

Approved By:	Signature	Date:	Notes
ORI Executive Director	*Signature on File		Date First Effective: 11/18/2013
Biomedical Chair	*Signature on File		
Social Behavioral Chair	*Signature on File		Revision Date: 01/23/2023

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

## 1. Objective

The purpose of this SOP is to describe requirements for informed consent, including informed consent content, process, and documentation of informed consent. This SOP also describes processes and requirements for requesting waivers of informed consent and waivers of documentation of consent. These requirements are consistent with the Belmont Principle of Respect for Persons, and with the requirements outlined in [45 CFR 46.116](#), and [21 CFR 50.25](#).

## 2. General Description

With few exceptions, an investigator conducting human subjects research must obtain and document legally-effective informed consent from a prospective subject or their legally-authorized representative (LAR), prior to involving the subject in the research.

This SOP describes the requirements for consent processes and forms, as they apply to research reviewed at the expedited and full board level. Consent requirements for research reviewed at the exempt level are different. See SOP 5.04 - Exempt Determinations, for more information on consent requirements for exempt research.

### 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.

*Written, or “in writing”* - refers to writing on a tangible medium (e.g., paper) or in an electronic format.

## 3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/Study Personnel (SP), Office of Research Integrity – Human Subjects (ORI-HS) Staff, IRB Members

## Investigator Responsibilities

Investigators are responsible for obtaining and documenting informed consent from each prospective study subject or their legally authorized representative (LAR). The informed consent process and form(s) used by investigators to obtain and document informed consent must meet the basic requirements for informed consent (outlined in the next section), and the informed consent form(s) must contain all required and additional applicable elements of consent, outlined in the regulations as well as those required by UNLV policy. These elements of consent are described in the next section.

Investigators must seek informed consent from prospective subjects only under circumstances that provide the prospective subject or their LAR sufficient opportunity to consider whether or not to participate, and which minimize the possibility of coercion or undue influence.

Investigators who propose to waive the requirement to obtain consent, propose waiving or altering specific elements of consent, and/or propose waiving the requirement to document consent, are responsible for explicitly requesting such waiver(s) from the IRB, and must provide adequate justification for the use of the waiver(s). Justifications for the use of consent waivers must be study-specific, and must address all the requirements for the usage of such waivers as outlined in the applicable regulations.

Investigators are responsible for retaining signed informed consent forms in a secure manner for a minimum of 3 years following completion of the research. This retention requirement may be longer for certain types of research. For example, studies utilizing HIPAA-covered data will be required to retain records, including consent forms, for a minimum of 6 years.

## IRB Responsibilities

The IRB is responsible for ensuring proposed informed consent processes are appropriate and meet regulatory requirements and institutional policies. The IRB is also responsible for ensuring that the informed consent form(s) used in a research study contain all required and applicable additional elements of consent outlined in the regulations, and any other information which may be required by other regulation or institutional policy. The IRB may require that investigators include additional information in the consent form(s) which, in the judgment of the IRB, would meaningfully add to a prospective subject's ability to provide fully informed and voluntary informed consent.

The IRB is also responsible for ensuring that informed consent is appropriately documented by the investigator, through the collection of required signatures on the consent form(s).

When an investigator proposes waiving the requirement to obtain consent, proposes waiving or altering specific elements of consent, and/or proposes waiving the requirement to document consent, the IRB must consider the applicable waivers, determine their appropriateness, and ensure that the use of the waiver(s) is fully justified according to the nature of the study and according to regulatory requirements for such waivers.

Adequacy of the consent process is of great importance. The IRB has the authority to observe or have a third party observe the consent process and the research.

## 4. Procedures

Informed consent must not be viewed solely as a form that is completed by potential subjects of research. Rather, informed consent is a process that begins with recruitment, is formalized through the signing of a consent form, and continues throughout the life cycle of a 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.

Investigators must not only provide relevant consent form(s) to the IRB in the IRB submission, but must also describe the procedures that will be utilized to ensure fully voluntary and informed consent from prospective subjects. Procedures for obtaining informed consent should also consider procedures for continually affirming consent throughout the study, as appropriate to the nature 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 and/or voice concerns at any time during the study.

The regulations outline requirements both for the informed consent process as well as the informed consent form. These are discussed below.

## General Requirements for the Informed Consent Process

The informed consent process should be seen as an educational endeavor, whereby the investigator provides prospective subjects or their legally authorized representative (LAR) with all the information needed for the prospective subject or LAR to make a fully informed and voluntary decision regarding participation in the research.

Therefore, the consent process must be conducted in, and the informed consent form written in, language that is understandable to the subject or their LAR. This is both in the sense of native language, as well as in the sense of utilizing "lay" language.

The following general requirements for the informed consent process are outlined in the DHHS regulations:

- An investigator shall seek informed consent only under circumstances that provide the prospective subject or their LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence
- The subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether or not to participate
- The subject or LAR must be provided with an opportunity to ask questions and discuss the information provided
- Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that facilitates the prospective subject's or their LAR's understanding of the reasons why one might or might not wish to participate. Informed consent shall not consist merely of a list of isolated facts
- No informed consent, written or oral, may include exculpatory language. Exculpatory language is language which waives or appears to waive any of the subject's legal rights. Exculpatory language also includes language which releases, or appears to release, the investigator, the sponsor, the institution, or the institution's agents from liability for negligence

Investigators are required to use the most-recently IRB-approved consent form when conducting informed consent, regardless of consent modality (paper or electronic).

It is generally best practice for investigators utilizing a paper-based consent form to download the most-recently IRB-approved consent form from Cayuse, which may bear an approval "stamp" from the UNLV IRB in the margins, to ensure the correct version is being used.

Investigators conducting consent using an electronic consent (eConsent) platform must ensure their electronic consent form matches the most recently IRB-approved consent form in Cayuse.

## General Requirements for the Informed Consent Process

The regulations outline requirements for the informed consent form itself. These requirements address both the structure of the form, as well as the content.

The regulations refer to the concept of "elements of consent." In this context, "elements" of consent are simply the individual pieces of information that must be included in a consent form, and which collectively deliver the information considered essential for fully informed consent.

Basic elements of consent are the pieces of information that must be included in a consent form for **all** research projects that are reviewed at the expedited or full board level. The additional elements of consent are those that **may** need to be included in a consent form, depending on the nature of the research.

## Requirements for the Structure of Informed Consent Forms

Informed consent must begin with a concise and focused summary of the key information that is most likely to assist the prospective subject or their legally authorized representative (LAR) to understand the reasons why one might or might not want to participate in the research. This portion of the consent form must be organized and presented in a way that facilitates comprehension.

[According to available guidance](#), if the information included in the key information summary contains sufficient detail to satisfy the required basic and additional elements of informed consent, then the information included at the beginning in the key information summary section does not need to be repeated later in the form. This means that, for relatively simple research studies, the key information summary will likely comprise most of the consent form.

It is important to note that the key information summary is considered a requirement of the structure of the consent form, and is not considered an element of consent. This means that the key information section of the informed consent form may not be waived.

The referenced guidance also explains that the specific content of the key information summary is flexible. However, it is generally expected that the key information summary will include the following information:

- The fact that consent is being sought for research
- The fact that participation is voluntary
- The purposes of the research
- The expected duration of the prospective subject's participation in the research
- The reasonably foreseeable risks or discomforts
- The reasonably expected benefits to the prospective subject or others
- Appropriate alternative procedures or courses of treatment, if applicable.

## Requirements for the Content of Informed Consent Forms

Informed consent must contain all the basic elements of informed consent, and any additional elements of consent that are applicable to the research. In some cases, an element of consent will not apply to a given research study, in which case such elements may not be required to be included. However, every effort should be made to include any and all elements which may add to the research subject's understanding, regardless of how significant the information may seem.

### Basic Elements of Informed Consent

The basic elements of informed consent can be found at [45 CFR 46.116\(b\)](#). These elements are required to be included in a consent form, unless a waiver or alteration is requested. Waivers and alterations of consent are discussed in a later section in this SOP.

The basic elements of informed consent are:

1. 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 that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject
3. A description of any reasonably expected benefits to the subject or others
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject  
Note: if there are no alternative procedures or courses of treatment, this element can be omitted. It is not necessary to state "there are no alternatives to participating in the research."
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
6. For research that is greater 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 can 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
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. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
  - a. 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 investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; OR
  - b. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

### Additional Elements of Informed Consent

The additional elements of informed consent can be found at [45 CFR 46.116\(c\)](#). These elements are required to be included in a consent form, if applicable to the research study. If an investigator wishes to alter or omit any of these additional elements of consent, when they otherwise would have been required, a waiver or alteration of consent must be requested. Waivers and alterations of consent are discussed in a later section in this SOP.

The additional elements of informed consent are:

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) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR'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 that may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
10. For FDA-regulated research, the following statement must be included **verbatim** in the consent form: "A description of this clinical trial will be available on <http://www.clinicaltrials.gov> as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site any time."

### Requirements for Documenting Informed Consent

Unless a waiver of documentation is requested, informed consent must be documented in all non-exempt research at UNLV, by obtaining relevant signatures on a written consent form.

The individuals required to sign a consent form at UNLV include:

1. The subject must sign and date the informed consent form
2. The person obtaining informed consent must sign and date the informed consent form
3. If applicable, the subject's Legally Authorized Representative (LAR) must sign and date the informed consent form, and the form must include a line to indicate the LAR's relationship to the subject

In addition to signing and dating the informed consent form, a subject (or their LAR) must be given a signed and dated copy of the informed consent form for their own records.

A “copy” of the consent form can be achieved through two different methods:

1. A photocopy or scanned digital copy of the original signed and dated consent document
2. The participant signs and dates a consent form and gives this copy to the researcher. Then a second, identical form is signed and dated by the participant, which they keep with them

The requirement to provide a copy of the consent information to the participant may not be applicable if documentation of consent is waived (see waiver of documentation of consent section below).

The consent form may be presented in one of two ways:

1. A written consent document that includes all the required and applicable additional elements of consent discussed above. This form may be read aloud to the subject and/or their LAR, but regardless, the subject and/or LAR must be given sufficient time to read the form before it is signed OR
2. A “short form” written consent document. The short form document consists solely of a statement that the required and applicable additional elements of consent have been presented orally to the subject or their LAR. Only this short form statement would be signed and dated by the subject or their LAR. In addition, when a short form is used, a witness must sign and date the short form, as well as signing an IRB-approved summary of the information presented orally to the subject or their LAR. The person obtaining consent should also sign and date a copy of the summary. A copy of this summary shall be given to the subject or their LAR, in addition to a copy of the short form.

Generally, a short form consent process is used only with subjects and/or LARs who have Limited English Proficiency (LEP), when a fully-translated consent form is not being used. This is discussed in more detail below.

### **Short Form Consent for Individuals with Limited English Proficiency**

The short form consent process, described above, includes both a short written form that states the required and applicable additional elements of consent were orally presented to the subject or their legally authorized representative (LAR), and includes a written summary of the information presented to the subject or their LAR. This written summary and the short form itself must be approved by the IRB. In some cases, the English consent form may be used as the written summary.

Additional requirements for using short form consent with LEP individuals:

- The short form is written in a language understandable to the subject or their LAR
- There must be a witness, conversant in both English and the target language, present at the time of the informed consent discussion
- This witness must sign and date both the short form and the written summary
- The person obtaining consent signs and dates a copy of the summary and the short form

When investigators anticipate working with Limited English Proficiency individuals, it is most appropriate for consent forms and study documents to be fully translated to the target language(s).

Short form consent should generally only be used when investigators either (1) do not expect to encounter LEP individuals in their study population, or (2) when a participant speaks a language not originally anticipated in the study population. When a short form process is utilized multiple times in the same language, investigators are strongly encouraged to consider developing fully-translated study documents.

### **Translation of Informed Consent Documents**

When some or all of the expected subject population will have Limited English Proficiency (LEP), then the consent form should be translated from English into a language(s) understandable to the subjects or their legally authorized representatives (LARs).

To preclude the need for revisions to the translated versions of consent forms, for the initial IRB review, investigators must first 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 on the [UNLV ORI-HS website](#), if one is not initially provided by the translator.

### **Electronic Consent (eConsent) Signatures**

Some research studies may desire or require remote consent procedures, including obtaining and documenting consent electronically. When obtaining electronic signatures, the platform used must meet applicable requirements for the signature to be considered legally valid.

The method of obtaining electronic signatures will vary, depending on the risk level of the study, and whether the study is FDA-regulated. FDA-regulated research will have specific requirements relating to electronic signatures, under 21 CFR 11.

Investigators are highly encouraged to consult with ORI-HS if they need to obtain electronic signatures for their consent process, in order to identify the most appropriate method for obtaining electronic signatures, given the context of the study.

For minimal risk research, the easiest and generally best course of action is to request a waiver of documentation of consent (discussed below).

### **Waivers of Consent and Waivers of Documentation**

In some cases, obtaining informed consent, including all elements of consent in a consent process, and/or obtaining documentation of informed consent is not practicable or feasible. In those cases, the relevant waivers can be requested from the IRB.

#### **Waiver of Alteration of Consent for Public Benefit Programs**

Under [45 CFR 46.116\(e\)](#), “an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent ... or waive the requirement to obtain informed consent,” provided the IRB finds and documents that both the following conditions are met:

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:
  - a. public benefit or service programs;
  - b. procedures for obtaining benefits or services under those programs;
  - c. possible changes in or alternatives to those programs or procedures; or
  - d. 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

Note: this particular waiver is not commonly used, as it is specific to research that is (1) conducted on behalf of or under the approval of a state or local government; and (2) specific to specialized government programs. More often, the general waiver or alteration of informed consent (discussed below) is used.

There is no equivalent waiver for public benefit programs under FDA regulations.

### General Waiver or Alteration of Informed Consent

Under [45 CFR 46.116\(f\)](#), “an IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent ... 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 research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Note: the 3rd criterion above is not required for FDA-regulated research.

Note: While the FDA regulations do not currently include provisions for this kind of waiver in its own regulations, the FDA has stated in guidance that it does not intend to object to an IRB approving a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waiving the requirements to obtain informed consent when the IRB finds and documents that criteria 1, 2, 4, and 5 above are met.

If it is appropriate to provide a debrief or an explanation about the research after it has involved the participant (i.e.: when a study involves deception), the PI must submit such information by way of a written form, letter, or script for IRB approval. See SOP 6.03 for more information on the use of deception in research.

It is important to note that a waiver of consent need not apply to all subjects in a study. Rather, the waiver can be applied only to specific sub-groups of subjects as appropriate to the nature of the study.

### Waiver of Documentation of Consent

Under [45 CFR 46.117\(c\)\(1\)](#), an IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

1. That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) **will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern**;
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; or
3. If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or LARs with a written statement regarding the research.

Note: FDA-regulated research may not utilize a waiver of documentation of consent under conditions 1 or 3 above. Only condition 2 is allowable for FDA-regulated research. For Exception from Informed Consent for Planned Emergency Research, see SOP 6.04.

In cases where consent is being waived entirely under a waiver of consent, then documentation of consent is also waived, and a specific waiver of documentation of consent need not be requested in addition to the waiver of consent. However, if only some elements of consent are being waived/altered, then both the PI and the IRB must consider whether documentation of consent is warranted for the remaining information provided during the altered consent process.



## Screening, Recruiting and Determining Eligibility

Some studies require screening or other pre-entry activities to determine if prospective subjects are appropriate candidates for a research study. Such screening activities might include administering a survey or interview, reviewing existing records such as medical records, undergoing a blood test, and other activities meant to determine if a prospective subject is eligible for a study.

Under [45 CFR 46.116\(g\)](#), An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects **without the informed consent of the prospective subject or the subject's legally authorized representative (LAR)**, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or their LAR; or
2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

For all other screening procedures that are not limited to surveys/interviews or accessing existing records/specimens, informed consent must be obtained, or a waiver must be requested and approved, prior to engaging the prospective subject in any screening interventions.

Per [current guidance on screening procedures](#), having someone participate in a research-indicated procedure (either by act or omission) requires prospective informed consent. Examples include tests, fasting, taking a shower, refraining from exercise, refraining from smoking, withdrawal of medication (washout), etc. The IRB should receive a written outline of the screening procedure to be followed and how consent for screening will be obtained. The IRB should also approve any screening consent document that will be used.

Note: for FDA-regulated research, the above provisions for screening without consent do not apply. For FDA-regulated research, consent must be obtained or waived for all screening procedures, even those limited to survey/interview, or reviewing existing records.

While 45 CFR 46 regulations allow for approving specific screening procedures without informed consent or an informed consent waiver, if screening involves HIPAA-covered data, an appropriate HIPAA pathway is still needed (i.e.: authorization, a waiver of authorization, etc.).

## Requiring Revisions to the Consent Form

The informed consent form must be revised or updated when deficiencies are noted, or when additional information will improve the consent process. If revisions are significant, the IRB may require that currently enrolled subjects sign the revised consent form to indicate continued willingness to participate.

## Posting of Clinical Trial Consent Forms

Per [45 CFR 46.116\(h\)](#), For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee conducting the trial on a publicly available Federal web site.

The informed consent form must be posted on the Federal web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

The website to be used for posting clinical trial consent forms is ClinicalTrials.gov.

If a PI feels that certain information should not be made publicly available on a Federal web site (e.g. confidential commercial information), they should discuss this with their funding agency, and the funding agency may permit or require redactions to the information posted.

## 5. References

[45 CFR 46.116](#)

[OHRP Informed Consent tips](#)

[OHRP Informed Consent FAQs](#)

[FDA Guidance on Waiver or Alteration of Informed Consent](#)

[FDA Guidance on Screening Activities](#)

[Federal Register - Preamble on Informed Consent Key Information Summary](#)