SUNY ONEONTA

State University of New York – College at Oneonta Institutional Review Board

Continuing Review, Final Review/Termination, Modifications, or Adverse Events/Unanticipated Problems

This is a fillable form. Please type in or check as appropriate. Email completed form and attachments to IRB@oneonta.edu. Questions should be directed to the Sponsored Programs Office, x2525 or x2294 or to IRB@oneonta.edu.

Title of Project:

IRB #:

Principal Investigator:
Department:
Campus Address:
Campus Phone:
Email:

Investigator Status: ☐ Faculty/Staff (including adjuncts) ☐ Graduate Student

☐ Undergraduate Student ☐ Other (Explain):

If there are additional investigators, include their information as an attachment.

Is/was the research:

☐ Funded by an agency that requires IRB review?
☐ Undertaken for graduate studies?
☐ Undertaken by an undergraduate for a class?
☐ Undertaken by an undergraduate for a presentation being made outside of a class, such as the Student Research Show?

Are you using this form to report/request:

☐ **Final Review/Termination** of the research activity (for a study that is finished)?
If so, complete *I. Final Review*.

☐ **Continuing Review** of the research activity (for extending approval of an ongoing study)?
If so, complete *II. Continuing Review*.

☐ **Modification** of the research activity (for substantive changes to an ongoing study)?
If so, complete *III. Modification of Research*.

☐ **Adverse Events/Unanticipated Problems** in the research?
If so, complete *IV. Adverse Events/Unanticipated Problems*.

PLEASE READ THE APPLICABLE SECTIONS AND FILL OUT ALL REQUESTED INFORMATION. ALL SECTIONS REQUIRE ATTACHMENT OF ADDITIONAL INFORMATION.

I. FINAL REVIEW/TERMINATION

☐ All study activities are complete. IRB approval can be inactivated. Attach a final abstract of the research project.

☐ Study will not be done. IRB can close this file. Attach an explanation.

II. CONTINUING REVIEW

For studies that need IRB approval to remain active, submit a current research description (modifications previously approved by the IRB should be incorporated into the protocol). If changes were made to the protocol or research description, submit a current research description with changes underlined.

Note: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must be obtained before implementing any changes.

Research Progress:

☐ No subjects have enrolled to date.
Anticipated beginning date:
Anticipated completion date:

☐ Recruitment and/or enrollment of new subjects continue.
Date began:
Anticipated completion date:

☐ Study is closed to enrollment, but subjects still receive research-related interventions/procedures.
Anticipated completion date:

☐ The remaining research activities are limited only to data analysis.
Anticipated completion of analysis:

☐ Estimated project end date:

Funding Status:

☐ This study is not funded.

☐ Study is funded by:
Dates of funding:

Subjects Status:

How many subjects have completed the study since it started:

How many subjects have completed the study since the last report:

If more subjects will be recruited, how many:

How many subjects have withdrawn:
Why:

III. MODIFICATION OF RESEARCH
If substantive changes need to be made to the original study protocol, attach a brief description of the changes and explain why they are essential.

Attach revised consent and assent forms, if needed based on the proposed changes.

Note: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must be obtained before implementing any changes.

IV. ADVERSE EVENTS/UNANTICIPATED PROBLEMS
If there are/were any problems or complications in the study that affected the subject or others, attach a description/explanation of any such problems or complications and if/how they have been addressed thus far.

IRB Review (for office use only)

☐ Continuing review: ongoing protocol has been reviewed and approved for an additional one-year period. New dates of approval: _____

☐ Modification: ongoing protocol changes have been reviewed and approved

☐ Adverse events/unanticipated problems: this report of problems and complications has been reviewed and addressed.

☐ Final review/termination: the closing report for this terminated protocol has been reviewed and accepted. Date closed: _____