

Grand Valley State University Institutional Review Board	
Title: <i>Responding to concerns and complaints about human subjects research activities</i>	
Section: 1070.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 02/14/2012 Revised by HRRPPC: 01/23/2018	Approved by RIO/HRPA: 02/16/2012 Revisions approved by AIO/RIO: 04/16/2018
Effective Date: 05/01/2018	
Related documents: <i>1010: Modifications to approved protocols</i> <i>1030: Research non-compliance</i> <i>1040: Research post-approval audits</i> <i>1050: Suspension or termination of research activities</i> <i>1060: Closures of approved research studies</i> <i>OP-3: GV Policy on Research Integrity</i>	

## **Policy**

1. Any person may bring a concern or complaint to any member of the Office of Research Compliance and Integrity (ORCI), Institutional Review Board (IRB), or Research Integrity Officer (RIO) about any aspect of a particular human research study. Any ORCI staff or IRB members who receive such concerns or complaints should report the concern or complaint to the IRB Chairperson and RIO who is responsible for responding to concerns or complaints and for documenting follow-up actions as indicated.
2. ORCI or IRB members with knowledge of the concern or complaint will maintain the confidentiality of the identity of the complainant(s) and any study participant(s) to the extent allowed by law and university policies. The complainant and the individual(s) against whom a complaint is made shall be treated in a fair and reasonable manner and will be subject to objective administrative inquiry and investigative procedures. The complainant is responsible for lodging their concerns or complaints in good faith.
3. Complaints or concerns about the ORCI or the IRB should be made directly to the RIO.
4. Complains or concerns about the RIO should be made directly to the Provost.

## **Procedures**

1. Reporting a Concern or Complaint
  - a. Concerns or complaints may be made to ORCI staff, any IRB board member, or the RIO.
  - b. Complaints may be made anonymously. Information provided should include to the extent possible, all relevant details including date(s) of any problems or incidents, the name of the

principal investigator (PI) and title of the research project. Anonymous concerns or complaints will be investigated to the extent possible based on the information provided.

## 2. Responding to a Concern or Complaint

- a. Concerns and complaints shall be forwarded to the ORCI for initial assessment and response in consultation with the IRB Chairperson and/or RIO as appropriate.
- b. The IRB Chairperson and the RIO are each independently authorized to temporarily suspend any research activities or the involvement of any individual in a research project in order to minimize potential risks to current or future research participants, or for serious or continuing non-compliance with IRB policies.
- c. Response to concerns or complaints will be conducted in a timely manner and shall consider each of the following components:
  - i. The nature of the concern or complaint.
  - ii. Any evidence of risk or fact of harm to any enrolled or future participant.
  - iii. Whether the research activity concerned an approved protocol.
  - iv. Any deviations from the approved protocol procedures

## 3. Confidentiality

To the extent possible, the identity of a complainant(s) or relevant participant(s), and any witness shall be limited to the authorities identified in the above sections and any other authorities with a need to know, as determined by the IRB Chairperson and the RIO. All written materials and information relevant to the investigative proceedings shall be kept confidential and separate from the protocol file as retained in the ORCI's electronic database management system.