

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.

1. *Consent Forms* – all human subjects research requires informed consent from participants and assent forms for studies involving minors. The various elements of informed consent required by federal regulations are included in the sample consent templates available from USM's IRB website. The templates are intended as helpful starting points only and must be modified with appropriate details of your project. Various templates are available: standard (signed) consent, online consent, parental consent, and others. Other formats, such as a letter to potential participants, are also acceptable as long as all the required elements are included. USM's IRB requires that consent forms include the Principal Investigator's contact information (with a usm.edu email address) and the IRB protocol number.

2. *Research Instrument(s)* – this is a document (or documents) that will be utilized for data collection and/or study procedures. It tracks the specific information that you will be requesting from your participants or explains the nature of your experiment. For example, the instrument might consist of the questionnaire that you plan to use, a published and validated instrument, an interview script, your demographic questions, and/or your debriefing document.

3. *CITI Certificates* – All researchers conducting human subjects research must have active completion certificates for two CITI training courses: the Common Course and the Human Subjects Research course. Your CITI certificates will be automatically linked to your application provided you registered for CITI using your USM email address. If you did not, and instead used a Gmail, Yahoo, Hotmail, etc. address, you must change your email address in CITI. (Instructions for changing your CITI credentials are available [here](#).)

Your IRB application cannot be processed without including these certificates in your application. You can also upload your certificates manually at UA7 on the InfoEd form if they do not auto-populate.

4. *InfoEd Training Course Certificate* - USM students applying for IRB approval will also need to upload documentation showing that they've completed and passed the InfoEd training course. This course consists of 6 modules. In each module, you will be shown a short video clip and will be asked to respond to questions about what you

watched. Your responses will be auto-saved and you can come back at any time to finish. Completing the training in its entirety will take ~45 minutes. At the end, you will be given a score out of 13. In order to pass this training, you must answer at least 80% of the questions correctly (at least 11/13 correct). Should you fail to get 80% of the questions correct, you will need to go through the entire module again, so pay attention and don't attempt to simply guess your way through the questions!

5. *External Permission Letter(s)* – Should you be conducting research with an external (non-USM) organization—for example, you are conducting research in an elementary school—you will need to include documentation of official approval from the external organization. For an example letter, refer to the USM IRB website. The documentation could consist of a letter written on the organization's letterhead signed by an official of the organization or an email from an official at the external organization sent to you from the organizational email address.

6. *Recruitment Materials* – You will need a copy of any materials you will use to recruit your study participants. These may include templates for email messages, scripts for oral announcements, or print materials. All recruitment materials shared with research participants must include your protocol number and a statement that your project has been approved by USM's IRB. Please note that although your study has not yet been approved, this is what your participants will see once your study has been approved.

Logging In

Once you have gathered all of the necessary documents, you are ready to begin the application process. To sign into InfoEd, go to <https://usm.infoedglobal.com> and use your USM (SOAR) credentials—you must use the “w” (w+digits, without the “@usm.edu”).

You cannot log into InfoEd unless you are first registered in USM's InfoEd system. Most faculty members and graduate students are automatically pre-loaded, but if you are having trouble logging in, most likely you need to be added to the system. To be added, fill out the Formstack form on the USM IRB webpage. The direct link to the form is [here](#). Please note that it will take a few days to add new users to the system. If, after 3 days, you do not have access to InfoEd, please contact RISGA@usm.edu.

Initial Application

Once you get logged into InfoEd, you will be shown any applications that need your approval, any messages regarding your protocol, etc. The top yellow bar is where you will find everything you need. The first button is 'My Profile' – here is where you can add any additional details about yourself, although most of the information that is needed will auto-populate, so you do not have to add any additional information if you do not want to. There are also buttons for messages and assignments, although these can also be found on the home page.

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 application has 6 different sections of information for you to respond to. We will now walk through each of these sections and the different questions in each section. There will also be a separate video and set of questions for each section.

Investigator Information

The first section is the Investigator Information section. Here you will be asked for basic information about your project. First, type in your project's title. Next, you will be asked to indicate your research purpose. If your research purpose is a student project (e.g., capstone project, master's thesis, doctoral dissertation), you will be required to add a Research Advisor under the USM-affiliated Investigators section.

Next, you will be asked if any external (non-USM) organizations are participating in the project – for example, if you plan to collect data at an elementary school, you would check 'Yes' here. If you indicate 'Yes', you will be prompted to upload documentation of permission from the non-USM organization(s).

You can see here that some of the prompts have '?' mark icons next to them – these icons provide further detail if needed. So, if we toggle over the question icon for this item, you will see guidance on documentation of support.

IF9 is where you will upload the certificate showing that you've passed this training course. At the end of this course, provided that you've answered 80% of the questions correctly, an electronic certificate will be given to you with your name and completion date on it. That's what needs to be uploaded here at IF9.

USM-Affiliated Investigators

The next section is the USM-affiliated Investigators section. Here you will provide information about the researchers involved in your project (including yourself).

As you can see, your name will auto-populate 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.

There is a box to enter the end date of your serving as a PI, but this can be disregarded for initial applications. End dates are needed only if you are changing personnel and submitting a modification to a previously approved protocol. Next, you will be asked to indicate your role on the project. Again, here you will select 'PI'.

As mentioned at the beginning, in order to conduct human subjects research at USM, you must have completed two CITI training courses (the Human Subjects and the Common Course). Here is where you will need to upload your certificates if they do not auto-populate. To manually upload your certificates, you will select the '+' button here.

The next question asks you to indicate if there will be any USM-affiliated data collectors. These are individuals who are only collecting data and will not be involved in the project beyond data collection. An example of this could be students collecting some data for a faculty member's project. While this is rare, if it applies to your project, you will click the '+' button to add their information including their training documentation (CITI certificates). If this does not apply to you, you can disregard this question.

You may now add additional USM researchers, such as co-PIs or Research Advisors. All students conducting research must add their Research Advisor. To add USM researchers, scroll to the top of the page and click the "+" button next to 'Personnel – Review'. Here you will be able to search for them. Begin by typing the first three letters of the person's LAST name, and you should see a dropdown list of options appear. Once you locate the correct individual, click the name and press select. Now you will see a new section appear on the page with the added individual's information. Here, you will need to indicate the role of this person... so, when you add your research advisor you will select 'Research Advisor' as their role. Your research advisor's two active CITI certificates need to be included as well. These should be auto-populated when you enter in the name of your advisor. However, if not, you will need to upload their CITI certificates to section UA7 under the advisor's name.

Non-USM Affiliated Investigators

The next section is the Non-USM Affiliated Investigators section. If you are working with any non-USM researchers (ex: someone from another University), here is where you will provide specific information about them. If you will not be working with any non-USM investigators, you can disregard this section. To add a non-USM investigator, click the '+' button. You will need to type in the name and organization of each individual and indicate their role. Lastly, you will need to upload any training documentation associated with each researcher (CITI certificates or equivalent certification). Contact the IRB office if you have questions about equivalent certification.

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 5th 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 the protocol number for your project (located at the top of the investigator information section) and your contact information (usm.edu email address).

If you are working with participants over 18, check 'no' and proceed to the next questions regarding what type of consent you will be using. If you are confused by what

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 **MUST** include the protocol number for this project (located at the top of the investigator information section) and your contact information. Please include also a statement that the study has been approved by USM’s IRB.

RP8 - RP10

The next few questions ask for details on how you plan to conduct your study. Will there be multiple interactions? Approximately, how long will each interaction take? Where will the interactions take place?

RP11 - RP12

These next two questions are asking for specific details regarding how you plan to collect data. You will first indicate your means of data collection, then you will provide a *step-by-step* explanation of your data collection procedures in chronological sequence. Begin where you left off in RP 3 – the point of consent. Include enough detail so that the IRB reviewer can understand exactly what you are proposing to do. If your data collection involves the use of audio or video recordings, this should be explicitly mentioned in the consent documents.

RP13

Here is where you will upload all research materials. This includes questionnaires, previously developed instruments, interview scripts, educational materials, and debriefing text that you plan to show participants. All research materials must be approved by the IRB before being included in a study. If after receiving IRB approval you later change the research procedures, you will need to file a modification form and receive approval for the modification before collecting data. When doing interviews, sometimes it is difficult to know in advance all of the questions that may be asked during the interview, so do your best to describe the starting point questions each participant will be asked.

RP14 - RP15

The final items in this section are pretty straightforward. The first asks whether you plan to use hidden video/audio in your study, and the second asks whether your study involves human biological samples, the use of physical exercise, medical examinations or procedures, or the use of drugs or biological products. You can select yes/no for each

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 participation, 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 classification section. 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 will not 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 *further* IRB scrutiny.

Saving/Submitting/Validation

Now that you have walked through all the different sections of the initial application, you are ready to submit your application for review. You will notice at the top of the application, there are various buttons. When you are working through an application and are not yet ready to submit, you can always click the 'Save' button to come back to it later.

Once you are ready to submit, you will first click 'Validate' – validation ensures that you have answered all the questions that you need to and have not missed anything. Once you have validated the proposal, click 'Check to Submit.' This button prevents further edits from being made. Lastly, click 'Submit' to enter your application into the review process.

If you have done all of the above steps and after clicking submit, your application is still 'In Development'/your application does not submit, you need to make sure that your pop-up blockers are turned off. To submit successfully, you will need to allow pop-ups. After you have enabled pop-ups, retry submitting.

After you submit, the protocol will then need to be reviewed and approved by your co-PIs, if you have any, and your research advisor. Your co-PIs and research advisor will

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. Search for your protocol in 'Quick Find'

Locate my Records/Quick Find: - Under 'Locate My Records', you will see all of your applications currently in the system. Refer to the record status to determine the status of your application. If an application is 'In Development', this means it has not been submitted. If you have multiple submissions under one protocol (initial, modification, etc.), to determine where a specific submission is you will need to 1) click the icon with 4 lines, the "hamburger," 2) click 'View', and 3) click on the specific application you are trying to locate. Next, click 'Show Current Route' and you will be shown where exactly your submission is in the review process.

Figuring out where your application is helps you see who you should reach out to about pushing your application forward. For example, if your application is with your research advisor, reach out to your research advisor. Once with the IRB office, the review process may take up to 4 weeks. You should not expect to be able to start data collection shortly after submitting your IRB application.

Revising an Initial Application

If your study is sent back with revisions required, you will receive an email with a link where you can go into the submission and review/address any comments. To unlock the submission to make edits, you must click the 'Un-check to Edit' button. **DO NOT CREATE A MODIFICATION – YOU MUST REVISE YOUR INITIAL APPLICATION.** Yellow triangles indicate a comment that does not require a response, while red exclamations indicate a comment that requires a response. All comments requiring a response must be addressed prior to resubmitting.

To view/address comments, click on the comment icon. Once you read the comment, you can make the necessary revisions and type a response to the reviewer indicating the comment was addressed by clicking 'Reply'. **Do not create a new comment, you must reply to the original comment.** You must address all comments that have a required response prior to submitting. Once all revisions have been made and all comments have been addressed, you must click the 'Check to Submit' button followed by 'Submit'.