WESTCLIFF UNIVERSITY
Educate. Inspire. Empower.

IRB Standard Operating Procedure

SOP 8	Exempt and Expedited Reviews	Effective Date 1/1/2023

PURPOSE

IRB must review all projects that meet the definition of research and that involve human subjects before any data collection to determine the appropriate level of review, and, as appropriate, approve them. There are three major types of review: *Exempt, Expedited,* and *Full.*

DEFINITIONS

Minimal risk. According to § 46.104, "minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

Exempt Review. Studies that receive an exemption determination from IRB are exempt from the specific regulations and requirements in Title 45, Part 46 of the Code of Federal Regulations. Please note, however, that they are still considered human subject research. Exempt status shall be defined per https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104.

Expedited Review. Studies that involve no more than minimal risk, but which do not meet the criteria for exempt status, may be eligible for Expedited Review. Expedited status shall be defined per https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.110.

Full Review. If the proposed research does not qualify for *Exempt* or *Expedited Review* as defined above, it will be subject to a *Full Review*. Studies requiring Full Review are vetted by the entire IRB and discussed at a convened meeting.

POLICY

The IRB shall use the above definitions and the Decision Tables at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html to determine the required level(s) of review.

RESPONSIBILITIES

IRB Chair is charged with ensuring SOP 8.

IO will monitor compliance and revise the SOP, as needed.

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REGULATIONS

§ 46.104

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Title/Role
	IO
Brett Gordon	IRB Chair

DISCLAIMER

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as a suitable Institutional Official or IRB Member requests review or exception to this SOP.