

Grand Valley State University Institutional Review Board	
Title: <i>Suspension or termination of research activities</i>	
Section: 1050.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2011	Approved by RIO/HRPA: 02/16/2011
Related documents: <i>341: Unapproved research</i> <i>730: Collection, management and security of research information</i> <i>1010: Modifications to approved protocols</i> <i>1030: Research non-compliance</i> <i>1040: Research post-approval audits</i> <i>1070: Responding to concerns and complaints about human subjects research activities</i> <i>OP-1: GV Policy on Research Integrity</i> <i>OP-3: GV charge to the IRB</i> Updated 08/01/2012	

## **Policy**

1. The IRB will take appropriate action to minimize risks to the safety and welfare of research participants. These actions may include suspension or termination of some or all research activities. The reasons a research project may be subject to suspension or termination include, but are not limited to:
  - a. failure to comply with applicable laws, IRB policies and procedures, or instructions from the IRB
  - b. failure to submit required documents or reports in the time frame specified by the IRB
  - c. failure to obtain informed consent from research participants in the required manner
  - d. failure to promptly and accurately disclose to the IRB and to research participants important material information concerning known or suspected risks to research participants
  - e. implementation of unapproved research. See ORCI Policy **#341 Unapproved research**
  - f. falsification of documents or otherwise conceal information related to risks to participants from the IRB
  - g. failure to maintain records as required by the IRB including records of unexpected problems or adverse events
  - h. new information revealing a significant increase in potential risk to research participants

- i. serious unanticipated problems or adverse events
2. No Risk to Participants. The authority to suspend or terminate some or all research activities may be exercised by the IRB through a majority vote of board members in attendance at a convened meeting when a quorum is present.
3. Potential Risk to Participants. The IRB Chair and the university Research Integrity Officer (RIO), acting singly or in concert, may immediately and unilaterally suspend or terminate approval of some or all research activities as deemed necessary to assure the protection of research participants if identifiable harm to participants is deemed to pose an immediate or emergent risk, or in cases of alleged research misconduct, or continuing or serious noncompliance by one or more research investigators.

## **Procedures**

1. Notification of all protocol suspension or termination actions will be sent in writing to the principal investigator and his or her authorizing official within 5 business days, and will be communicated in a timely manner to additional internal and external entities as appropriate, including the federal Office of Human Research Protections (OHRP) in the Department of Health and Human Services. Notification of suspension or termination actions shall include all of the following:
  - a. the reason and rationale for the suspension or termination
  - b. which research activities have been suspended or terminated
  - c. action(s) required of the researcher(s) and the time-frame(s) for completing the action(s) to remove the suspension, and
  - d. the consequences for failure to comply with IRB directives.
2. The decision to suspend research enrollment, procedures, interventions or activities must be reviewed by the IRB at the next convened meeting. The IRB shall determine by majority vote when a quorum is present the conditions under which IRB approval that has been suspended may be reinstated. Reinstating IRB approval that has been suspended requires concurrence from both IRB and university administration.
3. The IRB may vote to reinstate approval, continue the suspension of approval pending specific corrective actions, or terminate the approval. Approval that has been terminated cannot be reinstated.
4. The PI will have an opportunity to respond in writing to the IRB to the notification of suspension or termination or to appear in person before the IRB.

## **Background**

1. Federal regulations require that the organization that authorizes research maintain the unilateral authority to suspend or terminate some or all research activities:
  - a. *An IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons of the IRB's actions and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head (45 CFR 46.113).*
2. In **OP-1: GV charge to the IRB** issued by the Provost on November 3, 2010, GVSU assigned the authority and responsibility to the IRB to suspend or terminate research activities in order to protect study participants, uphold ethical standards, protect the research integrity of the organization, and comply with university procedures and state and federal laws and regulations.