

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>Determining Engagement in Human Subjects Research</i>	
Section: 220	
Approved by IRBPPC: 05/03/2021	Approved by AIO/RIO: 05/06/2021
Approved by IRBPPC: 11/30/2021	Approved by AIO/RIO: 12/21/2021
Effective Date: 12/21/2021	
Related documents: <i>IRB Policy 210: Determination of Human Subject Research</i> <i>IRB Policy 1120: Collaborating Research with Investigators Covered by an External FWA</i> <i>Office for Human Research Protections (OHRP) Guidance on Engagement of Institutions in Human Subjects Research (2008)</i>	

## Policy

1. An engaged institution is one whose agents (faculty, staff or students):
  - a. Conduct recruitment activities beyond informing prospective participants about the availability of the research (e.g., answering questions about the research from prospective participants, providing prospective participant’s contact information to the researcher without the prospective participant’s permission, etc.),
  - b. Secure consent from participants,
  - c. Conduct interactions and/or interventions with human subject participants, or
  - d. Obtain private identifiable information or identifiable biological specimens for research purposes from any source.

GVSU is engaged in human subjects research when these or related activities are conducted by GVSU faculty, staff or students under their GVSU affiliation. **See the Guidance section below for additional information regarding activities that do and do not constitute engagement.**

2. IRB review is required whenever GVSU is engaged in activities that meet the definition of human subjects research as defined in *IRB Policy 210: Determination of Human Subjects Research*, regardless of funding source.
3. When GVSU is the direct (prime) recipient of federal funding for a human subjects research project, GVSU is engaged in the research even when all activities involving human subjects are performed through subcontract or other arrangements by the employees or agents of other institutions. The GVSU IRB must review all aspects of the research unless this review has been deferred to another IRB, consistent with *IRB Policy 1120: Collaborating Research with Investigators Covered by an External FWA*.

## Procedures

1. The IRB Chairperson or designee (including Office of Research Compliance and Integrity [ORCI] staff) makes engagement determinations when reviewing human subjects research submissions and requests from external researchers seeking data collection and/or recruitment of GVSU students, faculty, and/or staff. Individuals may also directly request an engagement determination

from the IRB Chairperson or ORCI. Upon receipt of a request for an engagement determination, the IRB Chairperson or designee shall make this determination in a timely manner, and will communicate to the requestor the decision regarding whether GVSU is or is not engaged in the research.

2. Engagement determinations are made solely based upon the information provided at the time of the determination. If subsequent changes are made to the research after a determination has been made by the IRB Chairperson or designee, it is the responsibility of the researchers to determine if those changes alter the original determination decision. If the researchers are unsure if the changes would alter the original determination, a new determination should be obtained from the IRB Chairperson or the ORCI.

### **Guidance**

1. GVSU is not engaged in human subjects research if GVSU faculty, staff or students' involvement is limited to the following common activities:
  - a. Conducting the following recruitment activities:
    - i. Informing prospective subjects about the availability of the research, such as by forwarding a recruitment email to potential participants;
    - ii. Providing prospective participants with the informed consent document or other IRB-approved materials, but do not obtain the individual's consent for the research or act as representatives of the researchers;
    - iii. Providing prospective participants with information about contacting researchers for information or enrollment; and/or
    - iv. Obtaining and appropriately documenting, such as with the use of the FERPA Permission to Release Non-Public Information form, the prospective participant's permission for investigators to contact them.
  - b. Serving as key personnel to analyze de-identified or coded data;
  - c. Serving as key personnel to design and develop research instruments, provided the individual does not have access to or interaction with participants and is not named on any participant-facing materials (such as recruitment materials or informed consent documents);
  - d. Allowing the use of GVSU facilities for interaction/interventions to be carried out without involvement of GVSU-affiliated researchers in the research procedures and without GVSU-affiliated researchers having access to personally identifiable information;
  - e. Releasing private identifiable information to researchers at another institution (e.g., school or health records); or
  - f. Other activities as described in the 2008 Office of Human Research Protections Guidance on Engagement of Institutions in Human Subjects Research.
2. GVSU is engaged in human subjects research when faculty, staff or students:
  - a. Conduct human subjects research using GVSU resources; examples include, but are not limited to:
    - i. Hosting an electronic survey under GVSU's license with the institutional survey provider;

- ii. Using GVSU's High Performance Computing Center to store or analyze research data; and
  - iii. Allowing an external collaborator access to GVSU data sources or tools for human subjects research, even if the collaborator would be the only individual accessing identifiable information;
- b. Conduct human subjects research outside of their institutional affiliation but still represent themselves as part of GVSU, such as through the use of institutional email;
- c. Intervene and/or interact for research purposes with participants by performing invasive or noninvasive research procedures or by manipulating the environment for research purposes;
- d. Obtain the informed consent of participants for the research;
- e. Obtain for research purposes identifiable private information from any source;
- f. Obtain for research purposes identifiable biological specimens from any source;
- g. Are named in any participant-facing materials (such as recruitment materials or informed consent documents); or,
- h. Conduct other activities as described in the 2008 OHRP Guidance on Engagement of Institutions in Human Subjects Research.