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

The following are some tips on completing the IRB Protocol for Determination of Human Research form for quality improvement (QI) projects. 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 is no request for clarification, no request for revisions thus facilitating approval/determination of the project. Requests for clarification 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. If you are using a more recent version of the form, some of this may not apply or additional information may be requested.

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

- The short title is required when submitting to the University of Arizona IRB through the eIRB system. 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 student 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. If self-funded, here

is a suggestion, check 'Other' and for 'Name of funding source' state Gift cards 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 results applicable to that setting only. They are not generalizable beyond the setting so the response to this question should be '**No**'. If the intent is to generalize then this 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 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 this is research. If this is a quality improvement project, not generalizable, and you responded to either or both questions in this section, read the instructions above again and remove the responses. 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**'

Again, 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 not be checked. If it is, remove it. If this is research, no options should be checked unless you are using a publicly available data set (check **Public Use Datasets**) or 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 with the name of the site 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 specific. Including the name of the site is recommended.

2. Describe the proposed methods and study procedures:

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 will it be posted. If flyers will be handed to potential participants, include who will be handing them out. A copy of all recruitment material should be included. 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 anticipated time needed to complete each survey should be included. Consistency across documents is very important. If the site authorization letter states you will be sending the recruitment email, the same should be stated here. It should not state in one document that you will be sending the recruitment email and in another state the manager of the clinic will be sending the recruitment email. Consistency across documents.

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

The inclusion criteria and, if applicable, the exclusion criteria should be stated. The approximate number of participants expected 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).

☐ 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 name of the site**.**

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 about 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:

☐ 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)
- 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.)
- Site authorization(s)
- Data collection tools (surveys, interview questions, focus groups questions, etc.)
- If applicable, educational presentation or outline of what will be included in the presentation
- Anything seen or heard by the participants

Other documents:

Consent document:

A template for a Disclosure form 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, make sure you are using the one for quality improvement projects. Since this is for a quality improvement project, there should be no mention of research in the Disclosure form.

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, 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 in 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 a month in the future.