

## **Policy #1104**

### **The Institutional Review Board on the Use of Human Subjects in Research**

**Date of Current Revision: June, 2008**

**Responsible Office: Chair, Institutional Review Board**

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#### **1. PURPOSE**

This policy provides for the establishment of the Institutional Review Board (IRB) at James Madison University to oversee all human research at the university. The Institutional Review Board for the Protection of Human Research Participants is an independent compliance committee mandated by the U.S. Department of Health and Human Services (HHS). (See Title 45 Part 46 of the Code of Federal Regulations.) The most recent version of the regulations, adopted in 1991, includes the adoption of the Federal Policy for the Protection of Human Subjects, generally known as the "Common Rule." This policy, promulgated by the sixteen federal agencies that conduct, support, or otherwise regulate research involving human participants, is designed to make uniform the human research participant protection system in all relevant federal agencies and departments.

#### **2. AUTHORITY**

James Madison 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 issued by Health and Human Service Office of the Protection from Research Risks, each proposed project involving human subjects must be reviewed by the University Institutional Review Board (IRB). The university is also subject to the rules and regulations of the Department of Mental Health, Mental Retardation and Substance Abuse Services of the Commonwealth of Virginia. See Code of Virginia Title 37.2, Chapter 4. Those rules provide that each institution that conducts human research is required to establish a human research review committee.

The University committee charged with this responsibility is the Institutional Review Board (IRB). The role of the IRB is to protect the rights and welfare of individuals recruited to participate in research activities conducted under the auspices of James Madison University. The IRB has the authority to approve, require modifications in, or disapprove all research activities involving human participants that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB. 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 Subject (from the Federal Regulations--Section 46.102(f) of 45 CFR 46):**

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

**Institutional Review Board (IRB):**

The human research review committee at James Madison University.

**National Institutes of Health (NIH):**

The federal agency that requires training for all researchers funded by this agency.

**Research—Section 46.102(d) of 45 CFR 46):**

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which 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.

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.

**4. APPLICABILITY**

This policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency. This includes 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 James Madison University unless the IRB has reviewed and approved the proposed human research project.

The National Institute of Health regulations state that all investigators and key personnel conducting research on NIH grants or contracts are required to undergo training in the protection of human subjects in research. To adopt the policies of Responsible Conduct of Research, JMU requires that all researchers complete at JMU-specific training course, including students and their faculty advisors. This on-line training will be coordinated by the [Office of Sponsored Programs](#) in conjunction with the Office of Research Compliance.

**6. PROCEDURES****6.1 Institutional Review Board**

See IRB membership Requirements at the following

URL:<http://www.hhs.gov/ohrp/humansubjects/guidance/rtcfr46.htm#46.107>

- Membership - 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 complete and adequate review of research activities commonly conducted by the institution. The membership will be drawn in compliance within the diversity, competency and professional guidelines established by Title 45, Part 46, Subpart A, Section 46.107 of the Federal Regulations. The members will be appointed annually by the President upon recommendation by the IRB chair and the Office of Sponsored Programs in conjunction with the Office of Research Compliance.
- Charge - The IRB provides for initial and continuing review of proposals 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 Categories of Research Subject to IRB Review

All research using human subjects must be reviewed and approved by the IRB prior to the initiation of the research project. Among the categories of human research which require direct IRB review are:

- Undergraduate student honor and Independent Study Projects.
- Graduate student theses.
- Studies expected to result in publication, presentation outside the classroom, or public dissemination in some other form.
- Research conducted outside the classroom and/or departmental research participant pool if they involve: minors (i.e. persons under the age of 18); a targeted population of adults whose ability to freely give informed consent may be compromised (i.e. persons who are socio-economically, educationally, or linguistically disadvantaged, cognitively impaired, elderly, terminally ill, or incarcerated); pregnant women and/or fetuses who may be put at risk of physical harm; a topic of a sensitive or personal nature, the examination or reporting of which may place the research participant at more than minimal risk, or any type of activity that places research participants at more than minimal risk.
- Faculty or staff research projects (including those which are funded).
- Research by an investigator not affiliated with James Madison University who proposes to involve James Madison University students, staff, or faculty as subjects in the proposed research project.

## 6.3 Criteria Used for Review of Proposals

The IRB must review and approve the proposed human research project giving consideration to:

- The adequacy of the description of potential benefits and risks and the adequacy of the methodology.
- The validity of subject selection.
- The degree of risk and whether the benefits outweigh the risks.
- Protecting human rights and welfare.
- Obtaining voluntary informed consent.
- Whether researchers are competent and qualified.
- Whether appropriate studies in non-human systems have been conducted prior to the involvement of human subjects.

## 6.4 Informed Consent

No human research may be conducted without informing the human subject (or subjects) or the legally authorized representative of the subject in writing of the risks, procedures, and discomforts of the research. Consent must be documented in writing and supported by the signature. A voluntary consent form will be included as a part of any questionnaire research. When research involves the use of minor participants, consent must be obtained from a parent or legal guardian. In addition, the minor participants over the age of 6 must provide their assent to participate, using a form appropriate for their age level. All relevant forms are located at [Office of Sponsored Programs Forms](#)

Voluntary Informed Consent assures a person's right to exercise free power of choice regarding participation in research. The basic elements of information necessary for voluntary informed consent are:

- A clear, responsible explanation of procedures and purpose in language appropriate for the subject group (with experimental procedures specifically identified).

- A description of expected risks or discomforts.
- A description of expected benefits.
- A disclosure of alternative procedures available.
- An offer to answer any questions raised by a subject regarding procedure, concerns, complaints, etc.
- Freedom to withdraw/discontinue participation at any time.
- Provide appropriate contact information for the researcher.
- Maintenance of anonymity/confidentiality of subjects.
- An explanation that any concerns regarding rights of the research subject should be directed to the chairperson of the IRB.

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

A researcher must submit a proposal to the IRB prior to initiation of the research project. The following steps are to be followed for each project:

##### Protocol - Exemption Request:

- Human Research Review Request form. Select the appropriate exempt request category.
- Attachment responding to questions 7-9 of this form.
- Additional relevant research materials (i.e. letter of consent, questionnaire, survey, must be provided where used).
- Submit the request and all forms/attachments electronically by email to [JMU Grants](#).
- Provide signed Research Review Request form to The Office of Sponsored Programs, MSC 5728, JMAC Building #6, Suite 26.
- Receive notification of exemption approval from the IRB prior to conducting the research. If a protocol is deemed 'not eligible' for exemption by the IRB faculty, a full research protocol will be requested.
- Notify the IRB of any substantial departures from the original protocol before continuing the research.

All relevant forms are located at [Office of Sponsored Programs Forms](#)

##### Protocol - Non-Exempt (Full):

- Human Research Review Request form.
- IRB Checklist (Complete the top of this form AND check all the elements you are including in your submission).
- Research Narrative (10 pages maximum, do not include your literature review)
- Additional relevant research materials (i.e. letter of consent, questionnaire, survey, must be provided where used).
- Prepare the research proposal using the items contained on the Research Proposal Checklist.
- Submit the research proposal electronically.
- Provide signed Research Review Request form to The Office of Sponsored Programs, MSC 5728, JMAC Building #6, Suite 26.
- Receive notification of approval from the IRB prior to conducting the research.
- Notify the IRB of any substantial departures from the original protocol before continuing the research.

All relevant forms are located at [Office of Sponsored Programs Forms](#)

Initial IRB approval is granted for the duration of the project dates indicated on the Review Request Form; but for no more than one year. Researchers must submit a follow-up report at the conclusion of their research. This should be submitted to the Office of Sponsored Programs when the project is completed or no later than two weeks prior to the approved ending date. For multi-year projects, this report form should be submitted annually. (Appendix D)

An on-line tutorial on how to complete an IRB application is available on the Sponsored Programs web site and in both Student (Appendix H) and Faculty (Appendix I) brochures.

#### 6.6 Statement of Concern/Complaint

Any person who has a complaint about a human research project shall submit in writing to the Chairperson of the IRB a statement of complaint and a brief description of the events that document the complaint. The Chairperson shall refer the complaint to the IRB to determine if there has been a violation of protocol.

If the IRB determines that this policy has been violated or that the project was conducted in violation of protocol, it shall recommend to the President the course of action the university should take, including the possibility of a sanction to be imposed against the researcher.

#### 6.7 Training

Every person involved in a research project that includes the use of human subjects must complete a [training course](#) and successfully pass a certification exam. The training and test can be found on the Sponsored Programs web page. Training is required regardless of whether the project is externally funded. Training must include key foreign and domestic personnel on subcontracts and consultants, and it applies whether or not these individuals are compensated from the award. The training requirement encompasses students and their advisors when conducting any kind of research, including classroom-based projects. Although subject to modification based on changing federal guidelines, training is currently required annually for each student investigator and recommended every 3 years for faculty/staff.

The web based training program required of all research personnel, including students and their research advisors, may be found on the [Sponsored Programs IRB](#) home page.

Investigators carrying out federally sponsored research that involves human subjects can obtain further training on the web at the [NIH website](#). Completing training through NIH does not release the researcher from having to complete the web-based training package provided by JMU.

#### 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 letter of approval from the appropriate site coordinator or senior administrative official must be obtained in advance and submitted along with the approval request.
- James Madison University will provide additional protections pertaining to research, development, and related activities involving fetuses, pregnant women, and in vitro fertilization of human ova and 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 will need to be provided to the IRB in accordance with JMU Policy 2203

## **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.

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

The Office of Sponsored Programs in conjunction with the Office of Research Compliance is responsible for updating procedures, forms and providing training for researchers through the web based program in section 6.7 above.

## **8. SANCTIONS**

Any researcher who fails to abide by this policy is subject to sanctions, up to and including termination of employment with the university for faculty and staff members, expulsion from the university for students, and being barred from any further research on the university campus for researchers outside of the university.

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

## **9. EXCLUSIONS**

In certain cases, the IRB chair or his/her designee may approve a protocol as being eligible for exemption from IRB review. Exemption requests must be submitted to the IRB, and approval received prior to conducting the research, using the procedure described in 6.5. Examples of studies which may be eligible for exemption follow:

- those conducted solely within the confines of the classroom or within a departmental research participant pool even when they
  - Are a general requirement of a course,
  - Have the sole purpose of developing the student's research skills, and
  - Will be overseen by a faculty member;
- those conducted outside the classroom and outside departmental research participant pools, provided they do not involve minors, do not target special adult populations, do not pose a risk of physical harm to pregnant women and fetuses, do not deal with a topic of sensitive or personal nature, or do not involve any type of activity that places the participants at more than minimal risk;
- those that are part of a larger research project that has current James Madison University IRB approval;
- those that are part of a larger research project that has current approval of a registered IRB at another institution, provided that, if research participants are to be recruited at James Madison University, the Institution's IRB has given permission for such on-campus recruitment;
- Those that are quality evaluation, learning assessment, or consumer acceptance studies.

## **10. INTERPRETATION**

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

Previous version: July, 2002

Approved by the President: June, 2008

### **Index Terms**

Institutional Review Board (IRB)

Human Research

Human Subjects

Sponsored Programs

### **Appendices**

All relevant forms are located at [Office of Sponsored Programs Forms](#).