# 

# RECORD AND REVIEW OF RESEARCH PROTOCOL

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

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

|  |  |
| --- | --- |
| Research Advisor: | Click here to enter text. |

## Academic Level

|  |  |  |
| --- | --- | --- |
|  | 1. Doctoral Dissertation/Capstone | |
|  | 1. Master’s Thesis/Capstone | |
|  | 1. Other | Click here to enter text. |
|  |

## Forms Check List

|  |  |  |
| --- | --- | --- |
|  | 1. Human Subjects Protocol | |
|  | 1. CITI Training Certificate\* | |
|  | * Check with your research advisor for training requirements * Training certificate cannot be older than 3 years | |
|  | 1. Consent Forms or Invitations | |
|  | 1. Instrument(s) | |
|  | 1. Other | Click 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. |  |
|  | |  | |

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| --- |
| Project Information |
|  |

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| Title of study (12 to 15 words maximum): |
| Click here to enter text. |

|  |
| --- |
| Research purpose or issue: |
| Click here to enter text. |

## External Research

If the research 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 research would be sufficient. The researcher 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 research approval documents from other organizations before receiving full approval from Wilmington University’s HSRC.

If the research 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. |

## Population Information

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Population to be studied: | Gender |  | Age |  | Race/ethnicity |  |

|  |
| --- |
| What is the anticipated sample size? |
| Click here to enter text. |

|  |
| --- |
| How will participants be recruited? |
| Click here to enter text. |

|  |
| --- |
| What inclusion criteria will be used to identify the sample’s participants? |
| Click here to enter text. |

|  |
| --- |
| What criteria will be used to exclude participants from the sample? |
| Click here to enter text. |

|  |
| --- |
| How will participants be selected? |
| Click here to enter text. |

|  |
| --- |
| What are the procedures that the participants will undergo in the proposed research project including the physical location and duration of participation? **Attach a copy of all research instruments, e.g., surveys, questionnaires, interview questions, etc.:** |
| 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. |  |  |  |

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

Research Protocol

Does this research involve?

|  |  |  |  |
| --- | --- | --- | --- |
|  | **YES** |  | **NO** |
| Prisoners, probationers, pregnant women (if there is a medical procedure or  special risk relating to pregnancy), fetuses, the seriously ill or mentally  or 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 (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 or modules that relate to this risk and discuss what you learned about reducing the risk from the training in the textbox below and/or by attaching the evidence to this document.

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

## Consent Forms

|  |  |  |  |
| --- | --- | --- | --- |
|  | YES |  | NO |
| Is a consent form included with this study? If **YES**, attach a copy. |  |  |  |
| Are child assent forms included with this study? If **YES**, attach a copy. |  |  |  |
| Is implied consent being used? If **YES**, attach a copy of the invitation. |  |  |  |

Minors must provide an affirmative consent to participate by signing a simplified form, unless the researcher can provide evidence that the minors are not capable of assenting because of age, maturity, psychological state, or other factors.

Please refer to the informed consent outline and checklist and the assent outline, which can be found in the Human Subjects Review Committee section of the Wilmington University website.

Implied consent – For some exempt or expedited research, it is not necessary to have a signed consent form. For example, a relatively short survey of competent adults which is anonymous and deals with noncontroversial topics could use a less formal means of providing information. In such cases, the person’s voluntary participation indicates implied consent. Typically, the invitation to participate would be less legal in tone than a consent form but would provide information about the researcher, study purpose, voluntary participation, nature/duration of participation, and anonymity/confidentiality.

|  |
| --- |
| How is consent being obtained? |
| Click here to enter text. |

**Additional Research Approval**

|  |  |  |  |
| --- | --- | --- | --- |
|  | YES |  | NO |
| Are you Wilmington University faculty conducting research that involves human subjects? |  |  |  |
| Are you a Wilmington University employee and a student at another school whose research involves collecting data from the University, its students, or employees? |  |  |  |
| Are you an outside researcher whose research involves collecting data from the University, its students, or employees? |  |  |  |

If you answered “**YES”** to any of the questions, an appropriate Wilmington University dean or executive must sign this form, prior to HSRC submission.

The executive signing this form is responsible for conferring with institutional research or other parts of the university which would need to support the research.

***Dean or Executive:***

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

Obligations of Researcher

Any substantive changes made to the research 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 |
| Research 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 researcher will submit document and form revisions and updates, as appropriate |  |
| The researcher 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 researcher’s signature below certifies that the Researcher has (a) read and understands the obligations as a researcher, (b) research 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.

*Researcher*:

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

Obligations of the Research Advisor

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

The research advisor’s signature below certifies that the advisor has (a) read and understands the obligations as an advisor and (b) that the information contained in and submitted with this HSRC protocol is accurate and complete.

***Research 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 the HSR Committee.*

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

The protocol and attachments were reviewed:

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The proposed research is approved as: | | | | | | | | | | |
|  | Exempt |  |  | Expedited |  |  | Full Committee |  |  | Provisional (see External Research section) | |

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

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

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| --- | --- | --- | --- |
|  | **YES** |  | **N/A** |
| The HSRC representative sent a copy of the HSRC Protocol to the VP of Academic Affairs for research requiring access to Wilmington University students, employees, or data. |  |  |  |

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

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)