Approved By:	Signature	Date:	Notes
ORI Executive Director	*Signature on File		

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 PHDQLQJIXOO\ DGG WR D SURVSHFWLYH VXEMHFW·V DELOLW\ WR

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,

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
- 7KH H[SHFWHG GXUDWLRQ RI WKH SURVSHFWLYH VXEMHFW·V
- 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 HOHPHQWV ZKLFK PD\ DGG WR WKH LQIRUPDWLYH QDWXUH RI WKH GRFXPHQW 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 QHFHVVDU\ WR VWDWH ´WKHUH DUH QR DOWHUQDWLYHV WR S

7. $Q H[SODQDWLRQ RI ZKRP WR FRQWDFW IRU DQVZHUV WR SHU 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 if 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

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.

´&HUWLILFDWLRQµ VKRXOG EH D VWDWHPHQW Qand experience to provide E\ WKH 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.

General Waiver or Alteration of Informed Consent

Under 45 CFR 46.116(f) ´DQ ,5% PD\ DSSURYH D FRQVHQW SURFHGXUH ZKLF DOO RI WKH HOHPHQWV RI LQIRUPHG FRQVHQW « RU ZDLYH WKH U 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.