

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

TITLE: Elderly Participants

SOP # 16

Revision # 1

Effective Date: 3/28/2022

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OBJECTIVE

To define elderly participants as a vulnerable population.

GENERAL DESCRIPTION

Older adults in the general population who are cognitively intact and capable of making choices and providing their consent can undergo general IRB procedures for adults.

Older adults that reside in a congregate living environment that are not cognitively intact or do not have the capacity for informed consent are considered vulnerable populations and must undergo Full Board IRB Review.

DEFINITIONS

Congregate Living Environment: A type of living environment in which each individual or family has a private bedroom or living quarters but shares with other residents a common dining room, recreational room, or other facilities.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/ Study Personnel, IRB Chair, IRB, ORI Staff, ORI Director, Provost and Senior Vice President for Academic Affairs, Vice Provost for Research, Economic Development and Innovation (VPREDI), Office of Sponsored Programs

PROCEDURES

1. See [Standard Operating Procedure \(SOP\) # 2: Initial and Continuing Review of Research](#) for additional information on the Full Board review process.

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	3/28/2022
01	Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI)	9/22/2023

SIGNATURE HISTORY

Name and Title	Signature	Date
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REFERENCES

[45 CFR 46.111\(a\)\(3\)](#)

[JMU Policy # 1104](#)