WESTCLIFF UNIVERSITY
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IRB Standard Operating Procedure

SOP 9	SOP 9: Obtaining Informed Consent	Effective Date 1/1/2023

PURPOSE

SOP 9 defines the minimal requirements for obtaining consent.

DEFINITIONS

SOP 1. Reference to SOP 1: Allowed and Banned Research.

POLICY

No primary investigator may include human beings as research participants unless they have obtained legally valid informed consent from the participant or their custodian/legal representative. Generally,

- The IRB adheres to 45 CFR 46.116; modified by SOP 1.
- The IRB may utilize 21 CFR 50.25 for studies following FDA guidelines; modified by SOP 1.
- The IRB may utilize 34 CFR 98 and 34 CFR 99 for studies involving students and educational institutions; modified by SOP 1.
- The IRB may utilize 32 CFR 219.116 for studies involving the Department of Defense (DoD); modified by SOP 1.
- The IRB may utilize 38 CFR 16.116 for studies involving Veterans Affairs (VA); modified by SOP 1.
- The IRB may utilize other statutes per https://www.apa.org/research/responsible/human; modified by SOP 1.

The IRB reviews the application and consent document to ensure the required elements of informed consent—and, when deemed necessary, additional elements of informed consent per the abovementioned CFRs. The IRB may request additional language and assurances.

The informed consent requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent in the Common Rule are not required but may be included.

These policies apply to adult consent and/or parental permission.

Procedure/Guidance

Whether written, electronic, or oral, consent is obtained per the following:

- Before involving a human subject in research, the investigator must obtain legally effective informed consent from the participant or the participant's legally authorized representative.
- Consent is sought under circumstances that provide the prospective participant or the legally authorized representative sufficient opportunity to ask questions and consider whether to participate. Further, the possibility of coercion or undue influence must be minimized.
- The information given to the participant, or the legally authorized representative, shall be in language understandable to the participant or legally authorized representative. The IRB encourages the use of Federal Plain Language Guidelines (https://www.plainlanguage.gov/guidelines/).
- Any information that a reasonable person would want to have to make an informed decision about participation should be provided to the participant or legally authorized representative.
- Consent must begin with a concise and focused presentation of the vital information that is most likely to assist a prospective participant or legally authorized representative in understanding why an individual may or may not want to participate in the research.
- The information must be presented in sufficient detail and organized and presented in a way that does not merely provide lists with isolated facts—but rather facilitates the understanding of why one may or may not want to participate.
- The consent process may not utilize exculpatory language through which the participant is made to waive or appear to waive legal rights or releases or appears to release the primary investigator or the University from liability for negligence.

The IRB determines whether the information provided to the potential participant includes the basic required elements of informed consent and when appropriate, the additional elements of informed consent as provided in the applicable regulations. Such determinations are made using the IRB Rubric.

For studies possessing no more than minimal risk, the additional elements of informed consent provided in the abovementioned CFRs may not be required. The IRB determines if any additional elements of informed consent should be included using the IRB Rubric.

The additional elements of informed consent provided in the abovementioned CFRs are required for studies possessing more than minimal risk. Such a determination will be determined and documented during a convened review.

Any elements of informed consent explicitly required for VA or DoD studies will be required as outlined in the abovementioned CFRs. Such a determination will be determined and documented during a convened review.

Additional Requirements

The IRB shall require the use of the template consent form as part of the application process; the IRB must approve changes to the template's language at the time of review.

The IRB follows applicable Federal, State, or local laws, which require additional information to be disclosed for informed consent to be legally valid. If applicable, this information must be provided.

In addition to information specifically required by applicable regulations, the IRB may require that information be given to the participants when (in the IRB's judgement) the information would meaningfully add to the protection of the rights and welfare of participants.

RESPONSIBILITIES

IRB Chair and Reviewers are charged with ensuring SOP 9.

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

REGULATIONS

§ 46.116

§ 50.25

§ 16.116

§ 219.116

§ 34.98 and § 34.99

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Title/Role
	Institutional Official
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.