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| **SUBJECT –** Institutional Review Board | **EFFECTIVE DATE -** 14 May 2013 |
| **TITLE –** Termination or Suspension of IRB Approval of Research | **APPROVED BY -** IRB; Deborah Tyksinski, Associate Provost / Institutional Official |

**SCOPE –** This policy applies to the SUNY Polytechnic Institute (SUNY Poly) IRB, Institutional Official, President of the University, and to all faculty, staff or students conducting human subject research within or under the auspices of SUNY Poly.

**PURPOSE -** To describe the conditions under which approval of previously approved research may be suspended or terminated, and the procedures to be followed for suspending or terminating research.

**POLICY –** The convened IRB has the authority to **suspend or terminate** approval of research that is not being conducted in accordance with IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with harm to the rights and welfare of human subjects *(45 CFR 46.113; 21 CFR 56.113).*

The IRB Chair, the Institutional Official, or the President of the University in consultation with the IRB Chair, each have the authority to **suspend** approval on behalf of the IRB when continuation of the previously approved research may adversely affect the rights and welfare of research subjects, or when the IRB needs additional information to ensure that the rights and welfare of subjects are protected and there is insufficient time to have the convened IRB review the situation.

**Definitions**

*Suspension* – An action taken by the IRB Chair or designated representative, or the Institutional Official to temporarily or permanently withdraw approval for some research activities, or temporarily withdraw approval of all research activities.

*Termination* – An action taken by the convened IRB to permanently withdraw approval of all research related activities, including the enrollment of new participants (except for follow-up activities necessary for the protection of the health and welfare of participants).

The Principal Investigator (PI) maintains authority to voluntarily suspend or terminate some or all of the research activities approved by the IRB. The PI's decision to suspend or terminate research activity is not considered a suspension or termination of IRB approval.

**Notifications**

The IRB must provide written notification of the decision and the reason for suspension or termination of IRB approval to the PI, appropriate institutional officials and to the department agency or head.

Reporting to federal regulating agencies is not required if the PI voluntarily closes the study to new subject enrollment or temporarily halts research procedures.

## Procedures and Responsibilities

### A. Suspension of IRB Approval

1. The **convened IRB** determines the reasons for suspending the research, any information needed from the PI, and/or corrective actions or events that need to take place for the IRB to consider withdrawing the suspension. A decision to suspend, and all required actions is made by a quorum vote of the convened Board. The IRB determines which Institutional Officials and external agencies to notify.
2. In the case of temporary suspension, the IRB Chair notifies the PI in writing of the suspension and the reason. The IRB Coordinator places the item on the Agenda for the next convened meeting and distributes a copy of the current consent document, protocol (or description of the study) and supporting information relevant to the suspension. The convened IRB discusses the suspension, and votes to continue, reverse or modify the suspension.
3. If the suspension includes the withdrawal of subjects from a research protocol, the IRB requires the PI to identify alternatives that protect subjects from harm that might be incurred from withdrawal.
4. Notification of suspension includes:
   - Explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis
   - Explanation of the reasons for the suspension
   - Offer for the PI to respond to the convened IRB in writing
   - IRB action plan and established timeline for reporting progress to the IRB
   - A request for a description of any procedures for the withdrawal of currently enrolled subjects that considers their rights and welfare
   - A description of whether follow-up of subjects for safety reasons is permitted or required
5. The PI notifies enrolled subjects of any suspended research protocol, and considers appropriate procedures for withdrawal of enrolled subjects that considers their rights and welfare.

### B. Termination of IRB Approval

1. The convened IRB determines the reasons for terminating the research, any information needed from the PI, and/or corrections actions or events that need to take place for the IRB to re-consider the termination. The Board also determines which institutional official to notify and whether an external agency must be notified.
2. If the termination includes the withdrawal of subjects from a research protocol, the IRB considers alternatives that protect subjects form harm that might be incurred from withdrawal. These considerations include but are not limited to:
   - Transfer of subjects to another investigator
   - Permit certain research activities to continue under the supervision of an independent monitor
   - Require or permit follow-up of participants for safety reasons
   - Notification of current and former participants

- Require reports of adverse events or outcomes to the IRB and the sponsor

3. The IRB Coordinator notifies the PI in writing of the termination. The notification includes:
   - Explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis
   - Explanation of the reasons for the termination
   - Explanation that any request for the IRB to reconsider termination must be made in writing within 30 days of notification
   - IRB action plan and established timeline for reporting progress to the IRB
   - A request for a description of any procedures for the withdrawal of currently enrolled subjects that considers their rights and welfare
   - A description of whether follow-up of subjects for safety reasons is permitted or required
4. The PI notifies enrolled subjects of any terminated research protocol, and considers appropriate procedures for withdrawal of enrolled subjects that considers their rights and welfare.

## C. Investigator Responsibilities

When notified that research has been suspended or terminated by the IRB, the investigator must:

1. Acknowledge in writing, to the IRB, receipt of suspension notification within 30 days
2. Stop enrollment and research activities as required by the IRB
3. Cooperate with the IRB investigation
4. Conduct any actions necessary to protect the rights and welfare of participants or as required by the IRB (i.e., notify, withdraw, follow-up)
5. Report in writing to the IRB Coordinator any adverse events or outcomes that occur during the suspension or termination of research

## D. Incident Reports to OHRP

Whenever it is determined that OHRP must be notified of suspended or terminated research, the incident report will contain the following information:

- Name of the institution conducting the research
- Title of the research project and/or grant proposal in which the problem occurred
- Name of the principal investigator on the protocol
- Number of the suspended or terminated research project assigned by the IRB, and the number of any applicable federal award/grant, contract or cooperative agreement
- Detailed description of the reason for the suspension or termination
- Actions the institution is taking or plans to take to address the suspension or termination (investigate noncompliance, educate investigator, research staff, additional monitoring of the investigator or research project, etc.)

## E. Lifting a Suspension

To reinstate a project that has been **suspended**, the investigator must satisfactorily resolve any pending issues required by the IRB. If the issues have not been resolved after one year following the suspension, the study will be terminated.

To reinstate a study that has been **terminated**, the investigator must submit the study as a new application. All past issues must be resolved to the satisfaction of the IRB.

## F. Documentation

The IRB Coordinator will document all discussion, actions and voting pertaining to suspension or termination of approved research in the IRB minutes. All documentation, including final reports and official written correspondence will be filed with the protocol and in the IRB minutes maintained in the Office of the IRB.

## References

Bankert, E. & Amdur, R. (2006). *Institutional Review Board Management and Function, 2nd ed.* Jones & Bartlett Publishers, Sudbury MA
Code of Federal Regulations: Title 45 Part 46.113
Code of Federal Regulations: Title 21 part 56.113
OHRP Guidance Document – *Reporting Incidents to OHRP (2011)*
OHRP Guidance Document – *Guidance on Written Procedures*
Ohio State University IRB – Human Research Protections Program Policies and Procedures
University of Kentucky IRB – Policies and Procedures
State University of New York - Binghamton IRB Policies and Procedures