Grand Valley State University Institutional Review Board (IRB)	
Title: *Voluntary Participation, Termination, and Withdrawal from Research*	
Section: 830.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 09/13/2011 Updated: 08/01/2012 Revisions Approved by IRBPPC: 02/03/2025	Approved by RIO/HRPA: 09/23/2011 Revision approved by AIO/RIO: 3/16/2020 Approved by IO: 06/15/2025
Effective Date: 06/15/2025	
Related Documents: *730: Collection, Management and Security of Research Information* *810b: Informed Consent: General [Revised Common Rule Version]* *813b: Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives [Revised Common Rule Version]* *OP-2: GV Athletic department policy on research involving varsity student-athletes* *G-8: OHRP Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues*	

Policy

1. Participation in research must be voluntary and free of coercion, both during recruitment 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 discontinue 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.

4. In rare cases, a researcher may terminate all or part of an individual's participation in the research, regardless of the participant's willingness to continue. The most common reasons for researcher-directed termination of participation are concerns related to participant safety, or because of participant noncompliance 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 their 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.

    c. See G-8: *OHRP Guidance on Withdrawal of Subjects from Research: Data Retention and Other Related Issues.*

2. FDA-Regulated Clinical Trials

    a. It is 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.

    b. Refer to the FDA guidance document, "Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials," dated October 2008.

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 IRB 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.

    c. Modification or rejection (cancellation) of a previously authorized HIPAA release must be

signed and dated by the research participant.