### PROJECT REVIEW COVER SHEET

Statement by Principal Investigator

**INSTRUCTIONS:** This form must be typed. If there is not sufficient space to answer a question, please attach additional pages. Please use the **TAB** to move from one block of text to another. The spell check option cannot be used with online forms.

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| --- | --- | --- |
| Investigator(s): |  | |
| Department/Program: | |  |
| Contact Phone Number: | |  |
| Email Address: | |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Faculty |  | Graduate Student | | |  | Undergraduate Student |
|  |  | Staff |  | Other (specify): |  |  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| If student, name of faculty project advisor: |  | Phone #: |  |

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| --- |
| Research Project Title: |
| Brief Description: |

Is this project being reviewed by any other institution’s review board?  Yes  No

If yes, provide name and location of institution:

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| Anticipated date of review? |  | (Please submit copy of review decision to Sponsored Programs). |

Is this project being submitted to a funding agency/organization?  Yes  No

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| --- | --- |
| Date by which proposal must be submitted to funding agency: |  |

1. a. Please indicate with an **** if your project involves any of the following populations

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Children under 8 years of age? |  |  | Economically disadvantaged |  |  |
|  | Children 8–17 (under 18 years of age)? |  |  | Educationally disadvantaged |  |  |
|  | Prisoners? |  |  | Individuals with impaired |  |  |
|  |  |  |  | decision-making ability |  |  |

NOTE: if you have checked any of the above-listed categories and your research study involves greater than minimal risk, the proposal must receive full review.

1. b. This project involves secondary data analysis.\*

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| --- | --- | --- |
|  | Data is: Publicly available data | Non-public data |
|  | Identifiable | Deidentified |

\* Secondary data analysis involves the re-use of data and specimens that were or will be collected for non-research purposes or from research studies other than the proposed research study. The research materials generally will be publicly available materials, medical records or existing repositories of clinical specimens. No contact between investigator and subject is allowed.

2. If you will be utilizing outside agencies to conduct your research, please submit the appropriate permission letters or emails from the agencies indicating their willingness to cooperate with your research?  YES  NO

3. Will you be recording any identifiable, private information about individual subjects?  YES  NO

Private information is considered to be identifiable when it can be linked to specific individuals either directly or indirectly through a coding system. For example, collecting detailed demographic information or information on personal experiences qualifies the data collected as identifiable private information.

IF YOU HAVE ANSWERED “YES” TO ITEM 3, PLEASE READ AND SIGN THE STATEMENT BELOW:

I understand that I am obligated to protect and keep confidential any identifiable, private information gathered about individual subjects through the conduct of my research; and I agree to keep such information confidential, unless I obtain the subject's express written permission to do otherwise.

Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Will you be utilizing audiotapes or videotapes in your research?  YES  NO

If the answer to Question 4 is YES, please provide a detailed description of what you are doing and why. Also, what will be the disposition of the recorded tapes after completion of your research? These tapes must be destroyed by a date certain, not to exceed three years from the completion of the research project. You will also need to inform the subject of your intent to record your audiotape and/or videotape, by including this information on the Informed Consent Form.

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5. If your research involves at least minimal risk to subjects, or if your subject pool includes any of the vulnerable groups identified in Item 1a, then you MUST obtain informed, written consent from your subjects and/or a legally responsible guardian (for children and persons incapable of giving informed consent).

The above statement is applicable. I have attached the Informed Consent document that I plan to utilize?  
  YES  NO

1. When you have completed your contact with the research participant, will there be a debriefing session?  YES  NO If your answer is YES, please describe the procedure that you will utilize.

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**ATTACHMENTS:** If you will be asking questions, testing performance, or manipulating the subject, please append copies of questionnaires, tests, interview protocols, or the methods sections of your grant proposal. If you have yet to pick the exact procedures you will be using, then provide specific, concrete examples of the types of test items, treatments, or questions you will use.

**ASSURANCES**

It is understood that I will keep on file (for at least three years) and make available, on request by the IRB, copies of signed Informed Consent Forms of all subjects participating in this research.

It is understood that students at the Simmons University should be initially recruited as research subjects by public announcements and not by personal solicitation.

I have completed the CITI Program educational tutorial, as required, prior to project approval.  YES

*Since 2010, the Simmons University Institutional Review Board (IRB) has required all individuals conducting research involving human subjects through the University to complete the CITI (Collaborative Institutional Training Initiative) Program, a web-based human subjects research investigator education program and include their certificate of completion in their IRB packet.*

I have completed any necessary documents regarding financial disclosure, as required, prior to project approval.

It is the responsibility of the researcher to ensure that a Final Report is filed when the project is completed. Continuing review of expedited research projects is no longer required. Continuing review is still required for active protocols that were reviewed by the full committee and any project which exceeds a period of one year must be reviewed and receive IRB approval prior to the beginning of the next year of the research project. (Details below.)

**In signing this statement I certify to the accuracy of the information pro­vided and reassert my intention to abide by the University’s policies and procedures governing research involving human subjects**.

# SIGNATURE(s):

Researcher(s) Date

# 

Researcher(s) Date

# SIGNATURE(s):

## Faculty Advisor (if Researcher is a Student) Date

**NOTE:** Faculty advisors must complete the regular investigator CITI training and submit their completion certificate in the student’s protocol packet or place it on file at [irbprotocols@simmons.edu](mailto:irbprotocols@simmons.edu).

Certificate attached  Certificate filed

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| The protocol should be submitted electronically or in hard copy. It must include the following items **collated in the order listed**: | | | |
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| A. |  | Project Review Cover Sheet. | |
| B. |  | Project Proposal. See Instructions to Investigators/Proposal Template for detailed information. | |
| C. |  | Instrument/Questionnaire(s), if applicable. | |
| D. |  | Authorization(s) from cooperating agencies or institutions. | |
| E. |  | Proposed Informed Consent Form(s). | |
|  |  |  | |

**NOTES TO INVESTIGATOR:** It is the responsibility of the researcher to ensure that a Final Report is filed when the project is completed.

**NEW:** Continuing review of expedited research projects is no longer required, if the protocol was approved after Jan 21, 2019 AND deemed exempt or expedited. You will instead receive an email reminding you to close your protocol if the research is completed, which will include a reminder to submit for approval modification requests for any changes.

Continuing review is still required for active protocols that were reviewed by the full committee, until the project’s investigators are no longer collecting data or conducting interventions and are in the data analysis phase of their projects.