WESTCLIFF UNIVERSITY
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IRB Standard Operating Procedure

SOP 4	Title of SOP CONVENED REVIEW	Effective Date 1/1/2023

PURPOSE

To define policies and procedures for conducting a full-board review of human subjects' research.

DEFINITIONS

Appeal - request for reconsideration of an Institutional Review Board (IRB) determination in research involving human subjects, including (but not limited to) decisions regarding approvals tatus, conditions for approval, or noncompliance. Note: An appeal is reviewed by the convened IRB responsible for the determination being appealed; for a decision made by expedited review, the corresponding convened IRB may review the appeal. Also: request for reconsideration.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Convened review - the review of proposed human subjects research by an IRB that meets the membership requirements specified in federal regulations regarding the number, qualifications, diversity, and affiliation of its members, at which a majority of the members are present including at least one non-scientist. Review by the convened IRB may be referred to as either "full review" or "full board review".

Minimal risk - the probability and magnitude of the 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

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Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

POLICY

All research involving human subjects reviewed by the convened IRB must be evaluated for issues in proposed study design and conduct that may affect the rights and welfare of human subjects, consistent with Federal Regulations, state and local laws, professional standards, and University policy. A study that involves greater than minimal risk (see definition, below) requires approval by an IRB composed of members qualified to review research in that field. Refer to SOP IRB Membership for details.
Research that requires full committee review may include one or more of the following (***NB – The examples below are prohibited research at the University per SOP 1***):

- Prisoners
- Pregnant women, fetuses, and neonates
- Individuals with impaired decision-making capacity
- Children and other vulnerable populations

This list is not exhaustive. The final decision as to whether an application is reviewed by the IRB at a convened meeting is that of the IRB chair and/or board. To be approved, research that is reviewed by the convened IRBs must satisfy all of the following requirements as defined by 45 CFR 46.111:

- Risks to participants are minimized (but not necessarily eliminated) by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk. Whenever appropriate, risks to participants are minimized by using procedures already being performed for diagnostic or treatment purposes.

- Risks to participants are reasonable in relation to anticipated benefits (if any) and the importance of the knowledge that may reasonably be expected to result from the research.

- Selection of participants is equitable, taking into account the purposes of the research and the setting in which the research will be conducted.

- Informed consent is sought, obtained, and appropriately documented for each prospective participant or the participant's legally authorized representative as required by the regulations.
- If the research involves greater than minimal risk, the data and safety monitoring plan

and/or data and safety monitoring board (where appropriate) makes adequate provision for monitoring the data collected to ensure the safety of participants.
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data in accordance with IRB policy.

- When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, adults unable to consent for themselves, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these participants.

PROCEDURES

The IRB typically meets once per month and meetings are conducted according to SOP IRB Meeting Procedures. A quorum, which consists of four (4) or more members (one of which must be the Chair or Co-Chair), must be present for official business to take place.

All members should be sent the IRB application for review at least five (5) business days prior to the meeting where the application will be discussed.

APPEALS

Investigators may appeal an IRB decision by submitting a request in writing, including a statement of the reason(s) for the appeal and any materials supporting the request. Supporting materials may include (but are not limited to) letters of support, current literature, and/or other information relating to the state of the art/science in the research discipline.
- Requests for reconsideration will be reviewed by the convened IRB responsible for the determination being appealed. Decisions made by expedited review can be reconsidered by expedited review, but rejection of an appeal can be made only by the corresponding convened IRB. Investigators will be notified of and may attend the IRB meeting at which this review will occur.
- Appeals must be made within 30 calendar days of investigator notification of the IRB decision in question. The IRB will review the request within 30 calendar days of receipt of the investigator's written materials. Investigators and institutional officials will be notified of the IRB's decision regarding the appeal within 14 days of convened review. University closures are exempted from the count of calendar days in this subsection, (e.g., Winter Break).
- Institutional officials may not overrule IRB disapproval decisions regarding appeals in research activities involving human subjects.

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RESPONSIBILITIES

IRB Chair is charged with ensuring SOP4

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

REGULATIONS

45 CFR 46.109, 45 CFR 46.111, 45 CFR 46.116

21 CFR 56.109, 21 CFR 56.111, 21 CFR 50.25

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.