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

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

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 are no requests for clarification, no requests for revisions thus facilitating approval of the project. Requests for clarification will only slow the process.

Please Note: All sections/questions need a response. If a section/question does not apply, state 'Not applicable'; do not leave it blank.

NOTE: This is for the IRB Protocol form version v2023-12. 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.

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

- The short title is required. 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 some 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. Suggest checking '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.

This is what you will be doing on the project even if you will be doing all research activities at the external site. If you will be doing all research activities at the external site, state this and include a description of these activities. If research activities will take place at University of Arizona sites and you will only be involved in these activities, state this and include a description of these 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. If participants will be enrolled at local University of Arizona sites, state the expected number to be enrolled.

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

If this is not applicable, state Not applicable 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.

Describe the recruitment process. If all participants will be recruited at the external site, state this. If participants will be recruited at local University of Arizona sites, state this.

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. 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.
If all consenting will take place at the external site, state this. If participants will be consented at local University of Arizona sites, state this.

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.**

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 will be accessed, state Not applicable.
If any will be 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.

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 will be identifiable, coded, or de-identified upon storage. If only anonymous surveys will be collected and stored in Box@UA, this should be stated. If coded questionnaires (link between a study number and identifying information) will be collected and stored in Box@UA Health, this should be stated. If data will be stored at the external site, 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 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.

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 biological specimens will not be collected, state this or state Not applicable.
If you will 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 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 site and shared across sites, check the appropriate boxes.
If you will be doing interviews or focus groups and a transcription service will be 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 PHI or a Limited Data Set will be transmitted or received, a Data Use Agreement is needed.

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, state this or state Not applicable.
If you will be sharing data, 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 will be de-identified, coded, or identifiable. If a transcription service will be used to transcribe interviews or focus group data, include the name of the transcription service.

Items needed for approval:

- Word versions of Consent document(s) and PHI Authorization Form(s)
- Appendix for Alteration/Waiver of Consent or PHI, if applicable
- Copy of the IRB approval letter from the external IRB
- Current PI CV or biosketch

- Advisor approval (Advisor Attestation if the PI is a student or resident)
- Department/Center/Section Review approval
- Scientific/Scholarly review approval
- Sponsor Protocol, if applicable
- Additional approvals, as needed (e.g., RAP/Banner feasibility, Export Control, Radiation, COI, CATS, Cancer Center SRC, school district approval, tribal approval, etc.)