1

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 Cri minal 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 proposal 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 exis tare 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, th e Tuskegee experiments conducted from 1932 to
1972 occurred when the U.S. Public Health Se rvice 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 n atural progression of untreated syphilis. Sadly, these experiments were conducted largely on poor African-American men who were to ld they were receiving free health care from the U.S. gove rnment. There are other ex amples of unethical treatment of individuals in scientific experiments, but these are some of the more notable examples.

3

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 pe opl, 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 res earch 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 be fore you can begin subject recruitment.

Slide 4
The information that you provide to the IRB is s ubmitted 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 th e 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: Fu ll Board, Expedited, and Exempt.

Slide 5

The first type of review that can be condu cted on a research project is termed a Full Board review. Quite honestly, few research projects gene rated 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 intrusiv e, tressful, or potentially traumatic events.
Let us first consider the former: members of a protected population.

Some research that proposes to gather data from ptected 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, in dividuals who are incarcerated, pregnant women, fetuses, individuals with mental health challenges, and individuals who are economically or educationally di stressed. 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

4

more than minimal risk because the women’s pregnancy is not directly related to nor potentially

5

data that are anonymous, so the researcher is not able to identify the source of the data. Exempt studies oftentimes include data th at 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 re views 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 o 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 th epurpose 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 in to 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 research ers submit their protocol to their faculty
advisor. The faculty advisor reviews the research protocol and mentors the student researcher until the research protocol is re ady for submission to the IRB for its review. When that occurs,
the student researcher submits th e 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 re ceive 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 assi

6

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 isfinally approved. It is actually fairly unusual for
a researcher to have a research protocol a pproved 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 typical ly takes longer than most researchers initially believe.

Slide 8

As was stated earlier, you will receive an emai l 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 ema il indicating what category of review your study was designated: whether it was designated for a fu ll 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 ar e 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 requi ring a review by full committee of the IRB, you
will be invited to the next IRB Meeting. The da te, 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 clar ifying 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 technol ogy 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, s eek clarifications, offer advice, and generally become more informed of your proposed research pro ject. Basically, the IRB just wants to find

7

out more about your study. IRB memb ers will ask questions, and res earchers 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

8

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 protoco l and, as applicable, assign collaborators and faculty advisors.

Slide 13

Here are some general tips on how to write a clea r, comprehensive research protocol that will result in a more efficient and pleasant experi ence 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 ar e just demographic information: your name, and,
as applicable, names and co ntact information of your collabor ating 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, soindicate a start time
for the project that seems reasonab le. 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 s ubjects are recruited, including appending the recruitment tools such as ema ils 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 descripti on of all these details within Microsoft Word or some other application and then copy / paste th at narrative into IRBManager. You can certainly do that. Note that when you pas te into IRBManager, sometimes th e 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 ar ticulate protocol.

9

Other researchers, however pref er to enter all the information directly into IRBManager. Please note that you can save your information by clicki ng “Save” and return to your protocol within IRBManager at a later point in time.

A final general note about wr iting 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

10

be completed using your IUP email account. Th is is because IUP pr ovides oversight of your
entire research project, and ther efore must be able to access your email if necessary. IUP does
not have ownership over your personal Google or Yahoo acc ount, 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 careful ly and thoroughly what your consenting subjects will do from the moment th ey 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 reques t revisions to clarify missing details.

While describing the steps of the research subjects’ participation t8u 0uful ofacis ht the yr ightexpre.3(i(en)-23.8(em. If ther)-23.8(g)]TJ 10.576 0 TD [mis)-9
p(s)-5.8y(c)6.8(oul)6.8ogiecalfr reotio(a)-13.2(l)6.8 h(a)6.8(me)6.8( )
pr)-24.6(vmentfr)-20(itr)]TJ 81854 0 TD -.0434 Tc .0434 Tw [igatef t((t r)-24.4()12.4as)-102(k. Thdes)-10.3(ep(rvr)-24

8ky)0((i)6.8(s)-5.8(ac)-13.2(t)6.8(t)6.8(h)0(e)6.8((h)-20(e)6.8(a)6.8(r)0tl)6.8(ofw.)-6.8hy(IR(s)-5.8(ne)6.8(h)0(i)6.8(s) R. Tthere weaisht researchersbr emtiful ofpotjetiar(i)6.8(s)-5.8ky andplcanbout
d ress theser s

ills)-9.2rr(earch t)-1768(te r)-24.4(alas)-102(t th)-2448(tep)-971 youuas(,s)-829(s)-102(u)]TJ 2092308 0 TD -.0017 Tc .0264 Tw

11

the focus group, but you cannot mon itor what focus group attendees te llothers outside the focus group. This all relates to the limits of guarantee ing the confidentiality of focus group conversation. Details like this s hould 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: priv acy 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 identi ty 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

12

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.

13

football or basketball team could potentially occ

14

Slide 18

Informed Consent is a process of clearly explaining to potential research subjects the purpose, activities, risks, benefits, and level of privacy a fforded 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 fo r review and approval. To that end, please
follow the embedded instructions in IRBManager when completing the fi elds to describe the
process of obtaining informed consent and when cr eating 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 infor mation that must be included, soplease 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 requid 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 requ ired elements to be provided in the informed
consent document; however, those listed he re are the elements of informed consent documentation that are often omitted.

Tell your subjects how long it will take them to co mplete 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 confus ing 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 tothem. 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 ha veto 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.

15

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 res earcher 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 a pproval. 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 isbeing asked to use site resources to help recruit subjects, then a site agreemen t 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 al low employees time dur ing 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 applie s 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 sitalready has in its possession, regardless of whether the data are from protected popula tions, must have a site approval letter
submitted with the research protocol. An exam ple might be gatheri ng 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 si te approval letter, provided on organizati on 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 a pproval letters: it is completely appropriate for the researcher to ghost write the letter for the site. Th is might be viewed as a helpful gesture to the site that is about to commit to allocating its resources for the benefit of the resear cher. Therefore, please consider assisting the site as it finalizes its letter of agreement on its own official letterhead.

Slide 20

16

the wrong set of ethics training modules and you will be asked to go back and complete the IUP-required modules. Specifically, afte r 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 mu st 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 et hics modules. Please return to the log in page and answer Question #1 correctly.

Assuming you have compl eted 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.

x Insufficient information is provided, or details are missing. If you read and follow the embedded directions in IRBManager, this should not happen.
x

17

subjects would be protect ed from that worst-case scenario. Details about these risks and protections against those risks must be c learly 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 experi encing a positive, efficient approval process. It really comes down to follo wing the embedded directions in IRBManager, the quality and clarity of your writing, and your abilit y to describe exactly what you want to do
in your research project.

The IRB would prefer that you have a good expe rience 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.