

SOP 6.01 - Informed Consent: Process, Documentation, and Waivers

1. Objective

In accordance with the Belmont Report ethical principle "Respect for persons," and 45 CFR 46.116, this SOP describes the basic requirements for obtaining ethical and legally effective informed consent from research subjects.

2. General Description

With limited exception, no investigator may involve a human being as a subject in research unless the investigator has obtained legally effective informed consent of the subject or the subject's legally authorized representative.

Definitions

Informed consent – includes all of the processes and documentation that allow human subjects to be made aware and give permission for participation in a research project.

Guardian (per NRS 159.017) – is any person appointed as guardian of the person, of the estate, or of the person and estate for any other person. The term includes, without limitation, a special guardian or, if the context so requires, a person appointed in another state who serves in the same capacity as a guardian in this State.

Per Chapter 159 (159.0805) of the Nevada Revised Statutes, court approval is required before a guardian may give consent for a ward to participate in research (in the state of Nevada).

Legally Authorized Representative – is an individual, or judicial, or other body, authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedures involved in the research.

3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/Study Personnel (SP), Office of Research Integrity – Research Protections (ORI-RP), IRB Chairs/Co-Chairs, Staff, IRB Members

Investigators

An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Investigators must keep signed informed consent forms in a secure location for a minimum of three years following completion of the research.

IRB

It is the general responsibility of the IRB or reviewing entities to ensure that the basic and applicable elements of informed consent have been met satisfactorily, with the idea that respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.

The IRB is responsible for reviewing the planned informed consent process to ensure that it meets the ethical and regulatory requirements for fully informed and voluntary consent to participate in research.

With exception to a claim for Exemption from the need for IRB review, consideration towards a waiver of some or all elements of informed consent must be justified and properly documented during the course of a review. However, even in the case of a claim for Exemption, the IRB-related review will consider the basic elements of informed consent as they are discussed here.

4. Procedures

Informed Consent Process

The generally accepted and traditional method for establishing informed consent begins with the recruitment process where upon potential subjects first hear about a research study, and ends when the study is closed (regardless of whether or not a prior participant is active when the study closes). Informed consent is an ongoing process that occurs over the entire duration of the study.

Investigators conducting studies which involve multiple interactions with participants should consider confirming the participant's willingness to continue throughout the course of the study and offer participants the opportunity to ask questions, voice concerns or both at any time during the study. In short, all communication with potential, actual, and past subjects intended to provide information to the subject about various aspects of the study is considered part of the informed consent process and subject to IRB, or IRB-related review and approval. The IRB reviews the planned informed consent process to ensure that it meets the ethical and regulatory requirements.

The basic elements discussed below are considered essential for providing proper informed consent:

- (1) The consent document begins with a concise and focused presentation of key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in research. This key information includes: A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- (9) The consent process and documentation as a whole presents information in sufficient detail, and facilitates the prospective participant's or legally authorized representative's understanding

Additional elements of informed consent should be considered when appropriate;

- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

- (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- (3) Any additional costs to the subject that may result from participation in the research;
- (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- (6) The approximate number of subjects involved in the study.

Informed Consent Disclosures

The IRB determines the required disclosures that will be provided to each participant or a legally authorized representative in accordance with legal and regulatory requirements.

Required disclosures include:

- If research involves the collection of identifiable information or identifiable biospecimens, an explanation of potential future use. (May be omitted if the research does not involve collection of identifiable information or identifiable biospecimens):
 - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another researcher for future research studies without additional informed consent from the participant or legally authorized representative, if this might be possible; or
 - A statement that the participant's information or specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- Whether additional disclosures are required for inclusion in the consent process.
 - A statement that the participant's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.
 - The amount and schedule of all payments.
 - The consequences of a participant's decision to withdraw from the research.
 - Procedures for orderly termination of participation by the participant.
 - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the participant, and if so, under what conditions.
 - For research involving biospecimens, a statement specifying whether the research will (if known) or might include whole genome sequencing.
- The consent process will be documented according to legal and regulatory requirements.

Waiver of Informed Consent Process

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that

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- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
- (2) The research could not practicably be carried out without the waiver or alteration.

Alternatively, an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

*The informed consent requirements noted above are not intended to preempt any applicable federal, state, or local laws, which require additional information to be disclosed in order for informed consent to be legally effective.

Informed Consent Documentation

With exception to a claim for Exemption from the need for IRB review; consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The consent form may be presented as:

- (1) A written consent document that embodies the elements of informed consent discussed above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
- (2) A short form written consent document stating that the elements of informed consent discussed above have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Short Forms

A short form is a written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, the subject or her or his representative must be given an oral summary of the research before the subject or her or his representative signs the short form.

The IRB must approve both the written summary of what will be said and the short form. In some cases, the English version of the consent form may be used for the summary. There must be a witness, who is conversant in both English and the language of the participant, to the oral presentation and the witness signs both the short form and a

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copy of the summary. The person actually obtaining consent also signs the copy of the summary. Following the oral presentation, the subject or her or his representative sign only the short form. A copy of the summary and the short form must be given to the subject or his/her representative.

Waiver of Informed Consent Documentation

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Waiver of Consent Process – Public Demonstration Project

- The research is conducted by or subject to the approval of state or local government officials.
- The research or demonstration protocol is designed to study, evaluate, or otherwise examine:
 - o Public benefit or service programs.
 - o Procedures for obtaining benefits or services under those programs.
 - o Possible changes in or alternatives to those programs or procedures.
 - o Possible changes in methods or levels of payment for benefits or services under those programs.
- The research cannot practicably be carried out without the waiver or alteration.
- The research is not regulated by the US FDA.

Waiver or Alteration of Consent Process: Obtaining Consent not Practicable

- If the research involves using identifiable private information or identifiable biospecimens, the research cannot practicably be carried out without using such information or biospecimens in an identifiable format.
- When appropriate, the participants will be provided with additional pertinent information after participation.

Waiver of Documentation of the Consent Process – Screening, Recruiting, and Determining Eligibility

- The researcher will obtain information through oral or written communication with the prospective participant or legally authorized representative, or
- The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
- The research is not regulated by the US FDA.

Waiver of Documentation of the Consent Process: Distinct Cultural Groups

- The participants or legally authorized representatives are members of a distinct cultural group or community in which signing consent documents is not the norm.
- There is an appropriate alternative mechanism for documenting that informed consent was obtained.
- The oral or written information provided to participants includes all required and appropriate additional elements of consent disclosure.
- The IRB/EC will determine whether the researcher should provide participants with a written statement regarding the research.
- The research is not regulated by the US FDA.

The IRB documents its findings within the Cayuse Human Ethics Platform the justification for the waiver or alteration.

Non-English Speaking and Illiterate Subjects

When some or all of the prospective participants do not speak English, documentation must take the form of a written consent document drafted in language understandable to the participant that embodies all the elements necessary for legally effective informed consent.

When the researchers anticipate that many individuals in the sample population will not speak English, the best approach would be to have the IRB approved informed consent form translated into the languages they anticipate to encounter. If the researchers anticipate the sample population may include a few potential participants who do not speak English (as opposed to a majority), researchers may obtain consent using short form consent procedures that include oral presentation of informed consent information and a short form written document that is in a language readily understandable to the participant.

For the oral presentation, investigators may use an IRB approved summary or the approved English language informed consent document.

To preclude the need for revisions to the translated versions of consent forms, for the initial IRB review investigators may submit only the English versions of consent documents. The researchers may revise the English version as requested by the IRB and submit the revised versions for confirmation that the revisions are satisfactory. After hearing from the IRB office that the revisions are sufficient, the researchers may then have the documents translated. Upon completion of the translations, the investigators must submit all foreign language versions of the informed consent form, short form document and any other translated documents presented to the participants. Translations must be certified or back-translations must be provided. 'Certification' should be a statement provided by the translator noting their ability and experience to provide translation. A certification statement template is available for download and use in IRBNet if one is not initially provided.

Informed Consent Approval

Upon approval of the protocol, the Principal Investigator is notified that the research team is responsible for conducting the research as stated in the protocol most recently reviewed and approved by the IRB, which shall include using the most recently submitted Informed Consent/Assent forms and recruitment materials.

Clinical Trials and Consent

A clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

All UNLV research meeting the above definition of a clinical trial must post their study at ClinicalTrials.gov. The consent form must be posted on the site after recruitment has closed but no later than 60 days after the last study visit by any subject, as required by the IRB protocol.

To request not to post informed consent forms on ClinicalTrials.gov for federally funded trials, you must obtain approval for a waiver or redaction from the supporting federal department/agency. The request must justify why the document (or portions of it) should not be public.

5. References

The Belmont Report - Respect for persons 45 CFR



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46.116, 46.117

UNLV Rules and Procedures for Conducting Human Subject Research

Institutional Review Board Management and Function, Bankert & Amdur - Chapter 6

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