OBJECTIVE

To describe policies and procedures for determining the types of activities that qualify as human research and, therefore, require prior Institutional Review Board (IRB) review and approval.

GENERAL DESCRIPTION

In accordance with federal and institutional regulations and prior to project implementation, the IRB must approve any undertaking in which a James Madison University (JMU) faculty, staff, or student conducts human research. The JMU policy # 1104, in accordance with federal regulations, outlines what types of activities are human subjects research and therefore require IRB review and approval [45 CFR 46.102].

DEFINITIONS

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [45CFR 46.102(d)]. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Some research development or testing and evaluation may also meet this definition.

For purposes of this part, the following activities are deemed not to be research:

- 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.

- 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).

- 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.

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

NOTE: Internal studies by the institution of its own practices, aimed at improving those practices, but not at contributing to generalizable knowledge, are not considered research. However, the ORI should be contacted in advance to verify no additional review is required.

Human subjects (DHHS): A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens [45CFR 46.102(f)].

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 [45CFR 46.102(f)].

Interaction: Includes communication or interpersonal contact between investigator and subject [45CFR 46.102(f)].

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 which 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).

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 [45CFR 46.102(f)].

Principal investigator: May be a JMU employee, JMU student, or in rare cases may be an employee at a site with which JMU has signed an IRB Memorandum of Understanding, IRB Authorization, or Individual Investigator Agreement.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Study Personnel, Office of Research Integrity (ORI) Staff, IRB Members, IRB Chair.

PROCEDURES

Human Subject Research Determinations

1. It is the responsibility of each investigator to seek IRB review and approval prior to initiation of any research involving human subjects.

2. The investigator is responsible for making a preliminary decision regarding whether their activities meet the Department of Health and Human Services (DHHS) definitions of both "research" and "human subjects."

3. The investigator may contact ORI staff, the IRB Chair, or IRB members for advice on the applicability of the federal regulations and JMU policy.

4. In cases where it is not clear whether the study requires IRB review, the PI will need to complete a Not Human Subjects Research protocol through the electronic Research Administration (eRA) software system in order to receive a written response from the IRB. ORI cannot make an official determination of whether a study requires IRB approval via email or over the phone. The IRB Chair or their designee makes the final determination whether the activities meet the federal definitions.

5. The ORI communicates the decision of the IRB Chair or their designee to the investigator in writing through eRA.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	7/20/2015
01	Revision of SOP	11/8/2019

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.102
JMU Policy # 1104