SOP 906: PROTECTION OF RESEARCH PARTICIPANTS

PURPOSE
This SOP outlines the steps taken by the University of Utah Institutional Review Board (IRB) to protect the rights and welfare of participants in research following the implementation of an administrative hold, suspension, or termination of that research.

SCOPE
This policy applies to human subject research conducted at the University of Utah.

POLICY
Before an administrative hold, suspension, or termination is put into effect, the convened IRB or IRB designee considers whether any additional procedures need to be followed to protect the rights and welfare of current participants.

In this policy, an IRB designee refers to the following: IRB Chair, IRB Vice-Chair, IRB Director, Institutional Official, or a person designated in writing to temporarily assume the role of one of those persons.

PROCEDURES

1. The University of Utah IRB requires the investigator to submit proposed procedures for the withdrawal of currently enrolled subjects that consider their rights and welfare. The convened IRB or IRB designee reviews the proposed procedures. These procedures may include but are not limited to:

    - Submitting a list of all currently enrolled participants including their status within the study;
    - Transferring participants to another investigator;
    - Making arrangements for clinical care outside the research;
    - Allowing continuation of some research activities under the supervision of an independent monitor; or
    - Requiring or permitting follow-up of participants for safety reasons.

    The convened IRB or IRB designee may approve or request changes to the proposed procedures for withdrawal of enrolled subjects.

2. The University of Utah IRB requires the investigator to submit a proposed script or letter notifying all currently enrolled and former participants that are affected by the administrative hold, suspension, or termination. The convened IRB or IRB designee reviews the proposed script or letter and may approve or request changes to the proposed script or letter.

3. If follow-up of subjects for safety reasons is permitted/required by the IRB, participants should be so informed, and any unanticipated problems involving risks to participants or others must be reported to the IRB and others as required by the protocol and organizational policies and procedures.

4. The IRB may mandate oversight or transfer responsibility to another investigator to assure implementation of the above procedures.