Title: SUSPENSION OR TERMINATION OF IRB APPROVAL

1.0 Purpose:
The purpose of this Standard Operating Procedure (SOP) is to outline the circumstances and methods in which a study's approval status may be changed and subsequently reinstated.

2.0 Policy:
It is the policy of the Syracuse University (SU) Institutional Review Board (IRB) that all currently approved research is subject to modification or change in approval status, as deemed necessary by the SU IRB. The IRB may ask the Investigator to place research on administrative hold to gather information or the IRB may suspend or terminate its approval of research for the research not being conducted in accordance with the IRB's requirements or the Federal regulations or if it has been associated with unexpected serious harm to participants.

Examples of reasons for a suspension of IRB approval might include: (1) Inappropriate involvement of human participants in research; (2) Inhibition of the rights or welfare of participants; (3) Serious or continuing noncompliance with Federal regulations or IRB policies; or (4) New information regarding increased risk to human participants, etc.

In accord with the authority of the IRB to approve, require modifications in, or disapprove research involving human participants, the IRB has the authority to suspend or terminate approval of previously approved studies and withhold future approval of protocols submitted by investigators who have committed unethical research conduct.

3.0 References and Reference Documents:
45 CFR 46.113
42 CFR 50 Subpart A
OHRP Guidance Document, "Guidance on Continuing Review" dated July 11, 2002
SOP 014, Amendments to Previously Approved Applications of Claims for Exemption
SOP 015, IRB Continuing Review
SOP 028, Investigating and Managing Potential Issues of Non-Compliance.
SOP 030, Reporting to the Appropriate Institutional Officials and the Department or Agency Heads

4.0 Procedure:

4.1 Suspension or termination of approval of research or withholding of future approval shall be made by a majority of members at a convened IRB meeting at which a majority of IRB members are present. Grounds for suspension or termination may include:

- **4.1.1** Serious breaches of IRB policies and procedures by an investigator;
- **4.1.2** Unanticipated problems causing physical, psychological, social, or other harms to participants;
- **4.1.3** Changes in the risks and benefits of a study encountered during the conduct of the research; and
- **4.1.4** Other circumstances, which, in the judgment of the IRB, require action in order to protect human participants from harm.

4.2 The IRB Chair has the authority to temporarily suspend approval of a study when necessary to

protect human participants until the full IRB can be convened. All approvals suspended by the IRB Chair will be reported to and reviewed by the full IRB and recorded in IRB minutes. The Office of Research Integrity and Protections (ORIP) will report suspension or termination of approval in accordance with *SOP 030*.

4.3 The IRB may also impose sanctions or require Investigators to undertake corrective actions as a condition of continued approval of research when minor violations of IRB policies and procedures have occurred. Minor violations include:

4.3.1 Deviations from IRB policies and procedures or unauthorized changes in a previously approved protocol that have not placed participants at significantly increased risk or resulted in direct harm; and

4.3.2 A failure of investigators to respond to inquiries or requests from the IRB or the Chair in a timely fashion.

Sanctions and corrective actions include:

4.3.3 Destruction of collected data;

4.3.4 Completion of additional training in human participants protections as specified by the IRB;

4.3.5 Letter of apology to research participants and representatives of external organizations;

4.3.6 Memorandum addressed to the IRB explaining the actions of the Investigator, acknowledging a violation of IRB policies and procedures, and providing assurances that future violations will not occur;

4.3.7 The submission of a plan of correction to address deficiencies in human participants' protections;

4.3.8 An acknowledgement in published work or work submitted for publication that the research did not conform to IRB policies and procedures;

4.3.9 A formal memorandum of censure from the IRB to the Investigator and, where appropriate, the investigator's department head or dean; and

4.3.10 Other actions warranted by the specific circumstances surrounding the violation.

4.4 Sanctions or corrective actions may be imposed by either the IRB Chair, in consultation with one or more members of the IRB, or the full IRB at a convened meeting. Sanctions or corrective actions will be reported to the full IRB and recorded in IRB minutes.

4.5 Administrative Hold.

4.5.1 The IRB may require the Investigator to place some or all research activities on hold until additional information can be obtained in order to determine if a change in the risk-potential benefit profile has occurred, if a change in the rights or welfare of the participants has occurred or if potential areas of non-compliance exist in a currently approved research protocol. This may occur through various sources including:

4.5.1.1 A complaint received by the SU IRB;

4.5.1.2 An allegation of noncompliance to the IRB;

4.5.1.3 A discovery by the Investigator of potential additional risks; or

4.5.1.4 IRB Committee deliberations.

4.5.2 The IRB notifies the Investigator in writing of the IRB Committee's determination for "Administrative Hold" and the specific requested activities to be placed on hold.

4.5.3 At any point, the IRB Chair or the IRB Committee may require or make recommendations for additional education or compliance interventions for the Investigator and his/her staff through the ORIP Director or the ORIP/IRB Administrator.

4.5.4 If the additional information is evaluated to determine that no change to the risk-potential benefit profile has occurred, rights or welfare of participants have not been compromised and the issue of non-compliance has been ruled out, the IRB notifies the Investigator that the study may return to active status. Otherwise, the matter is referred to the convened IRB.

4.5.5 Administrative Holds are otherwise treated as Suspensions of IRB Approval following the procedures in Section 4.8.

4.5.6 Administrative Holds by the IRB chair or designee are reported to and reviewed by the IRB at the next convened meeting.

4.6 Sponsor-Imposed Suspensions.

4.6.1 Notification of suspension by a sponsor unrelated to risk is submitted to the IRB for review and approval as a modification to previously approved research. Such modifications are considered minor and may be reviewed by the expedited procedure (*See SOP 014*).

4.6.2 Notification of suspension by a sponsor possibly related to risk is submitted to the IRB for review by the full Committee for evaluation as a potential unanticipated problem involving risk to participants or others (*See SOP 014)* and as a review of a modification to previously approved research.

4.7 Study Expiration.

4.7.1 If an Investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the specified continuing review expiration date, the study expires. Enrollment of new participants cannot occur after the expiration of IRB approval and all research activities must stop.

4.7.2 If applicable, once notified of the expiration, the Investigator must immediately submit to the IRB Chair a list of research participants for whom cessation of the research would cause harm.

4.7.2.1 The full IRB Committee reviews this list and allows individual participants to continue participating in the research interventions or interactions only when the IRB determines that it is in their best interests.

4.7.3 The IRB notifies the Investigator in writing of the Study Expiration.

4.7.3.1 The letter indicates that after the expiration date:

4.7.3.1.1 Enrollment of new participants must stop;

4.7.3.1.2 All research activities must stop; and

4.7.3.1.3 Any continuation research activity is a violation of Federal regulations.

4.7.3.2 The letter also indicates that the Investigator must immediately submit to the IRB, a list of research participants for whom cessation of the research would cause harm.

4.7.3 Research studies not reviewed and approved within sixty (60) days of the notification of expiration are administratively closed by the IRB. Reinstatement of the research requires submission of a research protocol for initial review.

4.8 Suspensions and Terminations of IRB Approval.

4.8.1 All suspensions and terminations by the IRB Chair will be reported to and reviewed by full IRB and recorded in IRB minutes.

4.8.2 The IRB promptly reports all suspensions and terminations of IRB approval, in writing to the Investigator. The letter:

4.8.2.1 Includes a statement of the reasons for the IRB's action;

4.8.2.2 Requires the Investigator to submit to the IRB proposed procedures for withdrawal of currently enrolled participants that considers their rights and welfare. The IRB Committee reviews the proposed procedures. The IRB may mandate oversight or transfer responsibility to another Investigator to assure implementation of these procedures;

4.8.2.3 Requires the Investigator to submit to the IRB a proposed script or letter notifying all currently enrolled participants that are affected by the suspension. The IRB Committee reviews the proposed script or letter. If follow-up of participants for safety reasons is permitted/required by the IRB, participants should be so informed. The IRB may directly contact participants to fulfill this notification; and

4.8.2.4 Requires the Investigator to report any events to the IRB or sponsor that would have required reporting had the former participants continued to be enrolled in

the research. The IRB may mandate oversight or transfer responsibility to another Investigator to ensure implementation of these procedures.

4.8.3 Investigators receiving repetitive suspensions or terminations of IRB approval may necessitate institutional actions for serious and continuing non-compliance. All suspensions and terminations will be reported according to *SOP 030*.

4.9 Protection of participants

4.9.3 Before the convened IRB suspends or terminates the approval of research and before an IRB member imposes an administrative hold, the convened IRB or IRB member considers whether to take actions to protect the rights and welfare of current participants, such as:

4.9.1.1 Transferring participants to another investigator;

4.9.1.2 Allowing continuation of some research activities under the supervision of an independent monitor;

4.9.1.3 Requiring or permitting follow-up of participants from safety reasons;

4.9.1.4 Requiring harm to be reported to the IRB;

4.9.1.5 Notification of current participants;

4.9.1.6 Notification of former participants.

SOP 029: SUSPENSION OR TERMINATION OF IRB APPROVAL

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