### CONTINUING REVIEW COVER SHEET – 1/21/2019

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.

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | [ ]  | Faculty | [ ]  | Graduate Student | [ ]  | Undergraduate Student |

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

|  |
| --- |
| Research Project Title:       |

**PROJECT STATUS:**

PROJECT IS CURRENTLY ACTIVE (Seeking IRB Approval to continue.): [ ]

A. No enrollment to date [ ]

B. Enrolling subjects [ ]

|  |  |
| --- | --- |
| C. Closed to enrollment **[ ]**  | Date Closed to Enrollment:       |

PROJECT SHOULD BE INACTIVATED: [ ]  Please complete the remainder of the report form.

|  |  |
| --- | --- |
| D. Study completed [ ]  | Date Completed:       |

**PROGRESS/FINAL REPORT:**

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| --- |
| OVERALL STUDY PROGRESS TO DATE: (experience to date, enrollment since last review/approval, reason for slow enrollment or lack of enrollment, etc.)      |
| SUBJECT WITHDRAWALS: (why subjects withdrew or were withdrawn from participation in the study)      |

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| SUBJECT COMPLAINTS ABOUT THE RESEARCH:      |
| COMMENT ON ANY ADVERSE EVENTS OR UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS:      |
| SUMMARY OF NEW INFORMATION: (recent literature, findings to date or other relevant information, especially information about risks associated with the research)      |
| CURRENT ASSESSMENT OF RISKS AND BENEFITS (based on experience to date. If there is no change in risk benefit assessment, so state.)      |

**AMENDMENT(S):** The IRB must approve all changes to protocols, consent forms, questionnaires, recruitment letters, advertisements, etc., PRIOR to implementation.

Are any amendments proposed at this time? Yes [ ]  No [ ]

If YES, attach a description detailing proposed changes and copies of all amended documents.

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.

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**: |
|  |  |  |
| 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.