the research subject would be told that they have no expectation of privacy, and they would have to determine for themselves whether they wanted to participate.

Let me work backward in this list to provide some examples. *No expectation of privacy* would likely be the situation if you wanted to interview the President of IUP on their thoughts on the direction of the university. Any reasonable person could very easily identify who the President of IUP is, so if the president agreed to participate in the study, they would have no expectation of privacy.

Recall that a *confidential* research subject means that you know the identity of the research subjects and how they responded to the research materials, but you promise not to disclose their identities to the rest of the world. An example might be to conduct a series of interviews with law enforcement to obtain their perspectives on gun laws. To help your research subjects feel comfortable being as honest as possible, you tell them you will never disclose their identities to

the public. Therefore, these research subjects would be *confidential* research subjects. To maintain the confidence of their identities, you use pseudonyms, or fake names, and / or only report data in the aggregated form.

Finally, recall that an anonymous research subject is one who provided data to you, but even you cannot identify the source of the data. Research subjects' identities are unknown even to you. An example would be a survey of IUP students procured from a randomly selected panel of 1,000 IUP email accounts. The survey does not request any identifying information such as names, Banner IDs, social security numbers, or other personally-identifiable information.

By the way, IUP has access to an online survey platform called Qualtrics. Qualtrics is much like Survey Monkey or Google Forms. Qualtrics is the preferred platform for IUP researchers to conduct survey research. Qualtrics is a very simple, effective way to collect anonymous data for a research study.

When you are designing your research study, you should be thinking about what level of privacy you will afford your human subjects. That will dictate a number of things, including your research methodology and statements in your Informed Consent letter regarding subjects' afforded level of privacy and how your methodology is consistent with that level of privacy.

You have to be careful though when determining the level of privacy you afford your research subjects and the type and amount of data you will be procuring from them. Depending on the demographic questions you ask your research subjects, you *may* not be able to categorize your research subjects as anonymous or even confidential. It is possible that by cross-referencing or triangulating demographic data, you or others could identify the source of data.

For example, suppose you are surveying students at IUP using a survey that you intended to maintain the anonymity of the research subjects. Because they are anonymous, I do not know the identities of any participant. However, imagine if your survey asks the following three demographic questions: 1.) What is your major? 2.) What is your sex? and 3.) What is your race? In isolation, there would be no way to identify the source of data from responses from just one of those demographic questions. But if you or others had access to responses from all three questions, it might be possible that the source of the data is now identifiable.

Let us say, for example, there is only one Latinx, female nursing student at IUP. If that student participates in the survey and indicates "nursing major," "female," and "Latinx," then anyone could potentially triangulate those data and identify that research subject and her responses to the survey. That person is no longer anonymous – they are now confidential. This could be problematic because our informed consent letter – the document the research subject agreed to before participating – indicated that their identity would be anonymous, not confidential. In this hypothetical situation, the researcher has now inadvertently violated the privacy of a research subject.

Here is another example. Suppose you are researching the eating habits of IUP student-athletes using a survey intended to gather anonymous data. If the demographic survey asks for respondents to indicate their sport and their weight, a violation of a student-athlete on the

football or basketball team could potentially occur. Since height and weight information about some athletes is readily available on the IUP website, it would be fairly easy to identify the person who responded to the survey as being a 220-pound, male basketball player.

The point here is that by asking just a few demographic questions, a researcher could very easily violate the level of privacy afforded to a subject as indicated in the methodology and informed consent letter. The IRB errs on the side of caution - we just assume that it might be possible to identify research subjects given a handful of demographic data.

Importantly, all the above research examples could be approved at IUP. The researcher, however, has to be very clear about the level of privacy, and how that matches your methodology including the amount and quality of demographic data collected from research subjects.

Slide 17

Let's take a few moments to check your understanding regarding the different levels of privacy.

1. Suppose I interview the mayor of Indiana, Pennsylvania, and I identify in my research summary that my source of information is the mayor of Indiana, Pennsylvania. Is that research subject *anonymous*, *confidential*, or do they have *no expectation of privacy*? Think about your response for a moment. [Pause.] The correct answer is that that research participant has *no expectation of privacy*. Anyone who reads the research summary will be able to easily identify the major of Indiana, Pennsylvania by name.

2. Let us imagine that I push out an online survey asking for research subjects to tell me about their experiences learning a second language. In the survey, I do not ask research subjects to disclose any personal information. I do not ask for names, dates of birth, addresses, etc. In this scenario, are the research subjects *anonymous*, *confidential*, or do they have *no expectation of privacy*? [Pause.] The correct answer is that these research subjects are *anonymous*. As the researcher, I have no way of identifying a research subject in the data set because no identifying data were collected. Therefore, the research subjects are *anonymous* to me.

3. Consider a third study in which I want to collect the high school and collegiate grades of students at IUP along with their performance scores on the SAT examination to determine how well high school and SAT scores predict college performance. My research subjects give me their personal information such as names and Banner IDs so I can collect and link those data. But my research subjects are provided a protection from me that I will not disclose their identities to anyone else. In this scenario, are my research subjects *anonymous*, *confidential*, or do they have *no expectation of privacy*? [Pause.] The correct answer is that these research subjects are *confidential*. I am obtaining their personal information, including names, grades, and SAT scores; however, I promise to not disclose their identities to anyone else. Consequently, these research subjects are *confidential* participants.

I hope these three illustrations provide additional clarity regarding the three levels of privacy. Please make sure your methodology and informed consent processes are consistent with regard to the level of privacy provided to research subjects and that the maintenance of that level of privacy is consistent with the methodology employed.

Slide 18

Informed Consent is a *process* of clearly explaining to potential research subjects the purpose, activities, risks, benefits, and level of privacy afforded to them if they agree to participate. Informed consent is a *process* that often includes a document. Therefore, in your research protocol, you must describe the *process* of obtaining informed consent, but also – as applicable – provide a copy of the informed consent document for review and approval. To that end, please follow the embedded instructions in IRBManager when completing the fields to describe the *process* of obtaining informed consent and when creating the informed consent document that you upload for review.

The informed consent document is likely to be scrutinized the most and, as a result, often requires revisions. The reason the informed consent document is scrutinized this much is because it is one of the few documents that research subjects actually obtain from researchers to take home with them. Again, please make sure to follow the instructions as to what all must be included. There is quite a lot of information that must be included, so please attend to the details. We also have posted some sample informed consent documents. Please use the language from our examples - you do not need to recreate an informed consent document on your own.

Please make sure that everything that is required in the Informed Consent document is very clearly stated and written in language and terms that are understandable to the subjects. Be very mindful of the language you use in your informed consent document. You want to avoid jargon. If the informed consent document is to be printed out, please indicate that it will be printed on department letterhead. If the informed consent document is going to be emailed to potential subjects, please indicate you will email it from your IUP email account.

The following is not an exhaustive list of required elements to be provided in the informed consent document; however, those listed here are the elements of informed consent documentation that are often omitted.

Tell your subjects how long it will take them to complete all research-related activities. Tell them what they will be asked to do and what the direct benefits to them are if they choose to participate. This latter issue is sometimes a little confusing to researchers because the purpose of this is to clearly indicate what, if any, benefits there are *to the human subject,* not necessarily the benefits to the researcher or the rest of the world. The human subject might not really care how this research benefits you or the rest of the world. The purpose of this requirement is to tell them what benefits there are *to them*. If there are no direct benefits to them, simply tell them that.

If you have any funding sources, you have to disclose those funding sources in your informed consent document. If you are awarded a grant, you have to tell them that this project is being funded by that grant and specify the name of the grant.

You have to make sure that participants receive a copy of the informed consent document for their records. If you email the informed consent document to them or if your informed consent is the first question in your online survey, then you do not have to provide them with another copy because they had access to it in the email or before accessing the survey.

Finally, here's that boilerplate language that is required to be at the bottom of your Informed Consent letter. Please make sure that this language is included there as well.

Slide 19

There are times when researchers ask an agency, organization, or company to provide *substantive* support for a research project. When a researcher needs substantive support from an agency, organization, or company to complete the research study, a site approval letter must be submitted with your research protocol for review and approval. The most common instances in which a site approval letter is needed include:

(1) When the agency, organization, or company is being asked to help you recruit research subjects. If all the site has to do is push forward an email or hang a few flyers around, no site approval is needed. But if the site is being asked to use site resources to help recruit subjects, then a site agreement letter must be provided.
(2) When the site is being asked to use its own resources to help you in any way with your methodology, then a site agreement letter is needed. For example, if the agency, organization, or company is going to allow employees time during work hours to participate in your study, then we need a site approval letter.
(3) A site approval letter is needed when the agency, organization, or company is providing any data from protected populations. This applies to those protected populations such as children, prisoners, those with mental health challenges, pregnant women, and fetuses. Regardless of the level of privacy for those data, a site approval letter is needed.
(4) Finally, any data that are confidential that the site already has in its possession, regardless of whether the data are from protected populations, must have a site approval letter submitted with the research protocol. An example might be gathering data that the site already has in its possession. A site approval letter is needed in that instance as well.

In all of these cases, a site approval letter, provided on organization letterhead and signed by the appropriate authority, must be submitted with your research protocol. Recruitment and data collection cannot occur until that site has been approved by the IRB.

A final note about these site approval letters: it is completely appropriate for the researcher to ghost write the letter for the site. This might be viewed as a helpful gesture to the site that is about to commit to allocating its resources for the benefit of the researcher. Therefore, please consider assisting the site as it finalizes its letter of agreement on its own official letterhead.

Slide 20

Any student who wants to conduct human subjects research at IUP must complete the required ethics training. This training is completed through a third-party, the Collaborative Institutional Training Initiative or CITI. Students who complete the appropriate CITI ethics training are approved throughout their training at IUP, meaning your research ethics training completed at IUP never expires. Access to the training modules and directions are found at the link on this slide and are also hyperlinked from the IUP School of Graduate Studies and Research website.

When logging into and completing the required ethics training modules, please carefully read and follow the directions. Failure to read and follow the directions will result in you completing

the wrong set of ethics training modules and you will be asked to go back and complete the IUP-required modules. Specifically, after logging in, you will be prompted to answer a few questions. For the first question please make sure to select either (a) Biomedical; (b) Social, behavioral, and educational; or (c) Data / lab specimens. You must complete one of these three sets of modules. It does not matter to the IRB which set of modules you complete as long as it is one of these three modules, although we hope you complete the one set of modules that most closely aligns with your research project. After selecting one of the three appropriate modules for Question #1, choose "No" for the remaining questions.

You will receive a completion certificate in the form of a pdf once you have completed the training modules. Your certificate should list which of the three modules you completed. Notably, your certification should *not* state "Responsible Conduct of Research" or RCR. If "Responsible Conduct of Research" or "RCR" is listed after your module names, you have completed the wrong research ethics modules. Please return to the log in page and answer Question #1 correctly.

Assuming you have completed the correct research ethics modules from CITI, you simply upload that completion certificate into IRBManager.

Slide 21

The following is a very short list of typical omissions or errors in research project proposals submitted to IRBManager that require revisions.

- Insufficient information is provided, or details are missing. If you read and follow the embedded directions in IRBManager, this should not happen.
- Some researchers have a tendency to use technical jargon. Remember that it is very likely that the reviewer is unfamiliar with your discipline and jargon. Please write using language that is understood by laypeople.
- Be mindful of potential coercion that subjects may experience while voluntarily deciding if they want to participate in your research project. This occurs when researchers recruit participants from their subordinates, such as students in a class the researcher is teaching or employees over whom the researcher also supervises. Coercive practice must be avoided. Therefore, if you are planning on recruiting from your classes or supervisees, carefully consider a recruitment and data collection strategy that mitigates the possibility that potential volunteers feel compelled to participate in your research project. This affects a number of things including the recruitment and research activities. It also would affect the wording of your informed consent document in which you must specifically identify the dual role and how that dual role is mitigated to prevent coercion.
- Another omission or error is in relation to correctly identifying the level of privacy afforded to research subjects, correctly stating that to them, and demonstrating how your recruitment, research procedures, data analytic processes, and reporting of findings are consistent with that stated level of privacy. Most commonly, if you ask for specific, identifying information from your research subjects, they are minimally confidential participants; they cannot be anonymous.
- Last, a common omission or error is not thoroughly appraising the level of risk that research subjects could experience. You must think of a worst-case scenario and how your research

subjects would be protected from that worst-case scenario. Details about these risks and protections against those risks must be clearly articulated in your research protocol.

Slide 22

In conclusion, there is a direct relationship between the clarity, precision, and thoroughness of writing the research project protocol in IRBManager and experiencing a positive, efficient approval process. It really comes down to following the embedded directions in IRBManager, the quality and clarity of your writing, and your ability to describe exactly what you want to do in your research project.

The IRB would prefer that you have a good experience in receiving approval to conduct your human subjects research. We are not in the business of making your research efforts more difficult; however, the IRB has the responsibility to make sure that all aspects of the human subjects research enterprise meet, if not exceed, federal standards. The IRB is here to help and provide support. If you have questions, you can always email us while you are in the early stages of formulating your research project. We are more than happy to provide that kind of preventative support in advance of you submitting a research project protocol to the IRB.

Thank you, and best wishes in your research endeavors.