

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>Voluntary participation, termination and withdrawal from research</i>	
Section: 830.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 09/13/2011	Approved by RIO/HRPA: 09/23/2011 Revision approved by AIO/RIO: 3/16/2020
Related documents: <i>730: Collection, management and security of research information</i> <i>810: Informed Consent – general</i> <i>OP-2: GV Athletic department policy on research involving varsity student-athletes</i> <i>G-8: OHRP and FDA guidance on withdrawal of subjects from research: data retention</i> Updated 08/01/2012	

Policy

1. Participation in research must be voluntary and free of coercion, both initially and throughout the research process. A competent adult participant has the right to partially or completely withdraw from research at any time without penalty or loss of benefits to which the participant is otherwise entitled. If an individual chooses to completely withdraw from participation in a study, the researcher must, upon notification of the withdrawal, immediately discontinue research interactions and interventions with that participant and collection of individually identifiable private information ***unless*** discontinuing poses a risk of harm to the participant, such as abruptly stopping certain medications.
2. When a participant’s withdrawal from research activity is limited to a specific component(s) of the study, other types of participation that were previously consented to may continue by mutual agreement, e.g. follow-up interviews.
3. A participant’s legally authorized representative also has the right to partially or fully withdraw a participant from research, even if the participant originally entered into the research through informed consent given of their own volition. In Michigan, a legally authorized representative must be formally recognized by court order and/or by legally recognized written authorization signed by the person to be bound.
4. In rare cases, a researcher may terminate all or part of an individual’s participation in the research, regardless of that person’s willingness to continue. The most common reasons for researcher-directed termination of participation concern either enhancing participant safety, or because of participant non-compliance with required research procedures. According to both OHRP and FDA guidance, information from or about an individual enrolled in research may be retained and used in research if it was collected prior to the participant’s withdrawal or removal from the study.

Procedures

1. Continued Use of Data Following Withdrawal or Termination

- a. When a research participant voluntarily withdraws from a research study, or whose participation is terminated by the researcher, data gathered from or about the participant prior to the withdrawal or termination may be retained and utilized by the researcher. The consent process and its documentation should clearly indicate what withdrawal or termination entails regarding continued use of data. If a participant requests that his/her data not be used, the researcher should remove that participant's data from the data set to the extent feasible.
 - b. The researcher should clarify whether a participant is requesting to discontinue all types of participation in that study, or just participation that involves specific interventions or interactions. Similarly, if only some of an individual's participation needs to be terminated by the researcher, the researcher should ask about the participant's willingness to continue in other research activities for that study.
- See G-8: *OHRP and FDA Guidance on Withdrawal of Subjects from Research: Data Retention*

2. FDA Regulated Clinical Trials

- a. It is the FDA policy that participant data collected up to the time of withdrawal must remain in the data set in order for the study to be scientifically valid.
- See G-8: *OHRP and FDA Guidance on Withdrawal of Subjects from Research: Data Retention*

3. Documentation of Discontinuation of Participation in Research

- a. If an individual discontinues participation in research prior to completion of the research procedures, the researcher should document in the research records whenever feasible:
 - i. Whether the discontinuation is the result of voluntary participant withdrawal or researcher termination;
 - ii. Whether the discontinuation involves some or all types of participation;
 - iii. The reason for the discontinuation;
 - iv. Whether the HRRC or sponsor have been notified of the discontinuation as required by the research protocol.
- b. Verbal refusal to participate in research is sufficient to terminate participation. Modification or rejection (cancellation) of a previously authorized HIPAA release must be signed and dated by the research participant