Policy 1104
Institutional Review Board – Use of Human Subjects in Research

Date of Current Revision: April 2023
Responsible Officer: Vice President for Research, Economic Development and Innovation

1. PURPOSE

This policy provides for the establishment of the Institutional Review Board (IRB) at James Madison University (JMU) to oversee research involving human subjects at the university. This policy covers all faculty, staff, and graduate and undergraduate students intending to conduct research using living individuals or pre-existing data containing identifiable private information about living people. This policy applies to research funded by any source as well as unfunded research.

The IRB is dedicated to helping James Madison University researchers conduct research that protects human subjects and is compliant with the federal regulations. The IRB is governed by its Standard Operating Procedures (SOPs) which guides both the researcher and the IRB in conducting and approving research involving human subjects (e.g., university IRB).

The IRB SOPs assure that the risks of research conducted at JMU are compatible with the expected benefits, and are guided by the ethical principles described in the Belmont Report and formalized in the Code of Federal Regulations Title 45, Part 46. The federal agency responsible for administering this program is the Department of Health and Human Services (DHHS), through their Office for Human Research Protections (OHRP). These documents, as well as guidance from OHRP, provide the foundation and framework for the SOPs.

The IRB also carries out the function of a Health Insurance Portability and Accountability Act (HIPAA) privacy board as defined by 45 CFR 46.164 for the purpose of ensuring privacy protections of health information used or created in the conduct of human subjects research.

2. AUTHORITY

The Board of Visitors has been authorized by the Commonwealth of Virginia to govern James Madison University. See Code of Virginia § 23.1-1600; § 23.1-1301. The Board has delegated the authority to manage the university to the president.

The university is subject to the Federal Rules and Regulations to assure the Protection of Human Research Subjects. In accordance with the university's General Assurance of the Protection from Research Risks required by the Department of Health and Human Services, each proposed project involving human subjects must be reviewed by the university IRB.

The university is also subject to the rules and regulations of the Department of Behavioral Health and Developmental Services of the Commonwealth of Virginia. See Code of Virginia Chapter 5.1, § 32.1-162.19. Those rules provide that each institution that conducts human research is required to establish a human research review committee.

The IRB reviews all covered research through exempt, expedited and full board procedures specified in the SOPs. The IRB has the authority to approve protocols, require modifications to

secure approval, disapprove protocols, and suspend or terminate approval of research (SOP No. 6 and SOP No. 7). Research that has been reviewed and approved by the IRB is subject to continuing IRB review and must be reevaluated at least annually, or more frequently if specified by the IRB.

3. DEFINITIONS

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.

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

Institutional Official (IO)

The individual who is legally authorized to act for the institution and, on behalf of the institution, obligates the institution to the Terms of the Assurance. For the purposes of this policy, the institutional official is the Vice President for Research, Economic Development and Innovation.

Institutional Review Board (IRB)

The institutional review board established in accord with and for the purposes expressed in this policy.

Legally Authorized Representative (LAR)

An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, LAR means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research.

Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Office of Research Integrity (ORI)

Provides the administrative oversight for human subjects research. This involves serving as a resource for education and information, facilitating the creation and distribution of SOPs, maintaining communication mechanisms such as the website, providing guidance and feedback to investigators, providing administrative support to the IRB, ensuring all requirements of the federal wide assurance are met, and conducting quality assurance activities.

Principal Investigator (PI)

The individual with the responsibility for conducting the research or other activity described in a proposal for an award. The terms "principal investigator" or “project director" may be used interchangeably in accordance to the agency's program language. The PI is defined as all persons who contribute significantly to the design and implementation of a study protocol. PI’s do not participate in the research as participants.

Research

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 which 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:

- 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 for the purposes of this policy. However, the ORI should be contacted in advance to verify no additional review is required.

4. APPLICABILITY

This policy applies to all research involving human subjects, including research by any person who is a faculty or staff member or student at the university, regardless of where the actual research takes place. It also applies to research conducted by individuals who are not faculty members or students at the university, if the human subjects are members of the university community.

5. POLICY

No human research shall be conducted or authorized by the university unless the IRB has reviewed and approved the proposed human research project.
The university requires that all researchers complete a JMU-specific training course, including students and their faculty advisors. This online training can be found on the ORI website.

6. PROCEDURES

6.1 Institutional Review Board

The IRB will consist of a minimum of eleven members representative of a variety of professional disciplines, including at least one member of the student body and one person who is not affiliated with the university, with varying backgrounds to promote and complete an adequate review of research activities commonly conducted by the institution. The membership will be drawn in compliance with the diversity, competency and professional guidelines established by 45 CFR 46.107. The members will be appointed annually by the president upon recommendation by the IRB chair and the Office of Research Integrity.

The IRB provides for initial and continuing review of protocols involving human subjects. It assures that the rights of determination, privacy and confidentiality are maintained through its procedures, and it strives to protect subjects from undue harm by upholding the minimum risk requirement. The IRB follows the appropriate Federal Regulations and those of the Commonwealth of Virginia (see VA Code 32.1-162.16, 18, 20) in the responsible conduct of research and maintains records as required.

6.2 Research Subject to IRB Review

All research involving human subjects must be reviewed and approved by the IRB prior to the initiation of the research project. The procedures for determining what research activity needs IRB review and the process for submission are covered in SOP No. 1 and SOP No. 2.

6.3 Criteria Used for Review of Proposals

The IRB uses criteria for review outlined in SOP No. 2.

6.4 Informed Consent

Informed consent or assent will be sought from each participant or his or her legally authorized representative and appropriately documented, in accordance with and to the extent required by local, state, and federal regulations. Broad consent, waivers, or alterations to consent may be requested in the research protocol but must be in accord with §46.116 and approved by the IRB.

6.5 Procedures for Submitting Research Proposals to the IRB and Gaining Approval to Commence the Project

A researcher must submit a protocol to the IRB prior to initiation of the research project. The procedures are covered in the following SOPs. The electronic submission procedure and training manuals can be found on the ORI website. Additional procedures and criteria may be found in the following SOPs:

- Protocol - Non-Exempt (Full or Expedited) SOP No. 2
- Protocol - Exemption Request SOP No. 3

6.6 Statement of Concern/Complaint

The right of research subjects to lodge a concern (e.g., allegation), complaint or question and to be assured that the concern, complaint or question is taken seriously and resolved in a timely manner is of prime importance. The IRB Chair and the Director of the Office of Research Integrity are responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff. These issues are handled in a timely manner, assuring protection of human subjects, and the IRB holds any violators accountable to the applicable regulation. A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research study may raise concerns, complaints, or questions about a research project by telephone, in writing, anonymously online through the ORI website, or in person to the ORI Director or the IRB Chair. Each IRB approved informed consent document includes the contact information of the IRB Chair.

The procedure for submitting a complaint is described in SOP No. 10.

6.7 Training

Before the IRB can approve the research protocol, the PI, all co-investigators and all personnel named on the protocol who will have human subjects interaction or access to identifiable data must successfully complete the IRB online training addressing the appropriate conduct of human participant research through the Collaborative Institutional Training Initiative (CITI) Program. Proof of completion through CITI Program of this requirement by all investigators and key personnel is maintained in the protocol file by ORI. All researchers named on a protocol are required to renew their training every three years.

6.8 Special Circumstances

There are additional approvals required for specialized activities as follows:

- If a research project is to be conducted off-campus, a Site Letter of Permission must be obtained from the appropriate site coordinator or senior administrative official in advance and submitted along with the approval request when possible.
- The university will provide additional protections pertaining to research, development and related activities involving fetuses, pregnant women and in vitro fertilization of human ova, as well as for prisoners involved in research and additional safeguards in research when that research involves children, individuals institutionalized as mentally disabled and other potentially vulnerable groups in accordance with federal regulations.

- Federal guidelines require assurance that there are no conflicts of interest in research projects that could affect the welfare of human subjects. If a study presents a potential conflict of interest, additional information must be provided to the IRB in accordance with JMU Policy 1106.

7. RESPONSIBILITIES

The IRB is responsible for reviewing research protocols concerning human research, evaluating those proposals to determine if they meet the requirements, and approving or disapproving such proposals. Additionally, the IRB is responsible for monitoring ongoing projects previously approved, handling complaints concerning human research projects and making recommendations on sanctions to the president.

The Institutional Official (IO) is responsible for ensuring that the Human Research Protection Program (HRPP) functions effectively and that the institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO represents the institution named in the Federalwide Assurance (FWA).

In instances of an IRB finding of serious and/or continuing noncompliance, the IO is the ultimate decision maker regarding university administrative actions.

The IRB reviews all covered research through exempt, expedited and full board procedures specified in the SOPs. The IRB will approve qualifying research protocols only if it meets the following requirements:

- Risks to subjects are minimized
- Risks are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent is obtained or appropriately waived from all prospective subjects
- Subjects' privacy is protected and the confidentiality of data is maintained
- Appropriate safeguards are incorporated for vulnerable subjects

Faculty members are responsible for ensuring that projects conducted as part of a class are submitted for review by the IRB and for submitting their own research for review.

The Office of Research Integrity is responsible for updating procedures and the website and for providing training for researchers through the web-based CITI program discussed in section 6.7.

All departments, offices and employees that generate, receive or maintain public records under the terms of this policy are also responsible for compliance with Policy 1109 – Records Management.

8. SANCTIONS

Failure to comply with the requirements of this policy may result in (1) administrative actions including removal from a human subjects research protocol or removal as PI from a research grant or contract; and (2) disciplinary action up to and including termination and expulsion in accordance with relevant University policies.

Compliance is covered in more detail in SOP No. 6 and SOP No. 7.

Sanctions will be commensurate with the severity and/or frequency of the offense and may include termination of employment.

9. EXCLUSIONS

There are no exclusions to Policy 1104. Exclusions are not exemptions to research, which are covered under SOP No. 3**.**

10. INTERPRETATION

The authority to interpret this policy rests with the president, and is generally delegated to the Director of ORI and the IRB Chair.

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