Title:	Institution, Investigator, or Sponsor-Initiated Holds		
SOP Number:	801	Effective Date:	June 2, 2017
Previous Version Dates:			

1 Purpose

An "Institutional-, investigator- or sponsor-initiated hold" refers to a voluntary action by the institution, investigator or sponsor of the study to place some or all research activities associated with that study on hold. Institutional, investigator or sponsor holds may be the result of interim data analysis, inadequate drug availability, response to a DSMB report/recommendation, pre-planned stopping point or other information. An institutional-, investigator-, or sponsor-initiated hold is not a suspension or termination of IRB approval; therefore a study placed on "hold" is (i) subject to continuing review by the IRB; and (ii) not subject to reporting requirements as defined in SOP 1402, Management of New Safety Information.

An institutional, investigator or sponsor hold should be reported to the IRB as new safety information in accordance with SOP 1401, Reporting New Safety Information if the hold is a result of safety concerns. All other institutional, investigator or sponsor holds should be submitted as modifications to previously approved research.

2 Procedures

1. The submission should include the following information:
    a. Describe the basis for the hold
    b. Describe the research activities that will be halted. Research activities may include but are not limited to recruitment, screening/enrollment, research intervention/interaction, and follow-up.
    c. If applicable, describe actions implemented prior to submission, in order to eliminate apparent immediate harm to subjects
    d. Provide a plan for how to notify research participants of the hold.
    e. Describe conditions that must be satisfied in order to lift the hold.
2. A Chair or the Safety Welfare Analysis Committee (SWAG) will review the institutional-, investigator-, or sponsor-initiated hold and may do any of the following:
    a. Approve the hold
    b. Request additional changes or information

c. Refer the study for review by the convened IRB

d. Suspend IRB approval and refer the study for review by the convened IRB

3. When a study or a part of a study is placed on hold by the institution, the investigator or the sponsor may not resume until the investigator submits and the IRB approves a modification or a new safety information follow-up report to lift the hold. If, in addition to the hold, IRB approval is suspended, research activities may not resume until the processes outlined in SOP 1402, Management of New Safety Information are followed.

3 Definitions

An “Institutional, investigator or sponsor hold” refers to a voluntary action by the institution, investigator or sponsor of the study to place some or all research activities associated with that study on hold.