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 v2025-10. 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:	
Principal Investigator (PI) Name:	
PI Department/Unit:	

- PI Department/Unit should 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 UA 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 by the PI.

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 the activities. You can include a copy of the IRB form submitted to the external IRB and refer to sections in the form for a complete description of the research 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 the activities.

2.2 Specify the subject populations to be enrolled in the study.

Include a description of the subject population. You can state the inclusion and exclusion criteria.

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

Confirm that potential participants will not be cold contacted (i.e., contacted directly by the research team without a prior relationship or appropriate permission):

☐ Yes, I confirm that no potential participants will be cold contacted by the research team, and that I will adhere to the UA requirements as outlined in the *Recruitment and Advertisements* **HSPP Guidance**.

☐ N/A

If requesting a Waiver of PHI Authorization for Pre-Screening and/or Short Form, complete Section 2 of the Appendix for Alteration/Waiver of Consent or PHI.

Check N/A if University of Arizona research team will not be involved in recruitment activities and/or no recruitment activities will take place at University of Arizona sites**.**

4.0 Consenting Process

Select the consent method(s) to be used locally:

☐ Informed Consent/Parental Permission – written, electronic, online or verbal (including combined Consent/PHI Authorization)
☐ Assent (participants under 18) – written, electronic, online or verbal
☐ Freestanding HIPAA Authorization Form
☐ N/A

Check N/A if University of Arizona research team will not be involved in consenting participants.

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

5.2 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:

5.3 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) and who may have access to the data.
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 is 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 and who may have access to the data. 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 with all having access to it, 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.

5.4 If collecting biological specimens, 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.

5.5 Storage of Research Records:

☐ I confirm that I will store research records for at least 6 years past the time the study is concluded, or until the youngest participant turns 18 if the study involves minors, or longer if required by law or the study sponsor.

5.6 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, review the Data Use Agreement (DUA) information from the HIPAA Privacy Program.**

If data will be collected at the University of Arizona site and shared with the external site, check 'Data/or specimens will be transmitted and/or disclosed to 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.

5.7 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.

6.0 Checklist for Investigators

Review the additional items below that may be required before submitting to the IRB (select all that apply):

☐ Consent Form(s)
☐ Appendix for Waiver or Alteration of Consent or PHI Authorization (as applicable)
☐ Sponsor protocol (if provided by sponsor)
☐ IRB of record approval (for non-commercial IRBs)
☐ Site Authorizations
☐ Current PI CV, biosketch, or resume
☐ Advisor approval (if the PI is a student or medical resident)*
☐ Department/Center/Section Review approval*
☐ Scientific/Scholarly review approval*

☐ RAP/Banner feasibility (if the study uses any Banner Health resources)*
☐ Radiation approval (if the study involves use of radiation)*
☐ UA Cancer Center SRC approval (if the study is cancer-related – see Scientific Review Committee)*
☐ eDoc number (if the study is industry funded or federally funded and the UA IRB is acting as sIRB of record of multiple sites – see Fees for Human Subject Research)*
☐ School district approval* and principal approval (if the study takes place within a school setting)
☐ Tribal approval* (if the study involves a specific Native American tribe or Indigenous population, or will take place on land under the control or jurisdiction of a sovereign tribe)
☐ Clinical and Translational Sciences Research Center (CATS) approval (if the study involves use of CATS resources and RAP approval is not applicable)
☐ Biosafety approval (if the study involves recombinant DNA, stem cells, or infectious material)

* If any applicable items marked with an asterisk are missing, the submission will be **returned** unreviewed.