Tips on Completing the IRB Protocol for Determination of Human Research form De-identified Research Data or Publicly Available Data

The following are some tips on completing the IRB Protocol for Determination of Human Research form for analysis of de-identified research data or publicly available data. 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 determination/approval of the project. Requests for clarification will only slow the process.

There are instructions at the beginning of the form to delete the red text. I would suggest deleting it just prior to submission in eIRB as the instructions are helpful as you complete the form and for those reviewing the form.

NOTE: This is for the IRB Protocol form version v2025-03. 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. 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 projects, there is no funding.
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.

2.0 Determination of “Research”

1. Does the proposed activity involve a **systematic** approach?

    For most projects there is a systematic approach so the response should be ‘**Yes**’

2. Is the intent of the proposed activity to **develop or contribute to generalizable knowledge**?

    If the intent is to generalize the findings, the response should be ‘**Yes**’.

Now stop and read the instructions that follow as they will tell you the next section to complete.

If Yes to BOTH questions the study is Research. Proceed to Section 3.0: Determination of "Human Subject."

If the answers to one or both questions are NO, skip Section 3.0 and proceed to Section 4.0: Determination of "Human Subjects" per FDA Regulations.

If the response to both questions is ‘Yes’, proceed to section 3.0.

3.0 Determination of "Human Subject"

1. Does the activity involve obtaining information about living individuals through **intervention** or **interaction** with the individuals?

    Since the project involves data analysis only and no interaction with individuals, the response should be ‘**No**’

2. Does the activity involve obtaining **identifiable** and **private information** about living individuals?

    If the project involves analysis of de-identified data only, the response should be ‘**No**’.

Now stop and read the instructions that follow.

If YES to either question, the research activity is research that involves human subjects. STOP and submit the IRB Protocol for Human Subjects Research.

If the answers to both questions are NO, proceed to Determination of "Human Subjects" per FDA Regulations.

If the response to both questions is 'No' proceed to Section 4.0. If the response to either question is 'Yes' stop and complete the IRB Protocol for Human Subjects Research or the IRB Protocol for Human Subjects Research – Retrospective Data Review.

4.0 Determination of "Human Subject" per FDA Regulations

1. Is this a clinical investigation involving a test article including in vitro diagnostics with a human subject(s) or their biospecimens?

For most projects the response will be '**No**'

Follow the instructions in the form: ***If yes, answer questions a. and b.**

Neither question a. nor b. should have a response if the response to the question above is 'No'. If you responded to them, read the instructions in the form again and remove the responses to questions a. and b. If the responses are not removed, the IRB will ask you to do this with a request for clarification.

5.0 Coded private information and/or human biological specimens per OHRP

1. Does the activity involve the use of **coded** private information/specimens?

For most projects the response will be '**No**'

If the response to this question is 'Yes', additional documentation is required. If the additional documentation is not included, the IRB will ask for it with a request for clarification.
If the response is 'No', follow the instructions in the form **(if no, skip to section 6.0)**

6.0 Other Activities

If you will be using a publicly available data set, check **Public Use Datasets**. If you will be analyzing existing de-identified research data, check **De-identified Data Analysis**. If 'Native American/Alaskan Native' is checked, complete the Appendix for Native Americans and Indigenous Populations. This form can be found at https://research.arizona.edu/compliance/human-subjects-protection-program/HSPP-form/forms-index.

7.0 Summary of Activities

1. Provide a concise description of the purpose or objectives of the project:

This can be just one sentence stating the purpose of the project. Aims and objectives can also be included.

2. Describe the proposed methods and study procedures:

Since the project involves analysis of de-identified research data or publicly available data, suggest including the source of the data, a general description of what will be included in the data, and your plans for data analysis.

3. Describe the subject population, or the type of information/specimens to be studied:

A description of the data to be analyzed should be stated.

4. Select the appropriate box indicating where the information/specimens were or will be collected/obtained (i.e., identify the source of data/specimens):
Note: Provide a separate list of the specific data points, variables, and/or information that will be collected and/or analyzed (i.e., data abstraction form).

☐ Banner University Medical Center- Medical Records **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**.** Remember to provide a separate list of the specific data points, variables, and/or information that will be obtained.

8.0 Privacy and Confidentiality of Data (if applicable)

Completion of this section is only required for projects utilizing the Banner Health electronic medical record (EMR) and abstracting Protected Health Information (PHI). If the project will not utilize the Banner Health EMR or PHI, skip this section.

STOP - If you will obtain data from CERNER, review the information on the College of Nursing website about Research at Banner Facilities.
This section should be left blank.

1. List the PHI elements to be accessed, who will access them, and how the information will be obtained.

2. Indicate where the PHI will be stored:

☐ Box@UA Health
☐ REDCap
☐ Soteria
☐ HIPAA Research Computing Service
☐ Clinical Data Warehouse (CDW)
☐ Encrypted Drive
☐ Encrypted External Drive (hard drive, USB, disk)
☐ Banner Server/Platform, specify:
☐ Other, specify:

3. For EACH of the storage locations checked above, discuss the data elements to be stored, including if the data is identifiable, coded, or de-identified upon storage. Discuss who may have access to the data.

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

5. Identify the IT group that is providing support for this project.

6. Confirm that the project team will follow the Minimum Necessary rule and will only access the necessary PHI to satisfy the proposed activity.

☐ I confirm that the project team will adhere to the Minimum Necessary rule.

Items needed for approval, as applicable:

- Advisor approval (Advisor Attestation if the PI is a student or resident)
- List of data elements to be received or obtained
- Permission to use the de-identified research data, if applicable
- Consent document(s) from the parent study, if using de-identified research data
- If applicable, documentation explaining that the PI cannot ascertain the identity of individuals from coded private information/biospecimens