# REQUEST FOR AMENDMENT

# TO AN APPROVED *HSRC RESEARCH PROTOCOL*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Original HSRC Protocol Number: | | |  |  | |
| Researcher or Student: |  | Click here to enter text. | | Click here to enter text. | Click here to enter text. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | (Last) | (First) |  | (Middle) |

|  |  |
| --- | --- |
| Student ID: W | Click here to enter text. |

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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Original Type of Review: | | | | | | | | | | |
|  | Exempt |  |  | Expedited |  |  | Full Committee |  |  |  | |

## Degree Type

|  |  |  |
| --- | --- | --- |
|  | 1. Doctor of Business Administration | |
|  | 1. Doctor of Education (Ed.D) | |
|  | 1. Doctor of Nursing Practice (DNP) | |
|  | 1. Doctor of Social Science | |
|  | 1. Master’s Thesis/Capstone | |
|  | 1. Other | Click here to enter text. |
|  |

## Forms Check List

|  |  |  |
| --- | --- | --- |
|  | 1. Human Subjects Protocol Amendment | |
|  | 1. Modified Consent Forms or Invitations | |
|  | 1. Instrument(s): New or Modified | |
|  | 1. Other | Click here to enter text. |
|  |

|  |
| --- |
| Amendment Information: |

Amendments to previously approved research or a project require review and approval by the research/project advisor and one or more HSRC representatives or the full HSRC before implementing any changes to the research or project.

Reason for Amendment (check all that apply):

|  |  |
| --- | --- |
|  | Change in research personnel |
|  | Change in study design, methods, or procedures |
|  | Change to study population/sample criteria including increasing anticipated number of participants |
|  | Change in recruitment or compensation procedure |
|  | Change to data collection or research instruments |
| ☐ | Change to identifiers collected in the study or to procedure that would impact the privacy or confidentiality of the study participants |
|  | Change to the informed consent or introductory letter |
|  | Change in funding source |
|  | Other: |
|  | Click here to enter text. |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **YES** |  | **NO** | |  |  | | | | |
|  |  |  | |  | Was this amendment the result of a request from an external organization and/or Institutional Review Board (IRB)? If yes, please provide documentation of this request. | | | | |
|  |  |  | |  | Is External IRB approval / other permission documents required for the amendment? If **YES**, please attach the approval to this submission. | | | | |
|  |  |  | |  | Are the described changes within the scope of the original study? If **NO**, you must submit a new HSRC Research Protocol for review. | | | | |
| Provide a detailed description of the changes being requested:   |  | | --- | | Click here to enter text. |   State any potential impact on the risks or benefits to the research/project participants from the proposed amendment | | | | | | | | | |
| Click here to enter text. | | | | | | | | | |
|  | | | | | | | | | |
| Describe if the amendment may involve information that might change a participant/subject’s willingness to continue to take part in the research/project: | | | | | | | | | |
| Click here to enter text. | | | | | | | | | |
|  | | | | | | | | | |
| Please list any study documents that will be revised because of this amendment, such as consent forms, recruitment materials, questionnaires, etc. Also, please attach a copy of these revised documents to this application | | | | | | | | | |
| Click here to enter text. | | | | | | | | | |
|  | | | | | | | | | |
| **Current research/project enrollment status:** | | | | | | | | | |
|  |  | | # participants enrolled: | | |  | |  | |
|  | |
|  | | | | | | | | | |
|  |  | | Date enrollment began: | | |  | |  | |
|  | |
|  | | | | | | | | | |
|  |  | | Anticipated enrollment end date: | | | |  | |  |
|  | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Obligations of Researcher/Student**  Substantive changes to the research/project’s protocol must be reported to, reviewed by, and approved by your advisor and your college’s HSRC representative(s) or the full HSRC prior to implementing any change.  Direct or indirect activities related to risk may not continue when complications, adverse reactions, or changes in the original estimates of risks occur or are identified. Any complication, adverse reaction, or change in the original estimates of risks must be immediately reported to your advisor, who will request guidance from your college’s HRSC representative(s) or the full HSRC. | | | | | |
|  | | | | | |
|  | **YES** |  | **NO** |  | |
|  |  |  |  | Research or project data, including signed consent form documents, will be retained for a minimum of three years past the completion of the research/project in accordance with federal regulations | |
|  |  |
|  |  |
|  |  |  |  | The researcher/student will submit document and form revisions and updates, as appropriate | |
|  |  |
|  |  |
|  |  |  |  | The researcher/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 a renewal of the HSRC Protocol | |
|  |  |  |  |  |  |

The researcher’s/student’s signature below certifies that they have read and understand the obligations and that the information contained in and submitted with this amended HSRC protocol is accurate and complete.

**The HSRC reserves the right to request an updated Research Protocol document for review.**

*Researcher/Student*:

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

***Advisor***:

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

# PROTOCOL REVIEW

*This section is to be completed by an HSRC Representative or the HSR Committee.*

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

The protocol amendment and attachments were reviewed:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | | | |
|  | Exempt |  |  | Expedited |  |  | Full Committee |  |  | Provisional (see External Research section) | |

|  |  |  |
| --- | --- | --- |
| The proposed research/project amendment was approved pending the following changes: | | |
|  |  | See attached letter |
|  |  | Resubmit changes to the HSRC chairperson |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The proposed research/project amendment was disapproved: | | | | | | | | |
|  | | |  | | | See attached letter for more information. | |  |
|  | | |  | | |  | |  |
| **YES** |  | **NO** | |  | **N/A** | |  | | |
|  |  |  | |  |  | | For research involving Wilmington University students, employees, or data, the HSRC representative sent a copy of the HSRC Protocol to the VP of Academic Affairs. | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 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. |