

Policy II3F Informed Consent

Scope

This policy describes the requirements for legally effective informed consent for research involving human research participants. Additional requirements for obtaining informed consent in research involving children, decisionally impaired adults, and for HIPAA authorization are not described here but may be found in the applicable policies. See the Related Information section for links information. Policy Statement Investigators must obtain either 1) the legally effective informed consent of the participant or the participant's legally authorized representative or 2) IRB approval for a waiver of informed consent prior to a participant becoming involved in research in accordance with 45 CFR 46.116 and 21 CFR 50.

Note: Additional requirements apply to research subject to FDA and VA regulations. These are described separately, at the end of this document.

Reason for the Policy

Obtaining truly informed and voluntary consent to participate in research is a hallmark of research ethics. The ethical principle of respect for persons requires that prior to involving human participants in any aspects of a research study such as enrollment screenings, study interventions, or any other human data collection, the investigator obtain the informed consent of the individual who wishes to participate, or justify why it cannot be obtained and receive Institutional Review Board (IRB) approval for a waiver of consent. 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.

Definitions

Demonstration Project

Implementation of a method, technology, policy or idea to assess feasibility prior to full implementation. For example, proof of concept studies or the initiation of a benefit or service program or modification of such program for the purpose of assessing its ability to improve the provision of government programs.

Exculpatory Language

Language that waives or appears to waive any of an individual's legal rights or which releases or appears to release the investigator, sponsor, the institution or its agents from liability for negligence.

Family Member

For purposes of this policy, any one of the following legally competent persons: spouse; parents; grandparents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship. [21 CFE 50.3(m)]

Guardian (per NRS 159.017)

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.

Independent Data Monitoring Committee

An independent group of experts without University affiliation, established by the sponsor of a research protocol to periodically assess the progress of a study by evaluating the safety data and the critical efficacy endpoints (also known as a Data Safety Monitoring Committee). The committee makes recommendations to the sponsor whether to continue, modify or stop a trial. In some instances, the IRB may permit people with University affiliations to be members of a Data Monitoring committee so long as the majority of the membership is not affiliated with the University. However, no committee members may be affiliated with the research study.

Legally Authorized Representative

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.

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

Public Benefit or Service Program

A federal, state, or local government initiated or endorsed program to deliver financial or medical benefits such as those provided under the Social Security Act or services to improve public welfare such as social, supportive, or nutrition services as provided under the Older Americans Act.

Ward (per NRS 159.027)

Any person for whom a guardian has been appointed.

Overview

The IRB is responsible for the review of the informed consent processes in all research involving human participants and will only approve those processes that provide informed consent in accordance with this policy or which meet the criteria for waiver of consent or waiver of documentation of consent as described below.

I13F1 Informed Consent Requirements

The consent process must be conducted in a manner and language which is understandable to the prospective participant or her or his legally authorized representative (LAR) and which provides the prospective participant or LAR with sufficient opportunity to consider whether or not to participate. The informed consent process must be designed to minimize any potential for coercion or undue influence. No informed consent process may contain any exculpatory language.

The following eight basic elements of informed consent are required to be provided in the course of the consent process. The investigator must ensure that these elements and any others required by the IRB are presented in such a manner as to facilitate the prospective participant's ability to understand involvement in the research study. In some cases, the investigator may need to proactively query the participant's understanding of the consent materials.

I13F1a Required Elements for Informed Consent

Subjects must be given the following information before agreeing or declining to participate in a research study:

- a statement that the study involves research, an explanation of the purpose of the research, the expected duration of participation, a description of the procedures, and identification of the experimental procedures;
- a description of any reasonably foreseeable risks or discomforts;
- a description of any benefits to the subject or to others that might be reasonably expected from the research;
- disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject;
- a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained including as appropriate:
 - what records may be examined by the sponsor, the IRB, other University personnel, FDA, or other regulatory agencies,
 - whether or not the data collected will be retained, and, if so, for what purpose and for what period of time, or when the data will be de-identified and/or destroyed,
 - what procedures will be put in place to ensure that unauthorized individuals will not have access to this information, and
 - the limitations (if any) to these confidentiality procedures such as legal reporting requirements for specific diseases and in the case of suspected child or elder abuse;

- for research involving more than minimal risk, an explanation as to whether or not any compensation and medical treatment are available if injury occurs to the participant and if so, what they consist of or where further information may be obtained;
- identification of whom to contact for answers to questions about the research and the research participants' rights including whom to contact when the investigator may be unavailable or to discuss any other questions, complaints or concerns and whom to contact if the participant sustains a research-related injury; and
- a statement that research participation is voluntary, that the participant may discontinue participation at any time, and that the participant's refusal to take part or withdraw will not involve a penalty or loss of benefits to which the participant is otherwise entitled.

Note: For research funded by the Department of Defense and its components, stricter requirements related to research-related injuries may apply (see item 10.b. in the Department of Defense directive 3216.02 dated November 11, 2011, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research available online at <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>).

II3F1b Situational Additional Elements for Informed Consent

When appropriate, the following additional elements of informed consent must be provided to the participant or representative:

1. a statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are unknown or currently unforeseeable;
2. anticipated circumstances under which the volunteer's participation may be terminated by the investigator without regard to the participant's consent or willingness to continue to participate;
3. any additional costs to the participant that may result from taking part in the research, including whether or not such costs may be billed to a third party payor;
4. the amount and schedule of payments for participating in the research;
5. the consequences of the participant's decision to withdraw from the research and procedures for safe and orderly termination of participation;
6. a statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue to participate will be provided to the participant; and
7. the approximate number of participants involved in the study.

Note: The need to inform subjects of these additional elements is dependent upon research design, subject populations and level of risk. Investigators and the IRB will consider whether or not these additional elements are required on a case-by-case basis.

II3F2 Documentation of Informed Consent

Unless waived by the IRB in accordance with sections II3F3, II3F4 and II3F5 below, the consent information will be provided to the participant in writing and will be signed by the participant or their legally authorized representative (or guardian, with court approval). For a research project that is also under the purview of the Food and Drug Administration (FDA) regulations, the individual obtaining informed consent must also sign and date the form. Approved consent forms will be marked with the approval date and reviewing IRB. Participants must be provided with a copy of the consent document; it need not be signed.

Consent documentation may be provided through use of a

1. standard ICF, a form that includes all of the required elements of consent) which is signed by the participant, or
2. short form consent procedure (see II3F GD2) that includes both of the following:
 - a. an IRB-approved written summary to be read to the participant or her or his LAR that includes all of the required elements of consent, and
 - b. a short form that indicates that the elements of consent were provided orally to the participant or her or his LAR.

The short form must be written in a language understood by the participant, and must be signed by the participant (or her or his LAR) and a witness to the oral presentation. Both the witness and the individual providing consent must sign the IRB-approved summary. A copy of both the short form and summary must be provided to the participant or her or his LAR.

II3F3 Waiver or Alteration of Informed Consent

The IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent only if it finds and documents that:

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 (45 CFR 46.116(c))
 - public benefit or service programs,
 - procedures for obtaining benefits or services under those programs,

- possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs, and
 - the research could not practicably be carried out without the waiver or alteration; or
2. the research meets the following criteria (45 CFR 116(d)):
- it involves no more than minimal risk to the subjects,
 - the waiver or alteration will not adversely affect the rights and welfare of the subjects,
 - the research could not practicably be carried out without the waiver or alteration, and
 - whenever appropriate, participants will be provided with additional pertinent information after participation.

Note: Exceptions from informed consent requirements are justified for emergency research pursuant to 21 CFR 50.23 and 50.24 (see IRB Policy and procedure for emergency research: I7C and I7C PR3).

II3F4 Waiver of Documentation of Informed Consent

The IRB may waive the requirement for the investigator to obtain a signed consent from some or all participants if it finds and documents the following:

1. The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In such a case, each participant will be asked whether the participant wants documentation linking the participant to the research, and the participant's wishes will govern.
2. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

Note: Of these two conditions, only the latter condition is allowable for FDA-regulated research.

In situations in which the documentation requirement is waived, the IRB reviews a written description of the information that will be provided to subjects and may require the investigator to provide participants with a written statement or information sheet regarding the research.

Other restrictions may apply to research funded by the Department of Defense or its components (see the note at the end of section II3F1).

II3F5 Informed Consent for Non-English Speaking or Illiterate Participants

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 ((see IRB guidance II3F GD1 and II3F GD2).

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 Program Manager 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. After the IRB Chair or Program Manager receives the translated versions, approval will be certified.

II3F6 Informed Consent in Studies Involving Deception or Incomplete Disclosure

Studies which, at the time of informed consent, will not fully disclose the purpose, nature or other aspects of the study to potential participants; or that describe a study purpose that does not reflect the actual study purpose, may do so only when the deception is deemed necessary by the IRB for the conduct of the research and does not increase risks beyond what participants may agree to had they been fully informed (see IRB guidance II3G GD1 Deception in Human Research).

The IRB may approve a consent process involving incomplete disclosure of the eight basic elements of consent if the requirements for a waiver or alteration of consent described in section II3F3 above are met.

Investigators must keep in mind, that when deception is used, the fourth criterion applies: Subjects are to be provided additional pertinent information about the research after participation. More specifically, participants must be debriefed after participation unless doing so would harm them. In the latter case, investigators and the IRB must weigh the harms resulting from participation in the research with the ethical concerns related to the purposeful withholding or provision of false information to research participants without rectifying the situation at the conclusion of their participation.

When participants will be debriefed, they must be told that deception or incomplete disclosure were used and must also be told what constituted the deception or incomplete disclosure and why these were necessary. After the debriefing, researchers may ask subjects to not talk to others about the deception or incomplete disclosure to minimize the possibility that results may be skewed if latter subjects knew in advance that deception or incomplete disclosure was being used in the study.

II3F7 Ongoing Consent Requirements

Investigators are required to modify consent documents or create addenda to consent forms whenever they become aware of new information that may affect a participant's willingness to continue involvement in the research. Investigators may become aware of new information arising from the study itself, from publications related to the research or from the study sponsor. Revised consent information must be approved by the IRB before investigators present the materials to participants.

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.

II3F8 Record Keeping and Notification Requirements for Informed Consent

Investigators must keep signed informed consent forms in a secure location for a minimum of three (3) years (or more if required by the FDA or a sponsor) following completion of the research.

For multi-site research, if a University IRB determines that the research does not meet the criteria for a waiver of documentation of consent for studies that were reviewed in accordance with section II3F4, the IRB must report this determination to the principal investigator who in turn must report it to the sponsor. The sponsor is required to notify the FDA as well as other investigators and IRBs involved in this or other substantially equivalent studies by this sponsor.

II3F9 Informed Consent: Exceptions and Additional Considerations

II3F9a Exceptions to Informed Consent Requirements

The informed consent requirements described here are not applicable to and do not limit the ability of a physician to provide treatment or emergency medical care. Exceptions to the consent requirements described herein may be granted for the following:

1. planned emergency research as described in IRB Policy II4C Planned Emergency Research Which Necessitates a Waiver of Consent, and

2. if specific criteria are met, when clinicians seek to use an investigational drug or device in a therapeutic or diagnostic manner in an emergency (see I7 PR1 Emergency Use of an Investigational Drug or Device).

Additional considerations for informed consent for FDA-regulated and VA research are described in the following sections.

II3F9b FDA-regulated Research: Additional Considerations for Informed Consent

Subject Withdrawals and Research Data for FDA Research

When a subject withdraws from an FDA-regulated study, the data collected on the subject up to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the subject the option of having data removed.

A investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject must distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review. The discussion must also address how the subject's privacy and the confidentiality of her or his information will be maintained under the new conditions.

The investigator must obtain the subject's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.

If a subject withdraws from the research intervention for a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access the subject's medical record or other confidential records requiring the subject's consent, for purposes related to the study. Under these conditions,

- an investigator may review the subject's study data as long as these were collected before the subject's withdrawal from the study, and
- an investigator may consult public records (i.e., those establishing survival status) for information about a subject who withdrew.

II3F9c VA Research: Additional Considerations for Informed Consent

The VA Research Consent Form

Investigators obtaining signed consent from participants in VA Research must use the Department of Veterans Affairs Form 10-1086, Research Consent Form, or an electronic version of VA Form 10-1086, for the consent document, with the following exception: a Department of Defense (DoD) consent

document may be employed for active duty military personnel participating in VA research at DoD sites when VA-specific language is not necessary.

Additional, Conditional Elements of Consent for VA Research

When appropriate, VA requires that investigators provide additional elements of information to each subject (itemized below), and when any of these additional elements are appropriate, the VA requires these to be included in the IRB-approved consent document, unless documentation of consent is waived.

Commercial product: If the investigator believes that the human biologic specimens obtained could be part of, or lead to the development of a commercially valuable product, the investigator must inform subjects of this possible commercial use.

Future use of specimens: If the specimens are to be retained after the end of the study for future research, the investigators must indicate where the specimens will be retained, who will have access to them, and how long they will be retained.

Note: University policy; and VA, Nevada state law and other federal requirements must be met for handling, use and storage of biologic specimens and data.

Future use of data: If any of the data will be retained after the study for future research, the investigator must state where the data will be stored and who will have access to the data.

Note: University policy; and VA, Nevada state law and other federal requirements must be met for handling, use and storage of biologic specimens and data.

Re-contact: If the subject will be re-contacted for future research whether within or outside a VA facility, the investigator must inform the subject of this possible future contact.

Payment for participating in the study: If the subject is to receive any payment for participating in the study, the consent documents must state that payment may be provided for study participation, specify the payment amount and describe when and how such payments will be made, including information about prorated payments when applicable.

Disclosure of results: The investigator must inform the subject if she or he will receive a report of any results specific to the the subject or of aggregate results and describe the process by which this information will be provided.

Research related injury statement: For research involving more than minimal risk, the consent process and document must state that in the event of a research-related injury the VA has to provide necessary medical treatment to a subject injured by participation.

Note: For research involving no greater than minimal risk, VA regulations require the VA to provide care for all research-related injuries even if a statement is not included in the consent process or document

The consent process and document will disclose a statement that a veteran-subject will not be required to pay for care received as a subject in a VA research project except in accordance with federal law and that certain veterans are required to pay co-payments for medical care and services provided by the VA.

The consent document must include language explaining the VA's authority to provide medical treatment to research subjects injured by participation in a VA research project.

Additional Requirements for Photographs, or Audio or Video Recordings in VA Research

Additional requirements that apply to research involving photographs or audio or video recordings of participants involved in VA research are itemized below.

- Consent must be obtained from each research subject before investigators may take photographs or make voice or video recordings that will be used for research purposes.
- Unless the IRB grants a waiver of documentation of consent for research, the consent document for research must include the following:
 - discussion of why photographs, or voice or video recordings are being taken for the research,
 - identification of who will have access to photographs or recordings, and
 - what the disposition of these materials will be after the research is completed.
- Consent requirements for research involving photographs or video and voice recordings, when the research subject is a patient (either an inpatient or outpatient):
 - The subject must sign VA Form 10-3203 to permit use of photographs or video and voice recordings for research purposes *even if the IRB has waived the requirement for documentation of consent for research*. Photography or recordings cannot occur prior to the patient's granting such permission.
 - The subject's signed and dated VA Form 10-3203 must be placed into the medical record along with, if applicable, the signed and dated research consent document (i.e., VA Form 10-1086). The signed VA Form 10-3203 must be obtained and placed in the subject's medical record, even if the IRB has waived documentation of consent for research.

Use of Witnesses for Informed Consent in VA Research

The following apply when the IRB requires that informed consent be witnessed (e.g., the IRB may require a witness if the study involves an invasive intervention or an investigational drug or device):

- The witness is required to observe only the subject's or subject legally authorized representative's signature, not the consent process, unless the Sponsor or IRB requires the witness to observe the consent process.

- The witness cannot be the person who obtained consent from the subject, but may be another member of the study team or may be a family member.

Considerations for Individuals Obtaining Informed Consent in VA Research

If someone other than the investigator conducts the interview and obtains consent, the investigator must formally and prospectively designate in writing in the protocol or the IRB application, the individual who will have this responsibility.

The person so delegated must have received appropriate training to perform this activity. This person must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study. This designee must be a member of the research team.

VA Requirement for a Master List of Subjects from Whom Informed Consent Was Obtained

Under VA regulations (see 38 CFR16.117(c) and par. 34), the investigator must maintain a master list of all subjects from whom informed consent has been obtained whether or not the IRB granted a waiver of documentation of informed consent (with one exception, noted below). Investigators must not add a subject's name to the master list until after

- informed consent has been obtained from that subject, and
- when appropriate, informed consent has been documented using an IRB-approved informed consent form.

The IRB may waive the requirement for the investigator to maintain a master list of subjects for whom informed consent was obtained for a given study if the two conditions listed below are met *and* the IRB provides written documentation in the IRB minutes or IRB protocol file justifying the waiver:

- There is a waiver of documentation of the consent process.
- The IRB determines that including the subjects on such a master list poses a risk to the subjects from a breach of confidentiality.