

## Nursing Student Project 3-Step Process

1. Most likely your study will be observational (see below). You will also need to determine whether your project is a:

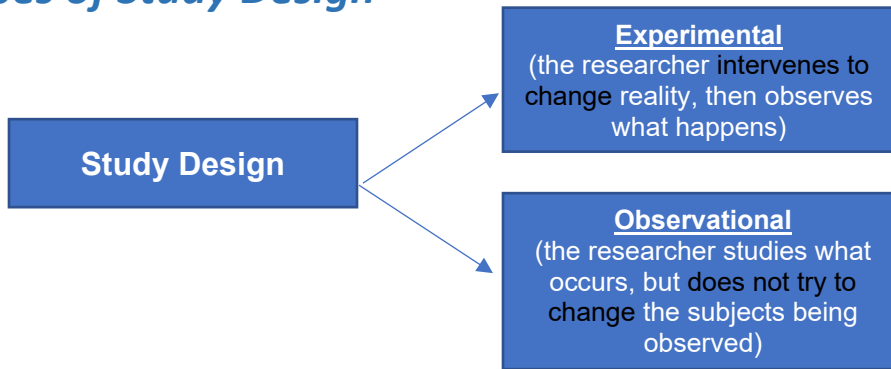
- Quality improvement (**QI**) project - does not need IRB approval
- Evidenced based project (**EBP**) - does not need IRB approval
- Human subject research (**HSR**) - needs IRB approval

Please use checklist on **page 2** to guide you and your advisor in making this determination.

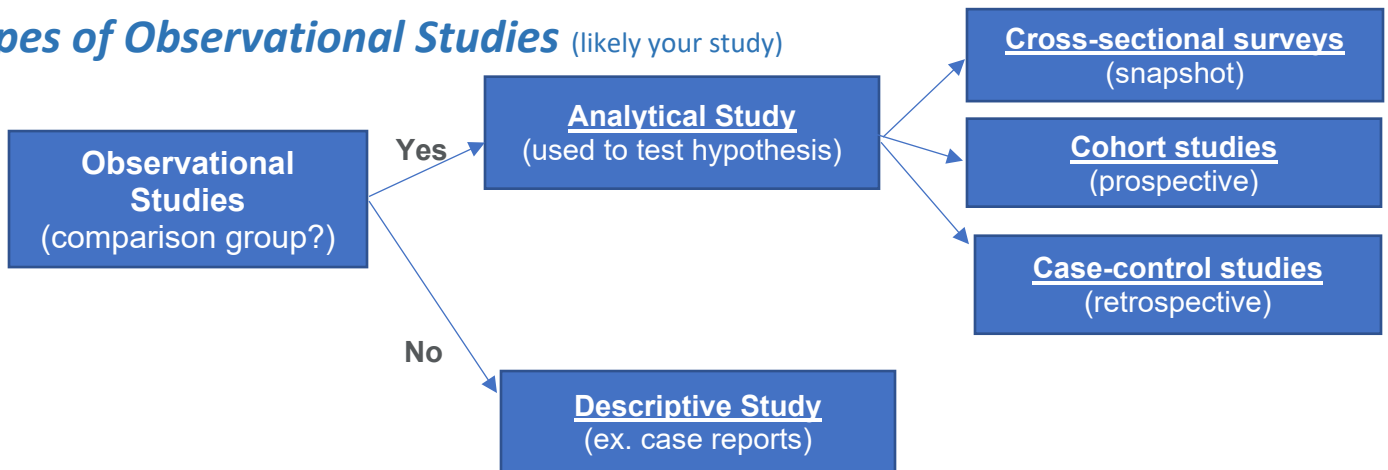
2. If your study is determined to be a human subject research project, an IRB application and consent(s) documents (if applicable) will need to be prepared. Please use the protocol guidance/template to help you in preparing this document (**pgs. 3-5**).

3. If your study is determined to be a human subject research project, you will need to submit your IRB application, consent(s) (if applicable), other study related documents (if applicable), **and** a letter of support from your scholarly advisor and immediate supervisor as part of your IRB submission.

## Types of Study Design



## Types of Observational Studies (likely your study)



Cincinnati Children's **Screening Checklist** for Quality Improvement (QI) or Evidenced Based (EBP) Projects

**This checklist will help you determine whether your project is QI, EBP, or Human Subject Research.**

**QI:** Improve quality or safety of processes or patient experience within the local clinical setting **or** evaluate changes in efficiency or flow.

**EBP:** Improve quality and safety within the local clinical setting by applying evidence in healthcare decisions.

**Human Subject Research:** Contribute to and/or generate new knowledge that can be generalized.

Consideration	Question	Yes	No
<b>Purpose</b>	Is the primary aim or motive of the project either to: <ul style="list-style-type: none"> <li>• Improve care right now for the next patient seen? OR</li> <li>• Improve operations or efficiency? OR</li> <li>• Translate knowledge with a goal of improving practice?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Rationale</b>	Is there sufficient evidence for, or acceptance of, this mode or approach to support implementing this activity or to create practice change, based on: <ul style="list-style-type: none"> <li>• literature,</li> <li>• consensus statements, or</li> <li>• consensus among clinician team?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Methods 1</b>	Are the proposed methods flexible and customizable, and do they incorporate rapid evaluation, feedback and incremental changes?	<input type="checkbox"/>	<input type="checkbox"/>
<b>Methods 2</b>	Do the methods include any of the following? <ul style="list-style-type: none"> <li>• Control group</li> <li>• Randomization</li> <li>• Fixed protocol</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Process or Outcome Measurements</b>	<ul style="list-style-type: none"> <li>• Do the measure of key indicators use tools with face validity and do not need established validity or reliability?</li> <li>• Do the measures include knowledge, attitude, behavior/practices, and outcome?</li> <li>• Are the measures simple, easy to use and administer?</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Risk</b>	Is the risk related to the project minimal and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care)?	<input type="checkbox"/>	<input type="checkbox"/>
<b>Participants</b>	Will the activity only involve participants (patients, parents, or CCHMC staff) who are ordinarily seen, cared for, or work in the setting where the activity will take place?	<input type="checkbox"/>	<input type="checkbox"/>
<b>Funding</b>	Is the project funded by any of the following? <ul style="list-style-type: none"> <li>• An outside organization with an interest in the results</li> <li>• A manufacturer with an interest in the outcome of the project relevant to its products</li> <li>• A non-profit foundation that typically funds research, or by internal research accounts</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>

If all of the check marks are inside the shaded gray boxes, then the project is very likely QI or EBP and not human subject research. Projects that are not human subject research **do not need** review by the IRB.

## Preparing an IRB Application for a Prospective, Retrospective, or Survey Study

**\*\*Make sure you include page numbers and put version 1.0 along with a date in the footer of the document\*\***

**Example:** *Version 1.0 March 15, 2021 Page 1*

### **Title:**

What is the title of your protocol?

*“Adverse Events in Nursing – a Retrospective Study” (or prospective or survey)*

### **Authors:**

Who is going to be working on this Protocol with you (Primary and Co-Investigators)?

### **Abstract:**

A few sentences describing what you’re going to do:

*“Patient safety is an important global issue. While it is well known that patients can suffer from adverse events in nursing care, there is a lack of knowledge as to how they experience them. We plan to examine adverse events in nursing care as they are experienced by patients and relatives. This is a retrospective study taking both a qualitative and a quantitative approach. It is based on data regarding adverse events in nursing care.”*

### **Purpose of study**

Short sentences describing what you hope to find out:

*“We hope to examine adverse events in nursing care as they are experienced by patients and relatives.”*

### **Background**

The previous research that led you to plan this study, and the significance of your study’s results:

*“Previous reports show that adverse events occur in health care. Patients’ safety may be at risk, due for example to medication errors, adverse drug reactions and hand hygiene practices. While the literature on improving patient safety is extensive, there is a dearth of studies from the perspectives of patients and their relatives.”*

### **Duration**

How long will the study take? One year is usually safe, longer if you think you’ll need it.

### **Risk and Benefit**

This assessment is really for prospective studies, but we need to answer it. The following should work for almost all of our studies. If your study does involve direct contact with patients, families, or their physicians, delete the first line.

*“There will be no contact with patients, families, or their physicians. There is no significant risk or benefit from inclusion in this study. There is minimal risk of loss of confidentiality. There will be no benefits to participants in this study. “*

### **Methods**

This is how you will collect your data. You also need to include how many records you are going to review and the exact dates that you are going to review them.

*“We plan on reviewing 200 records from January 2017- June 20019. Data will be obtained through My Chart word search and XYZ adverse event reports. All reports will be independently reviewed by an independent nurse with no clinical information. The subjects’ clinical record will be reviewed to identify the type of adverse event and interval between incident and reporting period.”*

### **Security**

This relates to the confidentiality of the data. The following can be used as written or modified for your study.

*“Each subject will be assigned a randomly generated study ID number. A single table will be maintained that links the study ID number to the medical record number. This table will be maintained on a secure server or in a locked file cabinet. Data will be destroyed five years after beginning the study or two years after publication of results, whichever occurs first. Electronic data will be erased and hard copy data will be discarded in confidential discard bins at that time. No lists will be retained after the data is destroyed.”*

### **Waiver of Consent**

This is the information the IRB needs to allow the study to be performed without consenting each subject. This section needs to explain why it is unreasonable to expect each subject to be consented.

*“This study is limited to previously obtained data from the subject’s chart review. There is no anticipated risk to subjects from participating in this study. In order to contact each subject it would be necessary to contact the patient’s physician or to use means such as the telephone directory to obtain contact information. This incursion on the patient’s privacy is felt to outweigh privacy concerns related to the use of data in this study. Subjects may have moved and their current location may not be available, limiting the sample size for this study.”*

### **References**

You must add references in your protocol to state where you retrieved your data.

**Here’s what it looks like without the explanatory notes:** Please add page numbers to your protocol

#### **Title:**

“Adverse Events in Nursing – a Retrospective Study”

#### **Authors:**

Jane Smith, MS, RN

James Jones, BSN, RN

#### **Abstract**

Patient safety is an important global issue. While it is well known that patients can suffer from adverse events in nursing care, there is a lack of knowledge as to how they experience them. We plan to examine adverse events in nursing care as they are experienced by patients and relatives. This is a retrospective study taking both a qualitative and a quantitative approach. It is based on data regarding adverse events in nursing care.

#### **Purpose of study**

We hope to examine adverse events in nursing care as they are experienced by patients and relatives.

## **Background**

Previous reports show that adverse events occur in health care. Patients' safety may be at risk, due for example to medication errors, adverse drug reactions and hand hygiene practices. While the literature on improving patient safety is extensive, there is a dearth of studies from the perspectives of patients and their relatives.

## **Duration**

Completion is anticipated by September, 2021.

## **Risk and Benefit**

There will be no contact with patients, families, or their physicians. There is no significant risk or benefit from inclusion in this study. There is minimal risk of loss of confidentiality. There will be no benefits to participants in this study.

## **Methods**

We plan on reviewing 200 records from January 2017- June 2019. Data will be obtained through Med Notes word search and MRWR adverse event reports. All reports will be independently reviewed by an independent nurse with no clinical information. The subjects' clinical record will be reviewed to identify the type of adverse event and interval between incident and reporting period.

## **Security**

Each subject will be assigned a randomly generated study ID number. A single table will be maintained that links the study ID number to the medical record number. This table will be maintained on a secure server or in a locked file cabinet. Data will be destroyed five years after beginning the study or two years after publication of results, whichever occurs first. Electronic data will be erased and hard copy data will be discarded in confidential discard bins at that time. No lists will be retained after the data is destroyed.

## **Waiver of Consent**

This study is limited to previously obtained imaging and clinical data. There is no anticipated risk to subjects from participating in this study. In order to contact each subject it would be necessary to contact the patient's physician or to use means such as the telephone directory to obtain contact information. This incursion on the patient's privacy is felt to outweigh privacy concerns related to the use of identified data in this study. Subjects may have moved and their current location may not be available, limiting the sample size for this study.

## **References**

- Guimaraes CVA, Kalra M, Donnelly LF, Shott SR, Fritz K, Singla S, Amin RS. *The Frequency of Lingual Tonsil Enlargement in Obese Children*. American Journal of Roentgenology 2008; 190:973-975
- de Jong, P.A., Tiddens, H.A., Lequin, M.H., Robinson, T.E., and Brody, A.S., *Estimation of the radiation dose from CT in cystic fibrosis*. Chest, 2008. 133(5): p. 1289-91; author reply 1290-1.

**The last thing you need to prepare is a copy of your data collection sheet. This should be very simple. One page with an appropriate heading for each column will work. If you are using a survey(s), this should also be included in your submission.**