SUNY Polytechnic Institute
Institutional Review Board

Application for Continuing Review of Research

Study Number:
Title of Project:
Principal Investigator:
Email:
Protocol Version/Date:
Department:
Phone:

1. STATUS OF STUDY

Please indicate the current status of the research project by selecting from the following. Submit any additional documents as required.

☐a. Active – Open to enrollment, or review of records continues.

☐b. Closed to enrollment, but subjects continue to undergo research-related interactions/interventions.

☐c. Closed to enrollment; all subjects have completed interactions/interventions, and the study remains active only for long-term follow-up of participants.

☐d. Closed to enrollment and follow-up but data analysis continues, including access to records/specimens either directly or through codes/links to associated data.

☐e. The only research activity is limited to data analysis excluding access to codes/links to subject, record, specimen or data.

☐f. Study is permanently closed and all study activities are complete.

☐ Submit a final abstract and complete all sections of this form for information that has not previously been submitted to the IRB.

☐g. Other Status

☐Attached is a summary of the current status of the study and all applicable supporting documentation is included.

2. PROGRESS REPORT

a. Since the last SUNY POLY IRB review, have there been any:

(1.) Multi-center trial reports

☐NO ☐YES (attached)

(2.) Data and Safety Monitoring Board (DSMB) Reports

☐NO ☐YES (attached)

(3.) Changes in research personnel

☐NO ☐YES (attached)

b. To satisfy federal regulatory continuing review requirements, please submit:

(1.) A current, complete copy of the protocol, including all previously approved amendments incorporated into the protocol.

☐NO ☐YES (complete copy of protocol submitted)

☐Not applicable (state reason)

(2.) If substantive changes are required to the protocol, submit a copy of the protocol with the changes underlined and include Modification Form explaining the changes and why they are necessary.

☐NO ☐YES Amended protocol with Modification Form attached.

(3.) A protocol summary that includes a status report on the progress of the research. If applicable, satisfy this requirement by:

☐ (a) If the research involves extramural funding, you may attach the most recent *Progress Report Summary* or project summary submitted to the funding agency; OR

☐ (b) If the study is Investigator Sponsored (conducted under your own IND/IDE), attach a copy of the current progress report sent to the FDA.

☐NO ☐YES (Protocol Summary and Progress report attached)

☐ (c) If neither A or B applies, enter summary here:

3. ENROLLMENT INFORMATION

a. Total number of participants to be enrolled in the study:

b. Total number of participants enrolled in the study since initiated:

c. Total number of participants enrolled since last approval date:

d. Total number of participants whose study treatment/interaction/intervention were terminated early or have chosen to/or been withdrawn from the study:

☐Describe specific reasons for withdrawals/terminations here or as attachment.

e. Number of participants considered members of vulnerable populations.

Population	No	Yes	Number
Individuals with diminished mental/physical capacity	☐	☐	
Children	☐	☐	
Pregnant Women	☐	☐	
Fetuses	☐	☐	
Economically/educationally disadvantaged members	☐	☐	
Prisoners	☐	☐	
American Indians	☐	☐	
Other (Please specify) Click here to enter text.	☐	☐	

4. INFORMED CONSENT

If the study is open to enrollment, please submit:

a. One copy of the currently approved consent/assent form is attached.

☐NO ☐YES (attached)

b. Changes in consent/assent form requested. One copy of the form with the requested changes is attached.

☐NO ☐YES (attached)

c. If the IRB approved a waiver to obtain a signed consent, please include:

☐NO ☐YES One copy of the currently approved document used for the informed consent process (i.e. phone script, cover letter).

☐NO ☐YES Changes are requested to document used for consent. One copy of the form with the requested changes is included.

d. Did any problems occur in the process of obtaining or documenting informed consent?

☐NO ☐YES (A description of the problem and resolution is included here or attached.)

e. Do you have a signed and dated IRP approved consent form/authorization form on file for each subject enrolled?

☐NO ☐YES (An explanation is included here, or attached) ☐N/A

f. Has each subject been given a signed and dated copy of the consent document/authorization form?

☐NO ☐YES (An explanation is included here, or attached) ☐N/A

5. ADVERSE EVENTS or UNANTICIPATED PROBLEMS

*Since the last SUNY POLY IRB review of this research study, if any of the following unanticipated problems or adverse events were previously reported to the IRB, summarize the problem/event as an attached document and describe the outcome. For those not previously reported, complete an **Adverse Event/Unanticipated Problem Form** or **Complaint Form** and attach with this submission.*

a. **Deviations** from SUNY POLY IRB approved protocol.

☐None ☐New (form attached) ☐Previously reported (document attached)

b. **Unexpected adverse events** of moderate or greater severity associated with the conduct of this research.

☐None ☐New (form attached) ☐Previously reported (document attached)

c. Unanticipated problems involving risks to participants or others.

☐None ☐New (form attached) ☐Previously reported (document attached)

d. Any **breaches** of subject confidentiality.

☐None ☐New (form attached) ☐Previously reported (document attached)

e. **Modifications** to the currently approved protocol or informed consent document that were not approved by the SUNY POLY IRB prior to implementation.

☐None ☐New (form attached) ☐Previously reported (document attached)

f. Any **complaints** about the research and the resolution.

☐None ☐New (form attached) ☐Previously reported (document attached)

6. RISK/BENEFIT ASSESSMENT

If any of the following risk/benefit considerations have been reported since the last SUNY POLY IRB review of this study, please summarize the changes as an attachment. For changes not previously reported, please complete the associated form and attach to this application.

a. Describe any change in the benefit and risk considerations of study participation as defined in the currently approved research protocol and associated consent form.

☐None ☐New – Modification Request Form attached, with Modified Consent Form

b. Have there been any new publications in the literature relevant to this research?

☐None ☐Yes (A copy of article is attached)

c. Is there any new information on risks and/or benefits associated with study participation that may influence the willingness of current or future research subjects to participate in this research project?

☐None ☐Yes

(A copy of the relevant information is attached, along with a description – here or attached – of how this information will be distributed to current and future research subjects).

d. Have subjects experienced any benefits from participation in the research?

☐None ☐Yes (Listed here or attached)

7. REQUIRED ATTACHMENTS

- ☐ Consent/Assent Document
- ☐ Protocol
- ☐ Protocol Summary
- ☐ Modification Form (as required)
- ☐ Unanticipated Problem/Adverse Event/Complaint Form (as required)
- ☐ Copies of any recent publications
- ☐ Summary of Findings (Data Analysis)

Please submit the completed application and all supporting documents to IRB@SUNYIT.edu. If you have any questions or require assistance completing this Application, please contact the Office of the IRB at 315-792-7270, or by email.