#

# RECORD AND REVIEW OF DOCTOR OF NURSING PRACTICE (DNP) PROJECT

|  |  |  |  |
| --- | --- | --- | --- |
| Researcher: | Click here to enter text. | Click here to enter text. | Click here to enter text. |
|  | (Last) | (First) | (Middle Initial) |

|  |  |
| --- | --- |
| WilmU Student Email: Student ID: W | Click or tap here to enter text. |
| Student ID | Click here to enter text. |

Stu

|  |  |
| --- | --- |
| DNP Project Advisor: | Click here to enter text. |

DNP Project Advisor’s Email: Click here to enter text.

## Academic Level

 [ ]  1. DNP Project

## Forms Check List

 [ ]  1. CITI Training Certificate\*

 \*Check with your DNP Program Chair for training requirements

 \*Training certificate cannot be older than three years

 [ ]  2. Instrument(s)

 [ ]  3. Internal and/or External Research Approval Letter

 [ ]  4. Other: Click or tap here to enter text.

*This section is to be completed by the HSR Committee*

|  |  |  |
| --- | --- | --- |
| Archive Number: | Click here to enter text. |  |
| Research Category: | Choose an item. |  |
| Final Approval Date: | Click here to enter a date. |  |
|  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Complete This Worksheet Prior to Completing This Form

|  |
| --- |
| **Purpose:**The purpose of this worksheet is to provide support for making Quality Improvement Project determinations when there is uncertainty regarding whether the quality activity contains Human Subjects. |
| **Directions:**For a proposed DNP project to be classified as containing only Quality Improvement activities—which permits use of the DNP HSRC form—answers to all of the questions in the worksheet must be ‘TRUE’ for each activity proposed in the DNP project. If one or more answers is ‘FALSE’, the project requires completion of the HSRC standard form and committee review. |
| **TRUE** | **FALSE** |  |
| [ ]  | [ ]  | The intent of the proposed activity is to assess and/or improve the quality of a practice, product or program to ensure established educational, clinical or program service standards are met or best evidentiary practices attained. |
| [ ]  | [ ]  | No activity proposed provides less than standard of care, services or instruction to participants. |
| [ ]  | [ ]  | No practice, product or program changes proposed are experimental and no test interventions or research questions are added that go beyond established or evidentiary best practice. |
| [ ]  | [ ]  | The proposed activity does not: (1) include a ‘control group’ in whom care, products, services or educational instruction are intentionally withheld to allow an assessment of its efficacy or (2) assign participants to receive different procedures, therapies or educational instruction based on a pre-determined plan such as randomization. |
| [ ]  | [ ]  | The proposed activity does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including “off-label” indications). |
| [ ]  | [ ]  | The proposed activity does not test an intervention or add research questions that go beyond established evidentiary best practice and/or are intended to generate generalizable knowledge. |
| [ ]  | [ ]  | The proposed activity would not increase harm—physical, psychological, social or economic—than would normally be encountered by the individual if s/he was not participating in this activity. |
| [ ]  | [ ]  | The lead person on the project has organizational responsibility and authority to recommend or impose a corrective action plan based on the outcome(s) of the activity, as applicable. |
| [ ]  | [ ]  | Interpretation of the data or any feedback to those who would benefit from the findings will not be deliberately delayed. |
| [ ]  | [ ]  | The proposed activity has merit and will likely be conducted regardless of any possibility of publication or presentation that may result from it. |

*Adapted from Rutgers HRP-309 (2017) with permission from Judith Neubauer, PhD.*  |
|  |
| DNP Project Information  |
|  |

|  |
| --- |
| Working title of DNP Project:  |
| Click here to enter text. |

|  |
| --- |
| Problem Description: provide a short summary of clinical practice problem you will address with your DNP project. What is the gap in practice and what evidence will you be translating to practice? What is the evidence-based practice change purpose? Include key literature citations (references) and information (1 paragraph) |
| Click here to enter text. |

## External Projects

If the DNP project will involve other organizations, it is necessary to obtain permission from these organizations prior to collecting data. Some organizations have Institutional Review Boards (IRBs), and it may be necessary to obtain formal approvals from these IRBs. In other cases, a document from an appropriate organizational executive specifically approving the DNP project would be sufficient. The DNP student is responsible for determining what type of approval is required and obtaining the approval.

In cases where approval from Wilmington University’s HSRC is required as a precondition to obtaining approval from another organization, the HRSC’s approval will be provisional, requiring the additional step of obtaining DNP project approval documents from other organizations before receiving full approval from Wilmington University’s HSRC.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** |  | **NO** |
| Does the DNP project involve other organizations? | [ ]  |  | [ ]  |

*If the DNP project involves other organizations, please answer these questions.*

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** |  | **NO** |
| Do these organizations require approval by their IRBs? | [ ]  |  | [ ]  |
| Has IRB approval been obtained? If **YES**, please attach the approval to this submission | [ ]  |  | [ ]  |
| Have other permission documents been obtained? If **YES**, please attach the approvals to this submission. | [ ]  |  | [ ]  |

|  |
| --- |
| Other relevant information or comments: |
| Click here to enter text. |

## Internal Research

If the DNP project will involve collecting quantitative (including survey) and/or qualitative data from Wilmington University, its students, or employees, it is necessary to obtain permission from the University. The appropriate WilmU Academic Affairs AVP will render consideration of permission for the DNP project via the HSRC Internal Research Request process. The approval email (document) must be attached to this protocol submission.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** |  | **NO** |
| Does this DNP project involve collecting Wilmington University data? | [ ]  |  | [ ]  |
| *If* ***YES****, please attach the approval email to this submission.* |  |  |  |

## Population Information

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Population of DNP project: |  Gender |   |  Age |   |  Race/ethnicity |   |

|  |
| --- |
| PICOT Question: Include the PICOT Question in a complete sentence and then break down each section, Population -; Intervention -; Comparison -; Outcome -; Time -. Include sufficient detail so that someone unfamiliar with the project would understand all aspects of the proposed DNP project. |
| Click here to enter text. |

|  |
| --- |
| How many participants (patients, providers, etc.) are anticipated for the DNP project? |
| Click here to enter text. |

|  |
| --- |
| What inclusion criteria will be used to identify the DNP project participants (how will participants be selected for participation from PICOT question)? |
| Click here to enter text. |

|  |
| --- |
| What criteria will be used to exclude the DNP project participants (how will participants be excluded from participation? |
| Click here to enter text. |

|  |
| --- |
| What are the procedures the participants will undergo in the proposed DNP project including the physical location and duration of participation? Provide a step-by-step outline of the project from start to finish. Describe where the DNP instruments are derived; if using a validated tool, explain its origin, authors, and attach acquired permissions (email or letter). Attach a copy of all DNP instruments, e.g., surveys, questionnaires, interview questions (if being utilized). |
| Click here to enter text. |

Confidentiality and Security

Select **YES** to certify that:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** |  | **N/A** |
| Procedures have been taken to ensure that individuals cannot be identified via names, digital identifiers (e.g., email address, IP address), images or detailed demographic information. | [ ]  |  | [ ]  |
| Code to name association data/information is securely and separately stored. (Participants are given codes and the codes are securely stored separately from their answers.) | [ ]  |  | [ ]  |
| All data is maintained in encrypted and/or password protected digital/electronic files. | [ ]  |  | [ ]  |
| Individually identifiable information will be securely maintained for three years past the completion of the research, and then destroyed rendering the data unusable and unrecoverable. | [ ]  |  | [ ]  |

|  |
| --- |
| Describe the procedures you are taking to maintain anonymity, confidentiality, or information security. |
| Click here to enter text. |

DNP Protocol

Does this DNP project involve?

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** |  | **NO** |
| Prisoners, probationers, pregnant women (if there is a medical procedure or special risk relating to pregnancy), fetuses, the seriously ill or mentallyor cognitively compromised adults, or minors (under 18 years) as participants |[ ]   |[ ]
| The collection of information regarding sensitive aspects of the participants behavior (e.g., drug, or alcohol use, illegal conduct, sexual behavior) |[ ]   |[ ]
| The collection or recording of behavior which, if known outside the research, could place the participants at risk of criminal or civil liability or could be damaging to the participant’s financial standing, employability, insurability, or reputation |[ ]   |[ ]
| Procedures to be employed that present more than minimal risk**[[1]](#footnote-1)** to participants |[ ]   |[ ]
| Deception |[ ]   |[ ]
| Possible or perceived coercion (e.g., a concern in power relationships such as teacher/student, employer/employee, senior/subordinate) |[ ]   |[ ]
| Benefits or compensation to participants (beyond the general benefits of the knowledge to be gained or small gifts/lottery prizes) |[ ]   |[ ]
| A conflict of interest/grant funded research (e.g., the researcher’s material or other interests may bias collection, interpretation, or use of data) |[ ]   |[ ]

If you answered “**NO”** to all of the questions, please proceed to the next page.

If you answered “**YES”** to any of the questions, provide evidence that you have taken the training module(s) that relate to this risk and discuss what you learned about reducing the risk or mitigating bias from the training in the textbox below and/or by attaching the evidence to this document.

|  |
| --- |
| Click here to enter text. |

Obligations of DNP Student

Any substantive changes made to the DNP protocol must be reported to and reviewed by your college’s HSRC representative(s) prior to implementation of such change. Any complications, adverse reactions, or changes in the original estimates of risks must be reported at once to the HRSC chairperson before continuing the project.

Select **YES** to certify that:

|  |  |
| --- | --- |
|  | YES |
| DNP data, including signed consent form documents, will be retained for a minimum of three years past the completion of the research in accordance with federal regulations | [ ]  |
| The DNP student will submit document and form revisions and updates, as appropriate | [ ]  |
| The DNP student will submit a renewal petition if the data collection has not been completed within one year of the most recent HSRC approval\* |  [ ]  |
| * **Note**: HSRC approval expires after one year, requiring renewal of the HSRC Protocol
 |

The DNP student’s signature below certifies that they have (a) read and understand the obligations as a DNP student, (b) DNP project approval expires one year after the final approval date shown on page 1, and (c) that the information contained in and submitted with this HSRC protocol is accurate and complete.

*DNP Student*:

|  |  |  |  |
| --- | --- | --- | --- |
| Print name: | Click here to enter text. |  |  |
| Signature: |  |  Date: | Click here to enter a date. |

Obligations of the DNP Project Advisor

The DNP project advisor has two major obligations. First, the DNP project advisor must ensure the DNP student completes all relevant training courses. Second, the DNP project advisor must ensure the DNP student submits all document and form revisions and updates, as appropriate for the research.

The DNP project advisor’s signature below certifies that they have (a) read and understand the obligations as a DNP project advisor and (b) that the information contained in and submitted with this HSRC protocol is accurate and complete. **A revised signature and date are required with modifications/each submission.**

***DNP Project Advisor***:

|  |  |  |  |
| --- | --- | --- | --- |
| Print name: | Click here to enter text. |  |  |
| Signature: |  |  Date: | Click here to enter a date. |

DNP Project advisor’s CITI certificate expiration date: Click or tap to enter a date.

# PROTOCOL REVIEW

*This section is to be completed by the HSR Committee.*

|  |  |
| --- | --- |
| DNP Student: | Click here to enter text. |
| Date Submitted: | Click here to enter a date. |

The protocol and attachments were reviewed:

|  |
| --- |
| The proposed research is approved as: |
| [ ]  | Exempt |  | [ ]  |  Expedited |  |  [ ]  | Full Committee |  |  |

[ ] Provisional (see External Research section) Provisional Date: Click or tap to enter a date.

|  |
| --- |
| The proposed DNP project was approved pending the following changes: |
|  | [ ]  | See attached letter |
|  | [ ]  | Resubmit changes to the HSRC chairperson |

|  |
| --- |
| The proposed research was disapproved: |
|  | [ ]  | See attached letter for more information. |   |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| HSRC Chair or Representative |  | Click here to enter text. |  |  |  |  |
|  |  | Printed Name |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  | Signature |  |  | Date | Click here to enter a date. |
|  |  |  |  |  |  |  |
| HSRC Chair or Representative |  | Click here to enter text. |  |  |  |  |
|  |  | Printed Name |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  | Signature |  |  | Date | Click here to enter a date. |

**References**

1. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests [↑](#footnote-ref-1)