

**James Madison University
Office of Research Integrity and Institutional Review Board
Standard Operating Procedures**

TITLE: Training of IRB Members and Staff

SOP # 14

Revision #0

Effective Date: 11/8/19

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OBJECTIVE

To describe the institution's programs for ensuring that all Institutional Review Board (IRB) members and Office of Research Integrity (ORI) staff are appropriately educated about the regulatory requirements and ethical considerations for the protection of human subjects involved in research.

GENERAL DESCRIPTION

The foundation for the effective implementation of all facets of the James Madison University (JMU) human research protection program (HRPP) and for efforts to promote compliance with HRPP requirements lies in a comprehensive, mandatory education program for all applicable personnel, including IRB members and research support staff in the ORI. JMU has a multifaceted human subjects' protection education program which is designed to provide essential training on ethics and regulations of research and local IRB policies/procedures as explained below.

RESPONSIBILITY

Execution of SOP: IRB members and Office of Research Integrity (ORI) staff

PROCEDURES

Education of IRB Members

Following appointment to membership on the IRB and prior to serving as reviewers, IRB members, *ex officio* members, and alternate members receive an orientation to the IRB by the IRB Chair and/ or ORI. All IRB members are required to successfully complete the IRB Member training through the Collaborative Institutional Training Initiative (CITI) Program prior to being assigned protocols for review and are required to renew their training every three years. All IRB members are required to review the IRB Standard Operating Procedures (SOPs) annually.

Upon request or as appropriate, the ORI presents training on selected topics at IRB meetings. ORI invites PI's or specialists in a specific area to address the IRB as needed.

ORI subscribes to and makes available applicable webinar presentations.

ORI staff disseminates educational materials and resources as necessary to all IRB members.

Education of ORI Staff

ORI staff receive hands-on training by designated experienced staff members.

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New ORI staff members review existing IRB Standard Operating Procedures (SOPs). New ORI staff are required to successfully complete the IRB Member training through CITI Program and renew their training every three years.

ORI subscribes to and makes available to staff various newsletters and publications.

ORI encourages and periodically requires its staff members to attend University, city, state, national, or regional IRB conferences, workshops, lectures, or webinars. As available, JMU provides funds for ORI to attend at least one national IRB conference per year.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	11/8/2019

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
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SOP Name	SOP #	Version #	Date Read
Determination of What Research Activity Needs IRB Review	1		
Initial and Continuing Review	2		
Exempt Review	3		
Security of Research Data	4		
Unanticipated Problems and Adverse Events	5		
Termination or Suspension	6		
Managing Noncompliance	7		
Mandated Reporting to External Agencies	8		
Study Closure	9		
Subject Concerns/ Complaints	10		
Membership of IRB	11		
Conduct of IRB Meetings	12		
IRB Minutes	13		
IRB Training	14		
Protocol Violations	15		

By signing below, I verify that I have read, understand, and will abide the James Madison University (JMU) Institutional Review Board (IRB) Standard Operating Procedures (SOPs) listed above.

Name (Printed)

Name (Signed)

Date