



# FRONTIER NURSING UNIVERSITY

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## Frontier Nursing University Institutional Review Board (IRB) Guide to Completing the IRB Application

### Pre-planning

- Here are some recommendations for you as you plan to complete the FNU IRB application.
- Assure that you have a completed a proposal of your study/project prior to completing the IRB Application. Although you will not be required to submit this proposal to the IRB, a complete and appropriate proposal oftentimes enhances the likelihood that you will be able to complete the IRB application with ease. In other words assure that you have a well-thought out plan of the study/project design, purpose, subjects/participants, plan of action, data to be collected, method for data analysis, and much more.

### Here are some questions and definitions of terms to consider prior to completing and submitting an IRB application:

#### 1. Is my study/project considered Research?

**Research** is subject to IRB review regardless of funding or exempt status, when it includes activities that are either of the following:

*Research involving human subjects as defined by DHHS regulations*

*Research (clinical investigation) involving human subjects as defined by FDA regulations. (At present there are no plans to implement clinical investigation research at FNU; but the definition is present if the circumstance should arise).*

**Research** is defined by DHHS regulation as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”

#### 2. Does my study/project involve Human Subjects?

**Human Subject** is defined by DHHS regulations as “a living individual about whom an investigator (whether professional or student) conducting research obtains either a) data through intervention or interaction with the individual or b)

identifiable private information.

**Human subject** is defined by FDA regulations as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. Subject [also] means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.”

Frontier Nursing University becomes "engaged" in human subjects research – and therefore bears responsibility for protecting participants involved in the research – when its employees or agents intervene or interact with living individuals or obtain individually identifiable private information for research purposes. The university is also engaged in human subjects research whenever it receives a direct DHHS award to support the research.

### 3. What is Exempt Research?

#### Exempt Research

##### 1. Overview

Research involving human subjects may be exempt from federal regulations requiring IRB review. The FNU IRB is responsible for determining whether research involving human subjects meets the criteria for exemption in accordance with applicable regulations. Investigators may not make this determination. Research that includes both exempt and non-exempt activities cannot be determined to be exempt.

The purpose of this policy is to describe exempt research as defined by DHHS and/or FDA regulations and the process by which the IRB determines that research involving human subjects is exempt from the regulations and the requirements for IRB review.

##### 2. Definitions

**Exempt research:** Research that involves human subjects that is not subject to regulations requiring IRB review and approval. Categories of research activities that may be determined to be exempt from review by the IRB are defined by federal regulations and university policy. *Note: Investigators performing exempt research must comply with the requirements of the IRB even when the research is exempt.*

##### 3. Research Eligible/Ineligible for Exemption

- Research that involves only activities listed in one or more of the categories specified in DHHS and/or FDA regulations may be determined to be exempt.
- Research involving prisoners (with the exception of emergency use) may not be determined to be exempt.

- Research that is subject to FDA regulations may not be determined to be exempt under DHHS exemption categories.
- The exemption in DHHS regulations for research involving survey or interview procedures or observation of public behavior (Category 2) does not apply to research with children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.
- At Frontier Nursing University, proposed research may not be greater than minimal risk to be determined exempt.
- At Frontier Nursing University, the regulatory exemption categories are not applied to proposed research (regardless of whether the research would otherwise be exempt) involving coercion, undue influence, deception, or any practice that does not uphold the ethical principles of respect for persons, beneficence, and justice as described in the Belmont Report.

#### **4. Exempt Determinations**

Exempt determinations are made by designated IRB members who have no direct involvement in the proposed activity. Investigators are not permitted to make their own determinations of exemption. Additionally, IRB members must determine that the research meets the ethical standards described in the Belmont Report and that adequate participant protections are in place as described below.

##### **A. Submission**

Investigators must provide sufficient information about proposed research to determine whether it is exempt and, when appropriate, that protections are provided to participants along with any required attachments. IRB requirements for submission of non-exempt research (i.e., regarding PI eligibility, completion of human subjects education, etc.) also apply to exempt research.

##### **B. Review**

The criteria for exemption specified in DHHS regulations are applied unless the research is FDA-regulated. For research subject to FDA regulations, only FDA exemption categories apply.

In addition to applying the applicable exemption criteria, IRB members will make the following additional determinations (as applicable) to ensure protection of potential participants:

- The research involves no more than minimal risk
- Selection of subjects is equitable
- When identifiable information is to be recorded, there are adequate provisions to maintain the confidentiality of data

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- There are adequate provisions to maintain the privacy interests of participants
- When there are to be interactions with participants, informed consent will be obtained by a process that will disclose adequate information, including that the activity involves research, participation is voluntary, a description of the procedures, and investigator contact information.

Upon review, the IRB Chair/member/committee will make one of the following determinations:

- The submission does not meet the federal definitions for research involving human subjects
- The proposed research activity *IS* exempt and may be conducted without full IRB review
- The research is *NOT* exempt, and before performed, must be submitted for full IRB review.

### **C. Notification**

Exempt research activities may not begin until the investigator receives notification of the exempt determination from the IRB Chair electronically.

## **What is the process for the IRB's Review of applications?**

The review of an IRB application follows the same process no matter the type of review with the exception of a full review at FNU.

1. The completed IRB application with all pertinent data scanned as one document is submitted via email by the Principle Investigator to the Chair of the IRB. If notification that the Chair is on vacation the application in full will be submitted to the Vice-Chair via email.
2. The application is reviewed in full for completeness and appropriateness by the Chair or Vice-Chair. In addition, verification of required IRB education is noted. The Chair or Vice-Chair make an initial determination as to whether an exempt, expedited or full review are required for the research project.
3. The Chair determines the reviewer for the application as follows:
  - a. Expertise in review
  - b. Reviewer workload and rotation
  - c. Potential conflicts of interest
  - d. Scientific or scholarly expertise
4. The reviewer is sent an email requesting them to complete the review. The reviewer is allowed 7-10 working days to review the IRB application. The reviewer is supplied the scanned document of the application and a decision template. The *IRB Reviewer Decision* sheet is returned with the reviewer's response.
5. If there are concerns by any reviewer a second reviewer is recruited to complete a review of the materials submitted.
6. Counsel with the Chair is arranged on large IRB applications with the reviewer or if questions arise about the conditions for approval.
7. Counsel is also arranged with the two reviewers and the IRB Chair on any IRB submission of concern by one reviewer after both decisions are returned to the Chair.
8. If the need arises a quorum of IRB committee members and the Chair meet to discuss any IRB submission to see if approval can be granted or not.
9. The Principle Investigator (PI) is notified via email of the IRB Committee decision by the Chair. The possible decisions include:
  - a. Approved
  - b. Declined
  - c. FNU does not approve with conditions. Instead it is considered declined and the student/faculty member can resubmit for reconsideration. In this case, the same reviewer is asked to complete the review but another member of the IRB committee is invited to review the submission as well.
10. At this point in time, FNU has not had any research that has continued for one year or longer. If there were a research project that met this criteria, an annual review of the project would need to be arranged with the PI.
11. All IRB applications that are approved and the IRB Reviewer Decision sheet are uploaded to the Google Drive folder for the IRB within the FNU system.

# FNU IRB Application Guide to Completing the IRB Application

## **Name of Investigator/Project Directors(s): (Include your credentials)**

Include the name and credentials of each investigator/project director.

## **Name of the Study or Project:**

Include the complete Title of the study or project and adhere to the Title guidelines within appropriate sources (i.e., APA 6<sup>th</sup> ed).

1. The following will be included as part of the study or project. (Select ALL that apply).
2. A. Human Subjects (Review the criteria for human subjects) and (Select ALL that apply)  
B. Non-Human Subjects - describe where/how data for the project will be obtained. (Review the criteria for non-human subjects). There is also Information that you must provide for non-human subjects. See section 10.
3. **A. Name, location and phone of the Principal Investigator/Project Director:** Include this information for the lead person:
  - Status within FNU (i.e., Faculty, Staff, Student, Other (indicate what that other is).
  - Address (i.e., provide only one (i.e., home, business, other)
  - Phone numbers (Best contact number)
  - Email/Fax (If FNU affiliate- provide FNU email address); Fax (if applicable)**B. NIH or CITI certificate (Provide the date completed here).** In addition you must provide a copy of the certificate in the Appendices.
4. **Abstract:** A one-page document (without references) to be included in the Appendices. The abstract should briefly address: background and significance, problem, purpose/aims, data to be collected, analysis of data, potential outcome.
5. **Inclusive dates:** Include proposed range of date for data collection. These dates must not be dates prior to IRB application submission and IRB approval. Anticipate that you will receive a decision from the IRB 3-4 weeks after submitting your IRB Application.
6. **Informed Consent or Letter of Informed Consent:** (There is a FNU IRB Consent Template available for your review/use). This IC template may need to be tailored to certain aspects of your study/project.  
FNU IRB Policy (see the FNU IRB Policy)

## **1. Overview**

Informed consent is an essential part of ethical human subjects research. Institutional Review Boards and investigators are responsible for ensuring that research subjects provide informed consent prior to participating in research, unless the requirement for informed consent is waived or altered (in non-exempt research) by the IRB.

This policy describes the requirements for valid informed consent processes, required and additional elements of consent disclosure, and the criteria for waiver or alteration of these requirements.

**Definitions:**

**Informed Consent:** Agreement to participate in research expressed by an individual (or his/her legally authorized representative) authorized under applicable law to make such decisions, based on sufficient information (e.g., regarding possible risks and benefits of the research) and adequate opportunity to consider voluntary participation. *Also: legally effective informed consent.*

**General Information:**

The consent process involves more than a consent form. Informed consent has been described as an “interactive process that involves the researcher informing potential participants of the purposes and procedures of the research, the risks and benefits associated with the study, and how the data provided by the participant will be protected and stored” This discussion must be culturally and linguistically appropriate for the population under study.

- For assistance in understanding the elements of Informed Consent (see the FNU IRB Policy **and** review the information):  
<http://www.hhs.gov/ohrp/policy/consentckls.html>
- Additional resource/video regarding the IC:  
<https://www.youtube.com/watch?v=URo4x4pv68A&index=12&list=PL5965CB14C2506914>

7. **If Human Subjects:** Indicate the approximate number of subjects/participants. There should be a rationale or evidence to support the information you provide here.
8. **Funding:** Indicate the approximate amount of funding needed for the study Describe how the funding will be used  
Indicate the source of proposed or actual funding for the study/project
  - If you are providing the funding, indicate whether there is a possible conflict of interest.Indicate whether or not external funding is supporting the study.
  - If yes, provide the agency/organization funding the study and the amount of support received.
  - If yes, indicate whether this funding source represents a conflict of interest.
9. **External Institutional Review Board:** If yes, place a copy of the approval in Appendices.
10. **Human Subjects Research (Complete if Applicable).** If not applicable

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Indicate (N/A). Please address each of the following items with a full description, organized format please.

- Scope of the problem: Include background information and significance and a clear and concise problem statement.
- Purpose (s): Include a clear and concise purpose/aim of the study or project.
- Question(s): Provide clear and well-written questions that they proposed study/project will answer.
- Setting: Describe the setting/site where the study/project will take place if applicable (If not applicable indicate- N/A).
- Sample/Sampling: Provide information about the Target population, the Sample (inclusion and exclusion criteria), proposed sample size, and the sampling method(s).
- Measures: In this section provide information items used to collect data: Briefly describe any survey instruments, measurement tools, questionnaires, scripts, interview question, or teaching outlines being used in the study. Include any established validity and/or reliability if applicable. If using an established tool, instrument, questionnaire, etc you must obtain approval from the primary source or developer (include a copy of the approval in the Appendices)
  - Include the number of items of measures and estimated amount of time for completion by participants
  - Include copies of any of the above in the Appendices.
- Procedures: Here is where you will provide a detailed picture of the following:
  - Interventions, group teachings, chart reviews, etc. (Include any scripts, instructions that you plan to use (place in the Appendices).
  - Recruitment: How do you plan to recruitment participants or subjects. Provide a step-by-step plan. Include all scripts to be used, include recruitment flyers, etc. (place in the Appendices).
  - Protection of human subjects: Provide information about how you will protect human subjects. For this section you may want to review the literature to identify ways in which you may protect human subjects. The FNU Research Committee is also a good recourse. Here are some resources/video focused on Protecting Human Subjects:
    - Module 1- <https://www.youtube.com/watch?v=174SkSszRVg>
    - Module 2: <https://www.youtube.com/watch?v=Up09dioFdEU>
    - Module 3: <https://www.youtube.com/watch?v=Cr-xd7hQhHo>
    - Review this video on Research Involving Vulnerable Populations: [https://www.youtube.com/watch?v=SqRw6FevuXg&feature=player\\_embedded](https://www.youtube.com/watch?v=SqRw6FevuXg&feature=player_embedded)

- Informed Consent (IC): You have indicated earlier in the document that an Informed Consent will be used or will not be used. If using an IC please provide the following information:
  - Indicate who will obtain consent for the study/project
  - Describe the location and procedures for informing and negotiating consent.
  - Describe measures to provide potential subjects with adequate time to consider whether or not to participate in the study
  - Indicate whether non-English speaking participants are being enrolled
    - If yes, describe the plan for obtaining consent
    - If no, indicate the reason for their exclusion
  - Indicate whether non-reading subjects will be enrolled
    - If yes, describe the plan for obtaining consent
    - If no, indicate the reason for their exclusion
- Confidentiality: Describe how the privacy of subjects will be respected and steps that will be taken to protect the confidentiality and anonymity of participants.
  - Here is the link to a resource with a discussion about confidentiality and anonymity:  
<http://www.statisticssolutions.com/confidentiality-vs-anonymity/>
  - Here are some additional resources for you to review.
  - Privacy and Confidentiality in Human Subjects Research:  
<https://www.youtube.com/watch?v=DPOxvNbVwKk>
  - Confidentiality in Research:  
<https://www.youtube.com/watch?v=Z-PHtJ5hlm8>
- Risk/Benefit Analysis: Provide any potential risks/benefits to subjects/participants. You may review this resource to review additional information: [http://www.hhs.gov/ohrp/archive/irb/irb\\_chapter3.htm](http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm)

**Risk Analysis:**

- Explain risks of any experimental procedures, if applicable
- Explain risks to control groups, if applicable
- Explain risks to any deviation from standard of care, if applicable
- Ensure risks to subjects are reasonable related to anticipated benefits (if any) and the importance of the knowledge that will be expected to result from this study
- Describe any risks of legal reporting acknowledged by the subject (i.e. HIV, STDs, child abuse, harm to self or others) (if applicable)

**Benefit Analysis:** Provide any potential benefits to the subjects/participants.

- Describe benefits to the participants, if any
- Explain how benefits of the study outweigh the risks
- Indicate whether there are any anticipated adverse effects as a result of the study/project.

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- If yes, describe in detail and explain how these adverse effects will be handled.
- Indicate whether there will be any cost to the participants for participation in the study.
  - If yes, explain the estimated costs and rationale.
- Indicate whether participants will receive any compensation or other incentives to participate in the study.
  - If yes, describe the compensation and the timing of when it will be provided, ensuring that it is reasonable and not coercive.

**11. Non-Human Subjects:** Please address each of the following items with a full description.

- **Scope of the problem:** Include background information and significance and a clear and concise problem statement.
- **Purpose (s):** Include a clear and concise purpose/aim of the study or project.
- **Question(s):** Provide clear and well-written questions that they proposed study/project would answer.
- **Setting:** Describe the setting/site where the study/project will take place if applicable (If not applicable indicate- N/A).
- **Data bases/Chart-Medical Record reviews/Education project (classroom, etc.)/Sample-Sampling:** Describe any databases to be used (is the information within the database private or public information), describe the process of medical record review- (retrospective, prospective, etc.), will there be any identifiable or de-identified information and at what point in the process will this occurs. If educational project(s,) has the project been implemented or is the project to be implemented. Describe the sample, sampling method, if applicable. Provide information about the, the Sample (inclusion and exclusion criteria), proposed sample size, and the sampling method(s).
- **Planned changes:** Overall, discuss (if applicable) a focus on changes (quality improvement, etc.) within the institution, clinical practice or organization.
- **Project/study evaluation:** For non-human subject projects: describe the methods to be used to evaluate the project's effectiveness, including identification of the outcomes of interest. Include a discussion of the risk and benefits for the institution clinical practice or organization of interest.

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Complete the Sections below for ALL Projects/Study  
(Human Subjects Research and Non-Human Subjects Research).  
This also applies to projects/study's that may be considered as Exempt.

**Include an institutional \* Letter of Support from the participating agency\*.  
This Letter must be on official Letterhead and signed and must state  
that the institution agrees to and supports the project and gives  
permission for what will be needed for the project to be accomplished.  
This also requires an official signature ( Place in the Appendix)**

**\*\*\*\*\*FNU Faculty/Staff:**

**\* FNU Faculty will require a Letter of Support from the participating  
agency, if data collection is taking place outside of FNU.**

**\*FNU Faculty will require the Deans signature on the “ Faculty Dean  
Approval Form” (See Attachments). Send IRB application to the Dean  
via email for support and signature prior to submitting IRB application  
to the IRB committee.**

**\*\*\*\*\*Students:**

**\*DNP students will be required to obtain the project chair's signature  
on the “DNP Project Committee Approval Form”**

### **The following items also apply to ALL study's/projects:**

12. Will participants receive compensation or other incentives (i.e., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement to participate in the study?) Yes (  ) please explain; No (  ) N/A (  )
13. Disclose any known financial interest for the researcher, project director, or other individuals associated with the researcher or project director? Yes (  ) please explain; None (  )
14. Do you anticipate any **adverse effects of the study/project**?
  - If yes, provide information about any anticipated adverse effects. In addition, please describe how these will be handled.
  - Indicate whether there will be any cost to the participants associated with anticipated or unanticipated adverse effects

- You are required to report to the FNU IRB any anticipated adverse effects and any unanticipated events.
- Although you will most likely not be aware of unanticipated events, here is some valuable information about your responsibility in reporting unanticipated events:  
[https://www.youtube.com/watch?v=hsUS0k3Ie\\_g](https://www.youtube.com/watch?v=hsUS0k3Ie_g)

15. How will the data be **analyzed and reported**? Describe the data analysis plan, ensuring that it is adequate to achieve the aims of the study. It is anticipated that you would have a plan for analyzing data prior to submitting the IRB application. You may want to consult a statistician or obtain other resources to assure that you have a plan for analyzing the data **Prior To** completing the IRB application.

- What methods of data analysis are anticipated?
- How will the data be reported?
- How will individuals (study or project participants) be identified in analyzing and in reporting the data?

16. Data **security measures** for collected data?

- Describe measures to ensure that all study data will be held in a secure manner.
- Describe the safeguards that will ensure there is only minimal risk of invasion of privacy and breach of confidentiality
- Describe the data destruction plan
- If recordings are made, describe the plan to disguise or destroy unintentional identifying information collected during the recordings
- Indicate who will have access to the data.
  - Provide a rationale for anyone accessing the data other than the PI(s) or project director(s).
  -
- Indicate where the data will be stored

17. Where specifically will the **data/findings** be reported?

- Describe how and where the data and findings will be reported, including journal publication, conference proceedings, and academic or clinical presentations, etc.

18. **Attachments:** Please attach **as Appendices** with this application:

- a) Copy of NIH Investigator Human Subjects Training Certificate or Copy of CITI Training Certificate
- b) Abstract
- c) Student: DNP Project Committee Approval (Signature Required)

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- d) Faculty: Dean approval (Signature Required)
- e) Letter of Support from another agency
- f) Questionnaires, teaching or class protocols, focus group protocols,  
scripts, pre and post-test, surveys...
- g) Consent (Informed Consent, etc)
- h) Outside IRB approval (If Applicable)
- i) Any additional supporting documents

**Please label Appendices as A, B, C, D...in the order in which they appear in your IRB document**

Please contact the FNU IRB committee with any questions and or for clarification.  
Send an email to [irb@frontier.edu](mailto:irb@frontier.edu).