OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #501.8 Revision 8	**TITLE: Informed Consent**	Effective Date: 3/8/2024
Approved By: OIRB Director	Signature	Date 3/8/2024
Approved By: IRB Chair	Signature	Date 3/8/2024

PURPOSE

To describe policies and procedures for obtaining and documenting informed consent/assent and for reviewing and requesting waiver of informed consent or waiver of documentation of informed consent for human research.

REVISIONS FROM PREVIOUS VERSION

Addition of 45 CFR 46.116 (g) Informed consent not needed for screening section.

POLICY

Informed Consent/Assent/Permission: Process and Documentation

A major requirement of research involving human participants is that researchers must obtain the informed consent of prospective participants before they include these individuals in research. Informed consent is an ongoing educational process that takes place between the researcher and prospective participant, allowing the researcher and the participant to exchange information and ask questions. In most cases, federal regulations require informed consent and documentation of the process. In certain circumstances, the federal regulations allow a waiver of informed consent documentation or waiver or alteration of the informed consent process.

Informed consent is a process that is guided by a consent document. The consent document is not a substitute for discussion among researchers and research participants. To ensure an effective informed consent process, the IRB and researchers comply with all applicable federal regulations (e.g. 21 CFR 50, 45 CFR 46.116, 117, and 28 CFR 512.16). These regulations mandate the inclusion of basic informed consent elements. Additional elements may be required, depending on the nature of the research. IRB policy also specifies the information to include in the consent process. The informed consent templates outline the required elements of informed consent.

Definitions

Assent is defined as affirmative agreement of a child or an individual with impaired consent capacity to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Permission is defined as the agreement of parent(s) or guardian(s) to the participation of their child or ward in research. Permission includes the element of consent set forth in federal regulations and outlined in the informed consent template.

In New Mexico, the terms *child* or *children* refer to all individuals under 18 years of age unless the individual(s) is legally emancipated. Individuals under 18 years of age who are not emancipated meet

the federal definition for "child". In New Mexico, *emancipated* minor means a person under the age of 18:

- Who is or ever has been married even if the marriage was annulled;
- Is currently on active U.S. military service;
- Is age 16 or 17 and has been emancipated by a Court Order and the Order does not exclude the emancipated minor's authority to make health care decisions for him/herself.

Legally Authorized Representative (LAR) is an individual who has the authority to make research participation decisions on behalf of another. In accord with state law and federal regulation, individuals who can serve as legally authorized representatives are as follows:

Permission and/or authorization by a legally authorized representative for children: Consistent with New Mexico statutes for choosing an LAR for children, the following responsible parties in the order of priority listed shall be authorized to make research participation decisions on behalf of the child: (a) the judicially appointed guardian of the person, if the guardian has been appointed and if the decisions to be made under the consent are within the scope of the guardianship; (b) the parent of the child. When research is conducted outside of the New Mexico or where there is a question whether a particular person is permitted under applicable law to consent to the inclusion of the child, the OIRB will obtain consultation from UNM Office of University Counsel.

Permission and/or authorization by a legally authorized representative for individuals with impaired consent capacity: In the absence of a legal designation or if the designee is not reasonably available, any member of the participant's family who is reasonably available may act as surrogate (e.g. spouse, life partner, adult child, parent, adult sibling, grandparent).

Consent by an LAR should involve all the same considerations that informed consent from a competent participant involves. In New Mexico, a *surrogate* is an individual who may serve as an LAR as defined above. These individuals meet the federal definitions for guardian.

Alteration and Waiver of Informed Consent Processes

The IRB may waive the requirement to obtain informed consent. In most cases, this occurs when the participant is not directly involved in the research procedures (e.g. record review, secondary data analysis) provided the researcher justifies the waiver using the criteria listed below (see #1).

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent provided the researcher justifies the waiver using the criteria listed below.

1. The IRB must find and document that the research meets the requirements for a general waiver or alteration of consent in 45 CFR 46.116(f). These include:
   - The research or clinical investigation involves no more than minimal risk to the participants.
   - The waiver or alteration does not adversely affect the rights and welfare of the participants.
   - The research could not practicably be carried out without the waiver or alteration.

- If the research involves using identifiable private information or biospecimens, the research could not 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.

2. Waiver of parental or guardian permission: when permission from parents or guardians is not a reasonable requirement because it poses additional risk to the potential participant or the parents' interest may not adequately reflect the child's interest (e.g. neglected or abused children), the IRB may waive parental or guardian permission in accord with 45 CFR 46 Subpart D and 46.408(c) and Subpart A 46.116. An appropriate mechanism for protecting the children who will participate in the research will be substituted. The research must not be FDA-regulated.

3. The IRB may waive the requirement to obtain informed consent if the research involves public benefit and service programs conducted by or subject to the approval of state or local officials. The IRB must find and document that the research meets the requirements in 45 CFR 46.116 (e) These include:

   (i) 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:
   - 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

   (ii) The research could not practicably be carried out without the waiver or alteration.

Informed Consent Not Needed for Screening

Per 45 CFR 46.116(g), an IRB may approve a research proposal in which a researcher will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective participants without the informed consent of the prospective participant (or LAR), if either of the following conditions are met:

- The researcher will obtain information through oral or written communication with the prospective participant or LAR, or
- The researcher will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Waiver of Documentation of Informed Consent

The IRB is allowed to waive the requirement to document the consent process by determining that the regulatory criteria for waivers are met. Waiving documentation means that the participant would not be required to sign the consent form.

1. The IRB must find and document that the research meets one the following requirements:
   - That the only record linking the participant and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether

the participant wants documentation linking the participant with the research, and the participant's wishes will govern.
    - That 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. (This type of documentation waiver is typically requested research involving for surveys and/or interviews).
    - If the participants or legally authorized representatives 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 participants and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
2. When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB reviews a written description of the information that will be provided to participants and will consider requiring the researcher to provide participants with a written statement regarding the research.
3. FDA regulated research: the IRB may waive documentation for some or all of the participants if the project meets the conditions listed in 21 CFR 56.109(c).
4. Non-FDA regulated research: the IRB may waive requirements to obtain a signed consent form for some or all of the participants if the project meets the requirements in 45 CFR 46.117(c).

RESPONSIBILITIES

Execution of SOP: Researchers, IRB, OIRB Staff.

PROCEDURE

Informed Consent Process and Documentation

1. The PI describes the proposed informed consent procedure, in the protocol's informed consent process section, and submits this with their IRB application prior to initiation of research. The PI indicates in the Project Team form which researchers will conduct the informed consent process.
2. The OIRB has informed consent templates which researchers use as a guide unless the IRB grants exceptions or a waiver. The consent templates contain the DHHS required elements, additional elements of informed consent, and additional IRB requirements for UNM research involving human participants.
3. At a minimum, the proposed consent process and form include the following elements:
    - Research statement: a statement that the project involves research, an explanation of the purpose of the research, an explanation of the expected duration of participation, a description of the procedures involved, and identification of any procedures which will be experimental. If applicable, include the funder/sponsor of the research (e.g. NIH, DOD, DOJ, etc.)
    - Reasonably foreseeable risks or discomforts: a statement that describes foreseeable risks or discomforts associated with the research, the likelihood and magnitude of their occurrence, and the ramifications associated with the risks (e.g. loss of confidentiality that may result in stigmatization). Plans for minimization of these risks may also be included.
    - Reasonably expected benefits to participants or others: a statement that describes benefits to participants or others that may reasonably be expected from the research including no benefit, if this is applicable. Payment for participation in a research project is not considered a benefit and the IRB will not consider compensation as a way of offsetting risks.

- Appropriate alternatives: a statement that describes with enough detail any alternative procedures or course of treatment that may benefit the participant. If no alternatives exist, the consent form may state that there are no alternatives except not to participate.
- Extent of confidentiality: a statement that describes the extent to which the researchers will maintain or not maintain confidentiality of records identifying the participants (e.g. law requires reporting child abuse, etc.) and describes how the research team will protect participants' records during and after the conclusion of proposed research. Any research that is subject to audit or inspection must identify who will have access to the participants' records (e.g. FDA, Department of Defense (DOD), National Science Foundation (NSF), National Institutes of Health (NIH), UNM or sponsors).
- Compensation or treatment for injury: **for projects with greater than minimal risk and potential for physical harm**, a statement explaining any compensation for injury and an explanation of any medical treatments available if injury occurs or where the individual may obtain further information. If medical treatments are available when the injury occurs, an explanation as to what it consists of and where further information can be obtained. The Additional Elements of Consent template contains standard statements in accordance with UNM policy.
- Researcher and IRB Contact information: a statement that describes contact information details, including telephone numbers, and whom to contact for the following situations: questions about the research (e.g. PI and other research team members), questions about participants' rights (e.g. Office of the IRB), comments, suggestions, or input and in the event of a research-related injury (depending on the nature of the research, the PI or a physician on the research team).
- Voluntary participation statement: a statement that describes clearly that participation in the research is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- Future research: a statement indicating whether identifiers might be removed from identifiable information or biospecimens and be used for future research (or not).

4. One or more of the following additional elements of information shall be provided to participants if appropriate, given the nature of the research:
    - Key Information Summary: For consent forms that are greater than 4 pages in length, include a bulleted list to provide key information to the participant that is concise and focused, and that will most likely assist a prospective participant to understand the research and choose to participate. The presentation of information is to be short, and can summarize information explained later in greater detail.
    - Unforeseeable risks to participants (or the embryos, or fetuses, if the subject is or may become pregnant): a statement warning participants that some risks are currently not known or foreseeable, when applicable;
    - Researcher-initiated termination of participation: a statement that describes the instances in which a researcher may terminate a participant's participation (e.g. participant noncompliance, participant not benefiting from research, etc.);
    - Additional costs: a statement that describes any additional costs a participant may encounter such as transportation, time away from work, parking, health costs, etc.;

- Early withdrawal/procedures for termination: a statement that describes a participant's right to withdraw from the research, consequences of withdrawal, and any procedures that may be necessary after an early withdrawal;
- Significant new findings: a statement that participants will be told of any new findings, developed during the course of the research, which may affect willingness to continue in the research;
- Approximate number of participants: a statement that explains the approximate number of participants to be enrolled in the research, nationwide and locally;
- Management and disposal of participant's biospecimens: For research involving biospecimens, whether the research will 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).
- Payment: a statement which includes all information concerning the amount and schedule of payment for participation;
- Return of research results: a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants and if so, under what conditions.
- Commercial profit: 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.

5. If the research involves vulnerable populations or sensitive issues, the researcher addresses additional regulatory and/or institutional requirements. The researcher may consult with the OIRB staff for guidance. The vulnerable populations and sensitive issues include, but are not limited to:
    - Research involving the participation of children;
    - Research involving individuals with impaired consent capacity;
    - Research involving HIV screening and/or AIDS research;
    - Research involving DNA banking, genetic research, or gene therapy;
    - Research activities directed toward pregnant women;
    - Research activities involving students;
    - Research involving collection of criminal behavior information;
    - Research involving prisoners.
6. The researcher also must address the following issues, if applicable:
    - Any waiting period between informing the prospective participant and obtaining consent;
    - The possibility of risk for an unborn child, a man or woman's ability to procreate, or a woman's ability to conceive or carry a child;
    - Additional requirements as required by the Sponsor.
7. Investigational drugs, devices, or biologics: In the IRB approved consent form, the researcher must inform the participant in the purpose that the research includes evaluation of the safety and/or effectiveness of the test article and state the test article is investigational, and, if applicable, not approved by the FDA;
8. For FDA regulated clinical trials, the IRB approved consent form must:
    - Inform the participant that the clinical trial will be entered into a national clinical trial registry data bank;
    - Include a statement noting the possibility that the FDA may inspect the records that will be provided to each participant;
    - Include a statement that de-identified results of the research will be posted on clinicaltrials.gov.

- Not include the option of having data removed upon withdrawal. When a participant withdraws from a project, the data collected on the participant to the point of withdrawal remains part of the research database and may not be removed. A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the research. Under this circumstance, the discussion with the participant distinguishes between research-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information. If this situation is not described in the original consent document, the research must obtain the participant's consent for this limited participant and the IRB must approve the consent form. If a participant withdraws from the interventional portion of a project and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the research the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review research data related to the participant collected prior to the participant's withdrawal from the project, and may consult public records, such as those establishing survival status.

9. If the research involves genetic testing, DNA banking, specimen/tissue repositories, or similar activities, the PI should contact the OIRB for guidance on unique requirements for consent.
10. The IRB assesses the PI's description of the informed consent process to ensure that the process meets the general requirements of informed consent (i.e. consent be obtained from the participants or their legally authorized representative; be in language understandable to the participant; be obtained under circumstances that provide the participant with the opportunity to consider whether or not to participate and that minimize coercive influences; does not include language through which the participant is made to waive their legal rights or releases the investigator, sponsor, or institution from liability for negligence).
11. The IRB determines whether disclosure of any researcher conflict of interest is warranted in the informed consent process and document.
12. The IRB is responsible for reviewing the proposed informed consent document(s) to ensure that all applicable federal and UNM requirements are met.
13. The researcher is responsible for ensuring that informed consent is obtained from each participant or their LAR after they have had an adequate opportunity to read the form and prior to participation in any part of the research, using the process and form approved by the IRB.
14. The participant or their LAR and the researcher providing the information to the participant sign and date the informed consent document at the time of consent. The participant or LAR receives a copy of the signed form.
15. The researcher's signature on the informed consent document is used to document that the research was explained to the participant and all questions were answered. The person who explained the research and obtained informed consent must be trained and qualified.

Posting Clinical Trial Consent Form

1. For each clinical trial conducted or supported by a Federal department or agency, the PI must post one IRB-approved consent form on a website specified by the US Federal government.
2. The consent form must be posted on the website after the clinical trial is closed to recruitment, but no later than 60 days after the last research visit by any participant as required by the protocol.

3. If the researcher wants to request an exception to the requirement to post the consent document and the process to redact confidential commercial information from the consent, they must follow guidance from the Federal agency.

Research Involving Individuals with Impaired Consent Capacity

1. The PI completes the IRB application, including forms, and after obtaining IRB approval implements the research in accordance with the requirements of the IRB approval.
2. In conducting the review, the IRB ensures additional safeguards are in place as appropriate.

Assent

1. The PI must develop processes and forms consistent with guidance provided in a number of IRB policies including but not limited to: SOP on Protection of Vulnerable Participants; Assent Form Template; and requirements found in the IRB protocol template related to assent.
2. The PI is responsible for including in the IRB protocol a description of the process/procedure for obtaining and documenting assent when research includes:
   - Children and/or;
   - Individuals with impaired consent capacity.
3. The IRB reviews the proposed process and/or waiver requests and, if applicable, the assent form to ensure compliance with IRB guidance and federal requirements.
4. Typically, a separate simplified child assent form is only required for children ages 7-11. Children ages 12-17 can sign the primary consent form.

Obtaining Informed Consent outside the State of New Mexico

1. If the PI conducts the research outside the state of New Mexico and the research involves children, an LAR, or a guardian, the researcher must follow the requirements of the state/country in which they will conduct the research (see SOP 511). The PI must also determine which individuals meet the federal definitions for child/children, LAR, or guardian in the location of the research.
2. The PI identifies the state law(s) applicable to the determination of legally authorized representative and contacts UNM legal counsel for review and determination prior to approval by the IRB (see SOP 511 Compliance with Applicable Laws and Regulations). If the PI is unable to identify applicable state law(s), the PI contacts UNM Office of University Counsel for assistance prior to approval by the IRB.

Non-English Speaking Participants

1. Researchers must deliver all information regarding informed consent/assent to potential participants or their LAR in the participant's native language(s) or one that the participant understands. The researcher must provide the IRB and prospective participants a translated version of the consent/assent form (see SOP 506 Translation for Non-English speaking Participants).
2. The researcher must describe to the IRB the process for translating and the qualifications of the translator(s). The OIRB staff may identify a cultural consultant to review the project and informed consent/assent document(s) for accuracy and cultural appropriateness. If OIRB staff are unable to identify an individual to serve as a cultural consultant, the researcher may be asked to provide a cultural consultant for review of accuracy of the informed consent form and cultural appropriateness.

Research that Requires Monitoring of Informed Consent/Assent Process

1. The IRB determines which research requires monitoring of the informed consent/assent process and the procedure and frequency with which such monitoring will occur based on the degree of risk to participants, the need for protection of vulnerable participants, or concerns related to an incident of noncompliance.
2. A designated IRB member(s) or other designee (as determined by the IRB) may monitor the informed consent/assent process. The monitoring may involve direct observation, interviews and/or surveys of participants, or other means as deemed appropriate by the IRB for the circumstances.

REFERENCES

21 CFR 50.20
21 CFR 50.23-25
21 CFR 50.27
21 CFR 56.109 (b),(c)
45 CFR 46.101(i)
45 CFR 46.109 (b),(c)
45 CFR 46.111
45 CFR 46.116
45 CFR 46.117
34 CFR 97 [Department of Education Subpart D]
28 CFR 512.16
FDA Guidance on IRB Waiver or Alteration of Informed Consent