

Rowan University
INSTITUTIONAL REVIEW BOARD
FOR THE PROTECTION OF HUMAN SUBJECTS (IRB)
Continuing Review/Final Report Form

Human subject protocols are generally approved by the IRB for a twelve-month period. Federal regulations require a continuing review for ongoing projects no less than annually. If the project is concluded, the PI must file a final report with the IRB. Please complete this form and return it to the Office of the Associate Provost for Research, Memorial Hall.

Principal Investigator:

Project Title:

Faculty Advisor (If student is PI):

Department:

IRB Number: _____

Original Approval Date: _____

This project has been completed (see FINAL REPORT section)

This project has not been completed (see CONTINUING REVIEW section)

For FINAL REPORT:

- | | |
|---|--|
| 1. Was there any deviation from the originally anticipated risks and/or benefits of the study? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Did any adverse events or unanticipated problems involving risks to the subjects or others occur? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Did any subjects withdraw or did you exclude anyone from the study? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Did any subjects express discomfort or concerns or complain about the research? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Did any subjects participate in the study without signing a consent (and/or assent) form? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. To the best of your knowledge, are there any long-term risks to the subjects that were not previously identified or anticipated? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

If you answered “**YES**” to any of the above questions, please attach a detailed explanation, including actions taken to reduce the risks or discomforts to subjects and/or to communicate new findings or knowledge to subjects.

(NOTE: Per Federal guidelines, future analysis of data from this study to address additional research questions will require a new IRB application.)

For CONTINUING REVIEW:

- | | |
|--|--|
| 1. Have the risks and/or benefits to the subjects changed from those originally anticipated? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Did any adverse events or unanticipated problems involving risks to the subjects or others occur? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Have any subjects withdrawn or have you excluded anyone from the study? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Have any subjects expressed discomfort or concerns or complained about the research? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Since the last IRB review, have there been any findings, publications, or other relevant information that relate to risks associated with the research? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. Are any subjects participating in the study who have not signed a consent (and/or assent) form? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

If you answered “**YES**” to any of the above questions, please attach a detailed explanation, including actions taken to reduce the risks or discomforts to subjects and/or to communicate new findings or knowledge to subjects. If you are still enrolling subjects in this study, please attach a copy of the current IRB-approved consent form.

CERTIFICATIONS: I certify that the approved protocol and the approved method for obtaining informed consent, if applicable, have been followed during the period covered by this report and/or will continue to be followed throughout the continuation period. If this request is for continuation, I will continue to observe the ethical guidelines and regulations regarding the protection of human subjects from research risks and will continue to adhere to the policies and procedures of the Rowan University Institutional Review Board. I agree to obtain informed consent of subjects who are to participate in this project according to the procedures approved by the IRB; to report to the IRB any unanticipated effects on subjects which become apparent during the course or as a result of experimentation and the actions taken as a result; to cooperate with the IRB in the continuing review of this project; to obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in the approved consent form; and, for IRB purposes, to maintain documentation of consent forms and other research notes for at least three years after completion of the research.

SIGNATURES:

Principal Investigator (Faculty advisor if PI is student)

Date

Date FOR IRB USE ONLY:

Project #:

IRB Signature:

Date Received:
