**SUSPENSION OR PREMATURE TERMINATION OF A STUDY**

# PURPOSE AND SCOPE

To protect study participants whose health or welfare may be compromised by the suspension or early termination of a clinical research study.

**APPLICABLE REGULATIONS AND UC POLICIES**

Policy II.02 *Reporting Unanticipated Problems in Human Subjects Research*

Clinical SOP 3-1 *Promptly Reportable Events*

**PERSONS RESPONSIBLE**

*Principal Investigator.* The Principal Investigator (PI) is responsible for assuring that procedures are followed when a study is suspended or terminated so that the health and welfare of participants are protected, participants get appropriate follow up treatment and that the appropriate agencies are notified.

*Clinical Research Coordinator/Nurse*

*Regulatory Manager*

*Data Manager*

**PROCEDURES**

1. If the trial is terminated prematurely or suspended for any reason and the termination or suspension presents an immediate threat to the health or welfare of participants, the researcher will promptly inform the participants and the IRB. If the termination or suspension does not present an immediate threat to the health or welfare of participants, the researcher should notify the IRB to get approval of any information to be given to participants. The research must provide appropriate therapy and follow-up to participants, and, where required should inform the sponsor.

2. If the investigator terminates or suspends a study without prior agreement of the sponsor, the investigator should inform the IRB. The IRB and the Office of Sponsored Programs should be provided a detailed written explanation for the termination or suspension. If the suspension is lifted the investigator should notify the IRB in writing.

3. If the sponsor terminates or suspends a trial, the investigator should promptly inform the Office of Sponsored Programs and the IRB and provide the IRB a detailed written explanation of the termination or suspension. If subjects were enrolled locally in the study, a final progress report must also be submitted to the IRB. If the suspension is lifted the investigator should notify the IRB in writing.

1. If the IRB terminates or suspends a study, the investigator should notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension. Any action taken to suspend or terminate a study must be reported to OHRP and the sponsor within thirty (30) days of the action. If the study involved a regulated drug, device or biologic, a report will be sent to FDA. When the PI has adequately addressed the concerns of the IRB the IRB may lift the suspension on the research. If the concerns are not addressed, the IRB may terminate the research or take other action in order to protect the health and welfare of the participants.