

SOP NO.	PROCEDURE NAME	DEPARTMENT
SP-LC/3030	IRB Review Procedure	Institutional Research and Effectiveness

LEAD PERSON/TITLE	REVIEW DATE
Justin Gaeta	08/16/2025

PURPOSE

To provide clear guidance on determining whether a proposed activity qualifies as **research involving human subjects** and requires review by the Institutional Review Board (IRB), in compliance with federal regulations (45 CFR 46).

SCOPE

This SOP applies to all research requests from internal individuals (staff, faculty, administration, and students) and external individuals and organizations.

RESPONSIBILITIES

Role	Responsibility
Principal Investigator (PI)	Conduct initial classification; consult IRB if unsure.
IRB Administrator or Chair	Review PI's classification and make final determination.
	Ensure researchers are aware of classification requirements.

RESOURCES

- U.S. Department of Health and Human Services, [45 CFR 46](#)
- Office for Human Research Protections (OHR): <https://www.hhs.gov/ohrp/index.html>

POLICY #, IF APPLICABLE

Policy #LC-3030

PROCEDURE: DESCRIBE THE STEPS TO COMPLETION INCLUDING NECESSARY APPROVALS

1. Identify if the research includes human subjects.

2. If no – Out of the IRB Purview
3. If Yes – IRB Application is completed <ul style="list-style-type: none"> a. Completion of Required Training: Human Research Protection Foundational Training HHS.gov b. Preparation of necessary documentation c. Submit application, certificate of required trainings and any necessary documentation to IRD@jccmi.edu
4. The Director of Institutional Research and Effectiveness will review the application and documentation
5. Determination is made. <ul style="list-style-type: none"> a. Except Research – Reviewed by IRB Executive Staff b. Non- Except Research – Requires full board review. c. Expedited Review – Review by IRB Executive Staff
6. IRB Determination – Letter to Researcher within ten business days

REVIEWER/APPROVAL	DATE

Date Of Change	Description of Change	Responsible Party
08/11/2025	Initial Release	Director of Institutional Research and Effectiveness