

James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
TITLE: Standard Operating Procedures			
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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), Provost and Senior Vice President for Academic Affairs, 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 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 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 bulk email.
2. Revision of an existing SOP
 - i. One or more IRB members, the IRB Chair, the IRB Coordinator, or the ORI staff can propose changes when changes are deemed necessary by one or more of those

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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 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 bulk email and will be applied to all preexisting protocols.
3. Ongoing Review of SOPs
- i. All SOPs will be reviewed no less than two years from the date of approval by the IRB Chair, IRB Vice-Chair, IRB Coordinator, 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.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	9/13/2023
01	Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI)	9/22/2023

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

None