IRB Prescreening Supplement

CHAMBERLAIN UNIVERSITY

IRB Prescreening Supplement Form

Student Name:

Student Email:

Student D#:

☐ *I fully understand I cannot collect any data and/or implement my project at the practicum site until my DNP practice change project is approved and I have received all required permission(s) from Chamberlain's Institutional Review Board (IRB), as well as the practicum site's IRB (if applicable).*

Working Project Title:

Practicum Site/Organization Name:

Practicum Site Contact Person:
Name, email address, phone number

Preceptor Contact Information:
Name, email address, phone number

Mentor Contact Information (if applicable):
Name, email address, phone number

Practicum Site Key Decision Maker(s) Contact Information:
Name, email address, phone number

SECTION I: Practice Problem – Need for Project

As you prepare to submit your Project to the IRB for review and prescreening approval, complete the questions below utilizing information you provided in your DNP Readiness Form from NR730 – Project course.

Provide a problem statement (no less than 5-6 fully structured sentences) to explain the problem/issue you are addressing. Please describe the current practice/process leading to the issue. Provide reports or currently available data to document the need identified by the primary decision-maker(s) at the practicum site. **NOTE:** In this section you must include in-text citations with your **evidence-based intervention**.

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SECTION II: Practice Question – Defined Population

Based on the needs of the practicum site, please provide your one-sentence practice question in the PICOT format clearly and concisely. Note your population cannot be students or faculty; your intervention cannot be educational only; and your time frame must be 8-12 weeks. Please be certain your population and outcome measure match.

Fully describe your proposed project's population (keep in mind students and/or faculty are not allowed). What is your anticipated population size and what inclusion, and exclusion criteria will be used to identify your population?

Please submit your completed John Hopkins Evidence Summary Table as a separate document. The Johns Hopkins Table should have 10 articles focusing on your selected intervention.

SECTION III: Week to Week Implementation Plan – Protocol

Provide a concise overview of what you will do each week during the implementation phase of your project to address the issue within the practicum site. Common language should only be used for weekly monitoring, including formative evaluation, feedback, huddle, and one-to-one conversation. The final weeks should include data analysis along with dissemination of the results. Note your intervention implementation must take place over a minimum of eight (8) weeks. Recruitment, education, and data collection weeks are NOT included in the eight weeks of intervention implementation. The information you place here should match what you said in your intervention plan on the DNP Practice Readiness Form from the NR730 Project course.

SECTION IV: Data Collection and Analysis Plan

During NR705 you will work with your course faculty and your preceptor to gain IRB prescreening determination within Chamberlain and the practicum site, if applicable. Please answer all questions within this section.

Explain your **data collection plan** to measure your intervention's impact on your project outcome. Include a concise description of the outcome you identified in your practice question. If using a questionnaire or a survey, provide the name of the questionnaire or survey and discuss its validity and reliability with in-text citations from supporting literature. Additionally, fill out the chart below to concisely convey your project outcome and include the name of the valid/reliable survey or questionnaire if you are using one to collect your outcome data.

Project Main Outcome Identified in the PICOT Question	Data Collection Process Pre- and Post-Intervention
1)	1)

Explain your plan for **data analysis** and how you will determine if your intervention impacted your project outcome and practice problem.

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Section V

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If using a survey or questionnaire to collect data, do you have written permission to use your data collection tool?

☐ Yes ☐ No ☐ N/A ☐ **The questionnaire/survey is available in the "Public Domain" If in the Public Domain, Add the WEBSITE in BOX Below (NOT URL to PDF.)**

Other than Chamberlain IRB Prescreening, are there any additional approval processes you are required to undergo within the practicum site? If you answer 'Yes', please describe the requirements below.

☐ Yes ☐ No Comments

Note: If practicum site IRB or committee approval on the project is not required, I affirm I have provided my course faculty with a letter from the decision maker at the practicum site to this effect.

☐ Yes ☐ No Comments

Will informed consent be required for your project? If informed consent is required, submit the informed consent with this document.

☐ Yes ☐ No Comments

What plan do you have in place to answer questions that arise from participants?

Will participants be able to drop out of your project without consequences?

☐ Yes ☐ No Comments

Describe the plan you will have in place to maintain the confidentiality of participants, both regarding the data you will collect and how you will protect their identity. Note: all data must be reported in aggregate form.

What safeguards will you have in place to protect the data over time? How long will you maintain the data (minimum 7 years) and what will be done with the data after this time?

Discuss your plan for project dissemination at the practicum site and Chamberlain College of Nursing. Do you have plans to share this project in the future as a podium or poster presentation?

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Step 1: Determination of Whether the Project is "Research" as Defined by the IRB

1. Is your project intended to generate new knowledge that will be or is desired to be applied beyond the setting(s) in which the project is conducted?

   ☐ Yes ☐ No

2. Is your project designed to expand theory or inform policy that goes beyond the project setting(s)?

   ☐ Yes ☐ No

3. Will your project implement an intervention that has not been published as being used/tested in your population of interest?

   ☐ Yes ☐ No

4. Will your project implement an intervention using a protocol that deviates substantively from how the protocol has been used previously?

   ☐ Yes ☐ No

5. Will the project replicate or extend a previous research study?

   ☐ Yes ☐ No

Step 2: Determination of Whether the Project Includes Human Subjects

1. Will your project involve collecting, studying, analyzing, or generating data, information, or biospecimens by interacting with or intervening with living humans?

   ☐ Yes ☐ No

2. Will your project involve collecting, generating, using, studying, or analyzing identifiable* private**information, identifiable biospecimens and/or protected health information?

   ☐ Yes ☐ No

*Data, information, or biospecimens for which the identity of the subject is or may be readily ascertained (i.e., through codes or other types of alternative identifiers) by the investigator or associated with the information or biospecimens.

**Data, information or biospecimens that occur are collected in a context in which the individual can reasonably expect that no observation or recording is taking place or will not be made public and for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information or biospecimens.

If you answered "Yes" to any of the questions #1-#5 in Step 1, then your project is congruent with Chamberlain's definition of human subjects' research, and you must submit the full IRB application packet for IRB Review.

Step 3: Additional Information

1. Does the practice setting require that this project be reviewed by the setting's IRB or other review committee?

   ☐ Yes ☐ No

2. Does the project involve interacting with or having a direct impact on any of the following populations? (Identifying a vulnerable population does not always require the project to go to the IRB for a complete review).

   ☐ Yes ☐ No Persons below the age of 18?

   ☐ Yes ☐ No Persons with cognitive impairment?

   ☐ Yes ☐ No Pregnant women, fetuses, or neonates?

   ☐ Yes ☐ No Persons institutionalized?

3. Will Chamberlain students, faculty, or staff be the subjects of the proposed project?

   ☐ Yes ☐ No

Student Signature:
Type Name in Signature line _____ Date: _____

Course Faculty: I reviewed the student's practice question and attest to the accuracy and completeness of the information on this IRB Prescreening Supplement form. All elements of the PICOT practice question are present and align with the project plan

NR705 Faculty Signature:
Type Name in Signature line _____ Date: _____

NR705 Course Lead Signature: _____ Date: _____

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Section VI: NR707 Project & Practicum IV

If changes to the project were made in NR707, Please document the change below and the rationale. NR707 Course Leader Signature and NR705 Course Leader Signatures required below.

NR705 Course Leader Signature Date

NR707 Course Leader Signature Date

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Section VII: NR709 Project & Practicum IV

During NR709 you will finalize your data analysis, DNP Project Manuscript, portfolio, and present your final project findings to the school. Under this section your NR709 course faculty will confirm various aspects of your project and its completion.

NR709 Faculty Confirmation

The DNP project identified in this document was prescreened by the IRB for Chamberlain University. My signature below as faculty affirms the project is complete and the IRB is now closed.

The DNP project identified in this document was prescreened by the IRB for Chamberlain University. My signature below as faculty affirms the project is complete and the IRB is now closed.

NR709 Faculty Signature: Date

**Your written name in the above box represents your formal signature.*