WESTCLIFF UNIVERSITY
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Standard Operating Procedure

SOP 10	SOP 10: Online Research/Online Consent and Documenting Consent	Effective Date 1/1/2023

PURPOSE

SOP 10 defines the minimal requirements of documenting consent.

DEFINITIONS

Short form. A short form is a consent document written in a language understandable to a non-English speaking individual or their legally authorized representative. It summarizes the required elements of informed consent outlined in the federal regulations, but it does not contain specific study information. Therefore, it is used in conjunction with an oral presentation of the IRB-approved English version of the written consent form in a language understandable to the potential subject

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

SOP 9. Reference to SOP 9: Obtaining Informed Consent

Written consent form. The consent form provides potential participants sufficient written information to decide whether to participate in a research study or not based on an explanation of the proposed research and the nature of the participation that is requested of them. Once approved, the consent form reviewed by the IRB is the only one that can be copied and administered to participants. Any changes to approved consent forms must be submitted to the IRB as proposed modifications prior to their use.

POLICY

The IRB may approve procedures for documentation of informed consent involving:

- a written consent form signed and dated by the participant or the participant's legally authorized representative; and/or
- a short form written consent form stating that the required elements of informed consent have been presented orally.

It is the responsibility of the IRB to determine whether the proposed method of documentation is appropriate—per SOP 1 and SOP 9.

Written consent form. The IRB requires that informed consent be documented using a written consent form approved by the IRB. The participant or legally authorized representative must sign and date the written consent form before participating in the study.

The IRB may approve the delivery of a written consent form via mail, electronic mail, or facsimile to the potential participant or the potential participant's legally authorized representative. Consent may be secured via telephone/VOIP when the participant or the legally authorized representative can read the consent document as it is discussed. All other applicable conditions for documentation of informed consent must also be met.

The written consent form must be electronically or physically signed and dated by:

- the participant or the participant's legally authorized representative;
- the person obtaining the informed consent; and/or
- a witness, if required by the IRB. The role of the witness is to witness the participant's or the participant's legally authorized representative's signature only unless the sponsor or IRB requires the witness to witness the informed consent process. The witness cannot be the person who obtained informed consent from the participant—but may be another member of the study team or a family member.

Short form/Oral presentation. 45 CFR 46.117 and 21 CFR 50.27 provide for oral presentation of informed consent information. During such events, the participant must receive:

- a short form written informed consent document stating that the elements of informed consent as required above have been presented orally to the participant or the participant's legally authorized representative; and
- a written summary of the orally presented information.

Consent, using a short form, requires:

- a witness signing and dating the short form and receiving copies of the short form and written summary;
- the participant (or legally authorized representative) must sign and date the short form; and
- the primary investigator must sign and date a copy of the written summary of the information that is presented orally.

Neither the primary investigator nor the individual obtaining consent may witness the consent process.

An oral presentation, grounded in the short form, may be used with participants who do not speak English. The oral presentation and short form must be (in a language) understood by the participant. The written informed consent document may serve as the summary during such events. However, the witness must be fluent in English and the participant's language.

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Translation. Expedited review of foreign language versions is acceptable if the IRB has already approved the protocol, the English language informed consent document, the English version of the short form document, and verification of translation is provided.

Illiterate persons. Illiterate persons may *make their mark* after having the informed consent form read to them (and appropriately discussed) according to the laws applicable in each state or country.

IRB documentation requirement. All primary investigators must file the current (up-to-date) informed consent document with the IRB. The IRB must retain copies of all consent forms in an appropriate fashion.

RESPONSIBILITIES

IRB Chair and Reviewers are charged with ensuring SOP 10.

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

REGULATIONS

§ 46.117

§ 50.27

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 SOP at its sole discretion.