WESTCLIFF UNIVERSITY
Educate. Inspire. Empower.

IRB Standard Operating Procedure

SOP 1	Allowed and Banned Research	Effective Date 1/1/2023

PURPOSE

To define the types of allowed and disallowed/banned research.

DEFINITIONS

Human subject. Human subject means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.

Human subject research. A human subject is "a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

POLICY

For IRB purposes, *research* is defined as a systematic investigation, inquiry, or analysis—such as scholarly or critical study or inquiry or scientific investigation, development, testing, or evaluation—designed to develop or contribute to generalizable knowledge. Research includes activities that aim to test a hypothesis, discover or collate facts, principles, or effects, reach new conclusions, or reexamine information by the critical study of a subject or by a course of scientific inquiry. Examples of *allowed human subjects research* at the University include:

- Interviews, surveys, tests, inquiries, and observations designed to elicit or obtain nonpublic information.
- Studies of existing records where the identity of the subjects is known or could be readily ascertained by the investigator.

The IRB has banned the following types of research:

- Research requiring the use of HIPAA protected information.

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- Research requiring experiments or medical procedures (however, simple interview or focus group games/puzzle solving may be permitted).
- Research requiring vulnerable groups or populations. (Vulnerable populations are individuals that are vulnerable to coercion or undue influence, such as children, prisoners, or individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.)
- Research involving the collection of biospecimens, clinical trials, and broad consent.
- Research requiring the waiving of informed consent.

RESPONSIBILITIES

IRB Chair is charged with ensuring SOP 1.

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

REGULATIONS

§ 56.102

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.