Grand Valley State University Institutional Review Board (IRB)	
Title: *The determination of human subjects research*	
Section: 210.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 04/12/2011 Revised: 09/10/2013 Reviewed: 10/28/2014 Revised by HRRPPC: 04/24/2018	Approved by RIO/HRPA: 05/12/2011 Revision Approved: 09/10/2013 Approved by AIO/RIO: 05/23/2018 Approved by AIO/RIO: 3/13/2020
Effective Date: 01/21/2019	
Related documents: *310: Researcher responsibilities, qualifications and training* *330: Authorization to conduct human subject research* *341: Unapproved research* *911: Exemption determinations and research ethics standards* *G-4: OHRP guidance on engagement in research*	

Policy

1. It is the policy of GVSU and the IRB that GVSU faculty researchers are permitted to determine whether a proposed activity of their own or of a student whom they are supervising as a research advisor constitutes research as defined under the federal regulations. The IRB and the ORCI are available to assist any GVSU faculty, staff or student in properly making this determination.

2. The determination of whether the research is exempt from the federal regulations may only be made by the IRB. All human subjects research including exempt research must be reviewed and approved by the IRB before recruitment and data collection may start.

Procedures

The IRB retains ultimate authority to determine whether an activity meets the definition of human subject research. Upon receipt of a request for a determination of human subject research application, the IRB Chair or designee (including ORCI staff) shall make this determination in a timely manner, and communicate to the lead researcher the decision on whether the activity does or does not meet the definitions as defined in the federal regulations.

Determinations are made based solely upon the information provided by the researchers at the time of the determination. If researchers make subsequent changes to the activity after a determination has been made by the IRB Chair 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.

Background

1. For an activity to be considered human subjects research as defined in the federal regulations by the

Department of Health and Human Services, it must meet the definition of "human subject" and "research" [45 CFR 46.102]:

a. "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(1) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(2) Interaction includes communication or interpersonal contact between investigator and subject.

(3) Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(4) Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(5) An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

b. "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or

conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

2. Human subject research is also defined by the FDA at 21 CFR 50.3 as:

    a. An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

    b. Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. The terms “research,” “clinical research,” “clinical study,” “study,” and “clinical investigation” are synonymous for purposes of FDA regulations.