Introduction

This training module is designed to introduce you to USM's IRB submission software, InfoEd. All research conducted by faculty, staff, or students involving human subjects requires prior approval from USM's Institutional Review Board (IRB) to ensure that proposed projects meet federal and institutional standards. Data collected before formal IRB approval is received may not be used under any circumstances.

Necessary Documents

To submit an application, you will need to have several documents prepared.

watched. Your responses will be auto-

The main button that you will use is 'Locate My Records'. Here is where you will be able to find all of your applications that are in draft and approved. To make any changes to a protocol, you will locate the project, then click the 4 lines – the "hamburger," as we call it to reveal more options. From here, you will be able to view your protocol, make edits, or delete any protocols you do not need.

While you may start an application to test out the system or by mistake, it is crucial that you delete any unneeded protocols. Deleting unneeded protocols helps the IRB office provide you with assistance on any protocols you submit and keeps the system clear of unnecessary clutter. To delete a protocol, select 'Locate My Records', find the protocol that you wish to delete, click the 4 bars, then 'Delete,' and then finalize the deletion.

Creating a New Application

Now that we have gotten oriented to the InfoEd platform, let's begin an initial application. To do so, click 'Human Protocol' in the black box on the left-hand side of your screen. Then you will click "Initial Application" to begin. You will see that the initial J 0.00 Tw -10.1w ( )-10(2.1 -8)(1)(4)-8 (t)ie1 (r)y103 a)]TJ 0 Tw (N)T (e)8distllo9 . 1

As you can see, your name will autopopulate here, and you will be asked to indicate whether you are the principal investigator (PI). The person submitting the initial application should always be the PI, so make sure you check this box.

Type 2 is a box to

Research Procedures

The next section is the Research Procedures section. Here is where you provide specific details regarding your project. You will be asked to describe your project and how you plan to conduct it. Remember that you should write your responses for non-experts, avoiding jargon that may not be familiar to the IRB committee member who will review your application.

RP1

This first item is asking you to describe the project and its goals. Here you should define your research question and the goals behind your project. In a nutshell, what are you proposing to do and what do you hope to determine?

RP2

Next, you will describe the intended population you plan to recruit from. How many participants do you plan to recruit? Are there specific requirements for eligible participants (for example, are you only planning to recruit 5 th graders from one elementary school)? If you are running multiple studies, describe the intended population for each study (e.g.: Study 1 = 100 participants, Study 2 = 500 participants).

RP3

The next item asks you to describe how you plan to obtain consent from participants. Remember, informed consent is a process, not a form. Describe that process in detail. Do you plan to print out consent forms and have each participant sign one? Do you plan to present an online consent form to participants once they navigate to your hosting site (e.g. Qualtrics)? Be explicit here. End at the point at which the participants provide their consent.

RP4 & RP5

Next, you will be asked whether you plan to involve any potentially vulnerable subjects and the methods you will take to protect vulnerable participants. You will also be asked whether or not any of the subjects will be under 18 years old. You will see here that if you indicate you will be working with participants under 18 years old, you will be prompted to upload a parental consent form as well as a minor assent form. If you need these, the ORI website has templates available for you to use. Again, we provide sample templates that include the types of information that should be included in a consent document, and while the use of these templates is not required, your consent document must include all of the elements required by federal regulations. Also, all consent forms MUST include both

is meant by these various consent forms, you can always toggle over to the '?' icon for more details.

RP7

The next section asks you to provide more details about how you plan to recruit participants . Describe your recruitment procedures in detail beginning with how you will gain access to the population, and depending on your response, you may be asked to include recruitment materials. Provide details on how you will initially contact potential participants. For example, if you plan to recruit via email, you must upload the email text that you plan to send out. As with the consent documents, all recruitment materials

of these depending on your specific research procedures outlined above, and proceed to the next section.

Risks and Benefits

RB1

The first item asks you how you plan to store the data and how you plan to dispose of your data. Here is where you would say, for example, that data will be locked in a lab/password-protected computer. Best practices on how to maintain and dispose of data vary by discipline, so make sure what you're proposing is in line with guidance for your type of research. You might say, for example, that data will be destroyed three years after the completion of the dissertation. (And if you say you're going to do that, then do it!)

RB2

This next item asks whether your participants will be anonymous. Anonymity means that even investigators cannot associate responses with individual participants. Personal interviews are by their nature not anonymous, assuming the interviewer knows the identity of the person being interviewed. If participants are not anonymous, you will be prompted to indicate if and how you plan to maintain their confidentiality. Confidentiality refers to refraining from disclosing a participant's identity when writing up your findings. Neither confidentiality nor anonymity is required; the point of asking these questions is to make sure you have procedures in place for managing anonymous or confidential data collection, storage, and/or destruction.

RB3

Next, you will indicate whether your research project involves sensitive information such as information about sexual history, past drug use, or personal health information.

RB4

Here is where you will select any possible risks, inconveniences, or discomforts that participants may experience. If there are none, you will check 'None' and move on. For many studies that do not involve the collection of sensitive information, the risks are no greater than one would otherwise experience daily, and so in those cases, you can select 'None.' If you do select any risks, you will also be asked to describe these in detail and describe how you plan to mitigate risks.

RB5

Next, you will indicate whether any incentives will be offered to participants. Incentives are any form of compensation that participants may receive for participating in your study. Incentives can include SONA compensation, gift card lottery entry, free meals, or monetary compensation. If you plan to offer incentives, you will be asked to list them and indicate whether participants who do not complete the study will still be given their incentives. If you do not plan to give incentives out to participants who are

unwilling/unable to complete their participatio n, you need to be clear about this in your consent documents.

RB6

Lastly, describe any benefits that participants may gain from participation. Benefits are any goods or valuable things that may be obtained from participating aside from the incentives. For example, if your project involves teaching participants a new skill, a benefit of participation would consist of learning that skill .

Research Classification

The final section is the Research classificationsection. Here is where you will be asked to select the category that your research project belongs to Indicating the category helps reviewers evaluate your project; the categories are defined in U.S. federal regulations. To read more about the different classifications, check the box 'Display All Category Definitions .' Read through each one and choose the one that best fits your research project. Most research falls under Expedited Category 7.

If your study qualifies as 'Exempt,' this does not mean that the IRB protocol need not be submitted. Whether it is in fact exempt must be determined by the IRB. If the study is approved as exempt, the researcher willnot have to file for a continuation if the study is to be extended beyond the standard approval period of one year. Effectively, 'Exempt' means exempt from 7 (f)-7 (i)4tt Tc 0 Tw d g ( )-8h

receive an email notification when it is ready for their review . Until your research advisor approves your protocol, it cannot be reviewed by the IRB office.

Locating Protocols After Submission

After you submit a protocol, your application is entered into the review process. There are a few different ways to find out where your protocol is in the review process:

1. Check under ‘Locate My Records’
2.