

Tips on Completing the IRB Protocol for Determination of Human Research form Quality Improvement Projects, Program Evaluation

The following are some tips on completing the IRB Protocol for Determination of Human Research form for quality improvement (QI) projects or program evaluation (PE). 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 for those reviewing the form.

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. 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 no funding and are giving compensation to participants such as a gift card or raffle for a gift card or providing food, the source of the funds needs to be stated or the IRB will ask the source of the funds. If self-funded, suggest checking 'Other' and for 'Name of funding source' state Gift card(s) will be self-funded or Food will be self-funded.

2.0 Determination of “Research”

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

For most projects there is a systematic approach so this should be checked ‘Yes’

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

Quality improvement projects are site specific with findings applicable to that setting only. Program evaluation is designed to assess a specific program. They are not generalizable beyond the specific setting or program so the response to this question should be ‘No’. If the intent is to generalize then the project is research.

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.

Since QI projects and program evaluation are not generalizable, response of ‘No’ to that question, skip Section 3.0 and proceed to Section 4.0

3.0 Determination of "Human Subject"

Neither question should have a response unless the project is research. If this is a quality improvement project or program evaluation, not generalizable, and you responded to either or both questions in this section, read the instructions above again and remove the responses to the questions in this section, Section 3.0. If they are not removed, the IRB will ask you to do this with a request for clarification.

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

Generally, the only option checked here should be **'Program Evaluation/Quality Improvement/Quality Assurance'**. 'Course-Related Activities' should only be checked if the project procedures are for educational or teaching purposes in a specific course. 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 with the name of the site or program included in the purpose statement, for example, 'The purpose of this project is to increase nurse practitioner knowledge of diabetic foot care at Two Kites Clinic.' If you include project objectives, project question, and/or aims, look at each to make sure it does not sound generalizable but rather is site or program specific. Including the name of the site or program in these is recommended.

2. Describe the proposed methods and study procedures:

For quality improvement projects, the description should include recruitment, the consent process, and study procedures. Include how participants will be recruited. If by email, include who will send the email. If by flyer, include if it will be posted and where it will be posted. If flyers will be handed to potential participants, include who will be handing them out. The consent process should be included. If using a Disclosure form, include when/how it will be presented to participants. If a pre-survey, educational presentation, and post-survey, include if it will be online or in person. A brief description

of what will be included in the presentation, how long the presentation will be, and the anticipated time needed to complete each survey should be included.

For program evaluation, include a brief description of the program being evaluated, the information that will be evaluated, and how the information will be obtained. If this is an ongoing program, consider including a Disclosure form as the information is also being used for your DNP project. If using a Disclosure form, include when/how it will be presented to participants.

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

The inclusion criteria should be stated. The type of information to be studied can be included here but it should also be included under study procedures.

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).

<input type="checkbox"/> Banner University Medical Center- Medical Records For Collaborative Activities with Banner Health, review the additional information needed for Non-Research Projects
<input type="checkbox"/> Data Warehouse, specify:
<input type="checkbox"/> Business Associate or Collaborator
<input type="checkbox"/> Other, explain:

If none of the first three options apply, check 'Other' and for the explanation, state the name of the site or the name of the program.

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 are doing your quality improvement project at a Banner facility, review the information on the College of Nursing website regarding Quality Improvement 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:

<input type="checkbox"/> Box@UA Health
<input type="checkbox"/> REDCap
<input type="checkbox"/> Soteria
<input type="checkbox"/> HIPAA Research Computing Service
<input type="checkbox"/> Clinical Data Warehouse (CDW)
<input type="checkbox"/> Encrypted Drive
<input type="checkbox"/> Encrypted External Drive (hard drive, USB, disk)
<input type="checkbox"/> Banner Server/Platform, specify:
<input type="checkbox"/> 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)
- If applicable, list of data elements to be received or obtained
- If applicable, documentation explaining that the PI cannot ascertain the identity of individuals from coded private information/biospecimens
- Recruitment material (recruitment flyer, recruitment email, etc.)
- Consent document(s) (Disclosure form, Consent form, etc.)
- Data collection tools (surveys, interview questions, focus groups questions, etc.)
- Educational presentation or outline of what will be included in the presentation, if applicable
- Site authorization letter(s)
- Anything seen or heard by the participants

Other documents:

Consent document:

A template for a Disclosure form for quality improvement projects can be found on the College of Nursing website <https://www.nursing.arizona.edu/resources/research-human-subjects-templates>.

Site Authorization letter:

A template for a Site Authorization letter can be found on the College of Nursing website <https://www.nursing.arizona.edu/resources/research-human-subjects-templates>. There are two, one for quality improvement projects and one for research. Since this is a quality improvement project or program evaluation, make sure you are using the one for quality improvement projects. Check that the title of the project in the site authorization letter is the same as the title of the project on the IRB Protocol form. Also check that what is outlined in the letter is the same as what is stated in study procedures. The date the project will be completed by should not have passed and should be far enough in the future to allow time for IRB determination/approval plus time to complete the project, suggest a minimum of one month.