# Tips on Completing the IRB Protocol for Human Subjects Research – Retrospective Data Review form

The following are some tips on completing the IRB Protocol for Human Subjects Research-Retrospective Data Review form. Complete this form when the project is limited to a review of identifiable data or specimens only. If the project will also involve recruitment, consent, or interaction with participants, do not use this form; complete the IRB Protocol for Human Subjects Research 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 Background (Limit 1,000 words):

**Provide the scientific or scholarly background for the proposed Human Research. Discuss relevant prior experience or preliminary data (e.g., existing literature).**

A couple of things here. The first is that all acronyms are spelled out the first time used. The second is that it is in lay language, no jargon. If this is copied and pasted from another document and there are reference numbers, remember to include the reference list.

## 2.0 Lay Summary:

**Provide a brief description of the proposed research using terms that someone who is not familiar with the science or discipline can understand.**

This is a lay summary. It should be fairly short, a paragraph or two, and in lay language. They are asking for a brief description of the proposed research so this should be included.

## 3.0 Purpose:

**Describe the purpose, specific aims, objectives, questions to be answered, hypotheses, and/or primary and secondary study endpoints of this Human Research protocol.**

Include a purpose statement. Include specific aims, hypotheses, and/or research questions as applicable.

## 4.0 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.**

If you have funding, be careful which option 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.

## 5.0 Resources Available to Conduct the Human Research:

**Describe the resources (facilities, time, emergency resources, etc.) available to recruit, consent, conduct study procedures, and analyze data.**

No specific guidelines for this. Consider including the source of the data and/or specimens. If you need special software to analyze the data, this should be included. If you will be receiving biological specimens and need access to a facility to store and analyze them, this should be included.

## 6.0 Study Population:

**6.1 Select all the categories of participants included in the research:**

| | |
|---|---|
| ☐ Healthy adults | ☐ Non-English-speaking subjects |
| ☐ Non-healthy adults | ☐ UA staff/faculty |
| ☐ Children (under 18 years old) * | ☐ UA students |
| ☐ Pregnant women, neonates, and/or fetuses* | ☐ Banner employees |

| | |
|---|---|
| ☐ Prisoners* | ☐ Refugees |
| ☐ Native Americans, Alaskan Native, and Indigenous Populations* | ☐ Other – please explain: |
| ☐ Adults unable to consent (i.e., cognitively impaired adults) * | |

***Complete and attach the appropriate HSPP Appendices if your subjects include children, pregnant women, neonates, prisoners, cognitively impaired individuals, or Native Americans or Indigenous Populations. eIRB tip: appendices should be uploaded in the "Other Attachments" section in eIRB.**

Include the appropriate appendix if any of the categories with an asterisk (*) is checked.

**6.2 For each of the above selected categories, describe the criteria that define who will be included or excluded in your final study sample. Indicate age range, gender, and ethnicity.**

Inclusion and exclusion criteria should be clearly stated. For ease of reading, this can be formatted as a bulleted list. Age range should be stated. If there are no gender and ethnicity restrictions, then it should be stated that all genders and ethnicities will be included or that there are no restrictions on gender and ethnicity. If the study targets specific genders or ethnicities, that should be stated.

## 7.0 Number of Specimens/Records to be Reviewed Locally:

**7.1 Describe the maximum number of specimens needed for this project.**

State the maximum number of specimens needed for the study and/or the maximum number of records to be reviewed.

**7.2 Specify the date range of records to be reviewed. (e.g., data will be reviewed from October 1, 2020 – July 31, 2023).**

State the date range for the records/data that will be reviewed. These dates must be in the past, not in the future as this is a retrospective data review. If either date is in the future, then this is not a retrospective study.

## 8.0 Research and Data Collection Procedures:

**8.1 Please select the methods of data collection that will be employed in this study (select all that apply):**

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

| |
|---|
| ☐ Previously collected biological specimens |
| ☐ Other, specify: |

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

**8.2 Select the appropriate box indicating where the information/specimens were or will be collected/obtained (i.e., identify the source of data/specimens):**

| |
|---|
| ☐ Banner University Medical Center- Medical Records<br>**For Collaborative Activities with Banner Health, review the additional information needed for Non-Research Projects** |
| ☐ Data Warehouse, specify: |
| ☐ Business Associate or Collaborator |
| ☐ Other, explain: |

If none of the first three options apply, check 'Other' and for the explanation, state the source of the data and/or specimens**.**

**8.3 List the data elements or specimens to be reviewed for this protocol. Alternatively, you can upload a data abstraction sheet which lists all data elements to be collected/reviewed to the "Other Attachments" section in eIRB.**

For data, include a list of the data elements that will be reviewed. You can include a general description here and upload a list of all the specific data elements or a data extraction sheet. Remember, if identifiers are not needed, they should not be included. If specimens will be received, include a description of the specimens and the number of specimens that will be received. If you will receive information/data with the specimens, include a description of the specific information/data that will be received.

## 9.0 Potential Benefits to Subjects:

**Describe the anticipated benefits of this study to society, academic knowledge, or both.**

The broader benefits to society, the discipline, or both should be stated.

## 10.0 Risks to Subjects:

**10.1 Describe all social, legal, and/or economic risk that could be associated with this research.**

**Risks not directly related to the research need not be included in this section. However, nearly all human research has some minimal level of risk, such as a loss of confidentiality when identifiable data is collected.**

If there are no risks, state no risks. If there are risks, state them. The risk of loss of confidentiality should be considered. However, if the data are de-identified with no identifiers being received and no links to identifiers, this may not be a risk. If there is a link between the data and identifiers, the risk of loss of confidentiality will need to be addressed.

**10.2 Discuss what steps will be taken to minimize risks to subjects/data.**

For each of the risks listed, state the steps to minimize those risks. If there are no risks, state no risks.

## 11.0 Privacy of Subjects and Confidentiality of Data:

**11.1 Will data/specimens be kept for future research, including unspecified future research and genetics? Yes☐ No☐**

**11.2 If yes to question 11.1, please describe future use plans here, including unspecified research, any storage in a repository (if applicable), and what data will be retained/reused.**

If data will not be kept for future research, state this. If data will be kept for future research, include what data will be kept and if it will be de-identified, identifiable, or coded (linked to identifiers). If the data will be stored in a repository, include what data will be stored; if it will be de-identified, identifiable, or coded; and the name of the repository, if known.
If specimens will not be used up in the analysis and the remaining portion will be retained for future use, include where they will be stored and if they will be de-identified, identifiable, or coded upon storage.

**11.3 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: |

**11.4 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, 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 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 the data will be identifiable, coded, or de-identified upon storage. This should be stated for data and specimens, as applicable. If you will have data and specimens, with data stored in Box@UA Health and specimens stored in the Biological Laboratory, 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, include if there is any possibility that the data can be re-identified.
It also asks who may have access to the data. 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.

**11.5 If obtaining 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 be obtaining biological specimens, state the type of specimen that will be received, where they will be stored and if they will be identifiable, coded, or de-identified upon storage.
If you will not be obtaining biological specimens, state this or state Not applicable.

**11.6 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: |

**11.7 Describe what security controls (e.g., administrative, physical, technical) are in place to make sure data/specimens are secure.**

This may include secure locations where data and/or specimens will be stored, encryption of data especially if it will be transmitted to or from an outside group.

**11.8 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.**

**11.9 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 data will not be shared, state this or state Not applicable.
If data will be received from an outside group or collaborating entity, include what information will be received and how it will be received, for example encrypted. If any identifying information will be received, this should be clearly stated.
If data will be shared with an outside group or collaborating entity, state who it will be shared with, what will be shared, and how it will be shared, for example encrypted.
If PHI or a Limited Data Set will be transmitted or received, a Data Use Agreement is needed.

**Additional items needed for review:**

- Current PI CVs or biosketch
- Advisor approval (Advisor Attestation if the PI is a student or medical resident)
- Department/Center/Section Review approval
- Scientific/Scholarly review approval

- Additional approvals, as needed (e.g., RAP/Banner feasibility, Export Control, COI, Cancer Center SRC, tribal approval, etc.)
- Appendix for Alteration/Waiver of Consent or PHI
- Permission to receive the data, if applicable
- Permission to access the medical record or receive the information from the medical record, if applicable
- Permission to receive the specimens and the information/data that will accompany the specimens, if applicable
- The appropriate appendices if data and/or specimens targeted from children, pregnant women, neonates, prisoners, cognitively impaired individuals, or Native Americans or Indigenous Populations

**Other items as applicable:**

- HSPP Appendices
- Sponsor protocol, if separate from this form