Tips on Completing the IRB Protocol for Projects Using External IRBs form Research projects

The following are some tips on completing the IRB Protocol for Projects Using External IRBs form. I will start at the beginning of the form and work my way through it. The goal is to have it in the best shape so when the IRB reviews the form, there is no request for clarification, no request for revisions thus facilitating approval of the project. Requests for clarification only slow the process.

Complete the IRB Protocol for Projects Using External IRBs if your project was approved with Expedited status or full committee approval at the other institution. In this case, the other institution will be the IRB of record. If your project was approved with Exempt status at the other institution, complete the IRB Protocol for Human Subjects Research. In this case you will have IRB approval at both institutions, the external site and the University of Arizona.

NOTE: This is for the IRB Protocol form <u>version v2023-12</u>. If you are using an older version of the form, stop and use the current version of the form. Older versions of the form will not be accepted by the IRB. They will be sent back and you will be instructed to complete the current version of the form. If you are using a more recent version of the form, some of this may not apply or additional information may be requested.

Basic Information	
Title of Study:	
Short Title:	
Principal Investigator Name:	
Principal Investigator's Department/Unit:	

- The short title is required when submitting to the University of Arizona IRB through the eIRB system. Please do not leave this blank or state 'N/A'. The short title in eIRB should be the same as the short title listed here.
- Principal Investigator's Department/Unit should at minimum be College of Nursing.

1.0 Funding Information
Indicate all sources of funding for the project, including gift funds, departmental funds, or other internal funding. For each funder, list the name of the funder, and the institutional proposal number or award number you received from Sponsored Projects. eIRB tip: For externally funded projects, the institutional proposal or award number provided must be linked in the "Study Funding Sources" section in eIRB.

For most student projects, there is no funding. If you have no funding and are giving compensation to participants such as a gift card or raffle for a gift card, the source of the

funds needs to be stated or the IRB will ask the source of the funds. Here is a suggestion, if self-funded you can check 'Other' and for 'Name of funding source' state Gift card(s) will be self-funded. If you have funding, be careful what is checked, especially if it asks for an institutional proposal or award number and it has not been routed through Sponsored Projects. This will cause a delay when submitted in eIRB.

2.0 Scope of Ceded Activities

2.1 Briefly summarize the research activities the local UArizona investigators will perform. If applicable, you may indicate that this site will perform all procedures described in the sponsor protocol.

Remember you are the University of Arizona investigator. This is what you will be doing on the project even if all activities will take place at the external site. If all activities will take place at the external site, state this and include a detailed description of the activities from recruitment to data collection to data analysis. Include your procedures for recruitment, consenting participants, data collection, and data analysis.
If you will only be involved in a portion of the research activities, include a description of those activities.

2.2 Specify the type of subject populations to be involved, and the expected number of local subjects to be enrolled in the study.

The inclusion and exclusion criteria and the expected number of participants should be stated. If all participants will be enrolled at the external site, state this.

2.3 If applicable, describe the location for storage and dispensing of drugs/biologics/devices.

If this is not applicable, you can leave this blank or state No drugs/biologics/devices will be used.

3.0 Recruitment Methods

3.1 Explain the recruitment process. Describe how potential subjects will be identified, where recruitment will take place, when recruitment will occur, and the methods that will be used to recruit individuals.

Include how participants will be recruited. If by email, include who will send the email. If by flyer, include where it will be posted. If flyers will be handed out to potential participants, state who will be handing them out. If participants will be recruited on social media, specify the group/groups you will be posting to and include if they are considered a publicly available group or if the group is considered private. If private, an approval from the individual running the group (letter or email) stating that you have

permission to post the recruitment material is needed. Include a copy of all recruitment material.

4.0 Consenting Process

4.1 Describe the consenting processes in detail. Specify the method of documenting HIPAA authorization (if applicable).

Describe the consent process. If using a Disclosure form, include when/how it will be presented to participants. If using a Consent form, include when/how it will be presented to participants and if it will be paper or online. If the person will sign the consent form, include if this will be an electronic signature or a physical/wet signature. If participants do not speak or read English, documents must be translated into a language they understand or an alternative process available. Include if a translated consent document will be available to potential participants if they do not speak English and how the translation was verified. If applicable, specify the method of documenting HIPAA authorization.

5.0 Privacy of Subjects and Confidentiality of Data

5.1 Indicate if the research team will be accessing any of the following records.

☐ Substance abuse records (HIPAA and 42 CFR Part 2)
☐ Medical records (HIPAA)
☐ Educational records (FERPA)*
☐ Employee records (ABOR Policy 6-912)*
☐ Other, specify:

*Access to information from a University of Arizona employee record or FERPA information requires the written permission of the participants.

If none of these are being accessed, it is fine that none are checked. Nothing additional needs to be stated.

5.2 For each record source selected above, list the data elements to be accessed, who will access them, and how the information will be obtained.

If none are being accessed, you can leave this blank. If any are being accessed, list the data elements that will be accessed; who will be obtaining the information, for example someone on the study or if the information will be supplied by someone else; and how the information will be obtained. It should be clearly stated if identifiers will be included and what they are. If the identifiers are not needed, they should not be obtained, minimum necessary.

5.3 Indicate where data will be stored:

☐ Box@UA	☐ OnCore
☐ Box@UA Health	☐ PACS medical imaging software
☐ Clinical Data Warehouse (CDW)	☐ Password Protected Drive
☐ Cloud Server	☐ REDCap
☐ Department Drive	☐ Transmitting/receiving subject data to/from an outside group
☐ Department Office	☐ UA Records Management & Archives
☐ Encrypted Drive	☐ Banner Server/Platform, specify:
☐ External Drive (hard drive, USB, disk)	☐Soteria
☐ Google Suite for Education	
☐HIPAA Research Computing Service	☐Other, specify:

5.4 For EACH of the storage locations checked above, discuss the type of data to be stored, including if the data will be identifiable, coded, or de-identified upon storage.
If data will be coded, specify who will maintain the code, where it will be stored, and when it will be destroyed. If data will be de-identified, explain if there is any possibility that the data could be re-identified.

> **Definitions:**
> - **Identifiable: The identity of the subject is or may be readily ascertained.**
> - **Coded: Data are separated from personal identifiers through use of a code. As long as a link to identifiers exists, data is considered identifiable and not de-identified.**
> - **De-identified: A record in which all identifying information is removed.**

This asks for multiple pieces of information. First it asks the type of data to be stored, including if data is identifiable, coded, or de-identified upon storage. If only anonymous surveys are being collected and stored in Box@UA, this should be stated. If, for example, coded questionnaires (link between a study number and identifying information) will be stored in Box@UA Health, this should be stated. If data will be coded, include who will maintain the code, where it will be stored, and when it will be destroyed. It is best that the list is destroyed at the conclusion of the study. If data will be de-identified, explain if there is any possibility that the data could be re-identified. If the study includes interviews/focus groups, include that the recordings will be deleted once transcription is complete and the transcripts have been checked for accuracy. It also asks who may have access to the data. Many times, this is not included. If everyone on the study team will have access to the data, this should be stated. If only the PI and the Advisor/Co-I will have access to the data, this should be stated. How long data will be kept also needs to be stated. University of Arizona policy is that data be kept for at least 6 years after the conclusion of the study or if the study involves children, at least 6 years after the youngest child reaches age 18.

5.5 If collecting biological specimens, please describe the storage location for the specimens, including if they will be identifiable, coded, or de-identified upon storage.

If you will have be collecting biological specimens, state the type of specimen that will be collected, where they will be stored and if on storage the specimens will be identifiable, coded, or de-identified.

5.6 Storage of research records (research records should be maintained for whichever of the following time periods is the longest, select one):

☐ I will store research records for at least 6 years past the time the study is concluded.
☐ For studies involving minors, I will store research records for at least 6 years after the youngest participant turns 18.
☐ I will store research records for the length of time required by law or study sponsor, please specify:

5.7 Indicate how data/specimens will be shared with collaborating entities:

☐ Data and/or specimens will not be shared between UA and any outside group or collaborating entity.
☐ Data/or specimens will be transmitted and/or disclosed to an outside group or a collaborating entity.
☐ Data and/or specimens will be received from an outside group or a collaborating entity.
☐ PHI will be transmitted to or received from an outside group or a collaborating entity. *
☐ A Limited Data Set will be transmitted or received from an outside group or a collaborating entity. *
☐ Data/specimens will be sold to pharmaceutical companies.

*If you will be transmitting or receiving any PHI, or a Limited Data Set, as a part of your project, please go to the following link to review the Data Use Agreement (DUA) from the HIPAA Privacy Program.

If you are doing interviews or focus groups and a transcription service is being used to transcribe the data, 'Data/or specimens will be transmitted and/or disclosed to an outside group or a collaborating entity' should be checked.
If data will be collected at the external site and shared with University of Arizona personnel, check 'Data and/or specimens will be received from an outside group or a collaborating entity.'
If data will be collected at both the University of Arizona site and the external sites and shared across sites, check the appropriate boxes.

5.8 Describe what information will be shared, who it will be shared with, and how it will be shared (e.g., secure file transfer, REDCap, etc.). Specify if the shared data will be identifiable, coded, a limited data set, or de-identified.

> If you will not be sharing data, you can leave this blank. If you will be sharing data, you will need to provide a response to all parts requested – information that will be shared, who it will be shared with, and how it will be shared. Also include if the data that will be shared is de-identified, coded, or identifiable. If, for example, a transcription service is being used to transcribe interviews or focus group data, include the name of the transcription service.

Items needed for approval:
- Word version of IRB Protocol form
- Word version of all recruitment material
- Word versions of Consent document(s) and PHI Authorization Form(s)
- If applicable, Appendix for Alteration/Waiver of Consent or PHI
- Data Collection Instruments
- Copy of the IRB approval letter from the external IRB
- Sponsor Protocol (if applicable)
- Current PI CV or biosketch
- Advisor approval (if the PI is a student or resident)
- Department/Center/Section Review approval
- Scientific/Scholarly review approval
- Additional approvals, as needed (e.g., RAP/Banner feasibility, Export Control, Radiation, COI, CATS, Cancer Center SRC, school district approval, tribal approval, etc.)