

<p style="text-align: center;"><b>James Madison University</b>  <b>Office of Research Integrity and Institutional Review Board</b>  <b>Standard Operating Procedures</b></p>			
<b>TITLE: Standard Operating Procedures</b>			
<b>SOP # 21</b>	<b>Revision # 2</b>	<b>Effective Date: 3/12/2025</b>	<b>Page 1 of 3</b>

## **OBJECTIVE**

To outline the Institutional Review Board (IRB) practice for creating, publishing, and routine review of its policies, procedures, and guidance documents.

## **GENERAL DESCRIPTION**

Standard operating procedures (SOPs) provide a framework for the ethical and scientifically sound conduct of human research. This SOP outlines the James Madison University IRB practice for creating, publishing, and routine review of its policies, procedures, and guidance documents. Supported by institutional policies and written procedures, the IRB SOPs ensure that the rights and welfare of human research subjects are overseen and protected uniformly, regardless of personnel changes.

## **RESPONSIBILITY**

Execution of SOP: Principal Investigator (PI)/ Study Personnel, IRB Chair, IRB, Office of Research Integrity (ORI), Vice Provost for Research, Economic Development and Innovation (VPREDI)

## **PROCEDURES**

1. Creation of a new SOP
  - i. If creating a new SOP is necessary, input from relevant\* stakeholders will be gathered, and an SOP will be drafted within 30 days of the stated need. The IRB Chair, IRB member, or ORI staff may write SOPs.
  - ii. The draft SOP will be sent to the full IRB and relevant stakeholders for feedback. Those receiving the SOP will have 5 business days to review and provide feedback.
  - iii. Once an SOP is finalized, the IRB will vote to approve it. A passing vote must consist of a majority of members (2/3) present voting in favor of the motion.
  - iv. All SOPs will include a header, title, unique SOP number, revision number, effective date, and revision history. Text will include an objective, general description, responsibility, procedures, and references (if applicable).
  - v. Once the IRB has approved the SOP, it will be assigned a number and published on the ORI website within 5 business days of the vote with an effective date. Revisions to the SOP are completed as needed and can be requested by any IRB member. The SOP approval cycle would begin again.
  - vi. The newly active SOP will apply to all active protocols. All faculty will be notified within 30 days of the change via the REDI newsletter and social media.
2. Revision of an existing SOP

<p style="text-align: center;"><b>James Madison University</b>  <b>Office of Research Integrity and Institutional Review Board</b>  <b>Standard Operating Procedures</b></p>		
<b>SOP # 21</b> <b>Revision # 2</b>	<b>TITLE: Standard Operating Procedures</b>	<b>Page: 2 of 3</b>

- i. One or more IRB members, the IRB Chair, the Research Compliance Manager, or the ORI staff can propose changes when changes are deemed necessary by one or more of those individuals. The SOP approval cycle would begin again once the changes on the SOP are made.
  - ii. Revised SOPs will be sent to the full IRB and relevant stakeholders for feedback.
  - iii. Once a revised SOP is finalized, the IRB will vote to approve. A passing vote must consist of a majority of members present (2/3) voting in favor of the motion.
  - iv. Once the IRB has approved the revised SOP, it will be published on the ORI website with a revision date. The revised SOP will replace the old version. The revision history of the SOP will be updated with a brief description of changes, revision number, and date of revision. All faculty will be notified within 30 days of the vote via the REDI newsletter and social media and will be applied to all preexisting protocols.
3. Ongoing Review of SOPs
  - i. All SOPs will be reviewed no earlier than two years from the date of approval by the IRB Chair, IRB Vice-Chair, Research Compliance Manager, and the Director & Associate Director of the Office of Research Integrity.
  - ii. There may be situations when SOPs are reviewed prior to the two-year period if at least two individuals mentioned in 3i support early consideration.
  - iii. Technical revisions, such as updates to a person's title or hyperlinks, do not require the full vetting process. These changes will be made directly by ORI staff and will be documented in the revision history. The IRB will be notified of any updates to an SOP.

### **REVISION HISTORY**

<b>Version No.</b>	<b>Brief Description of Changes</b>	<b>Created on Date</b>
00	Creation of SOP	9/13/2023
01	Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI)	9/22/2023
02	Clarified stakeholders and two-year time period, updated how PI's are notified of changes, removed Academic Affairs from Responsibility, added in technical revisions, and updated Research Compliance Manager title.	3/12/2025

### **SIGNATURE HISTORY**

<b>Name and Title</b>	<b>Signature</b>	<b>Date</b>

\*Relevant stakeholders will be determined by IRB Chair and Vice Chair.

<b>James Madison University</b> <b>Office of Research Integrity and Institutional Review Board</b> <b>Standard Operating Procedures</b>		
<b>SOP # 21</b> <b>Revision # 2</b>	<b>TITLE: Standard Operating</b> <b>Procedures</b>	<b>Page: 3 of 3</b>


**REFERENCES**

None

\*Relevant stakeholders will be determined by IRB Chair and Vice Chair.