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 non-exempt human research.

REVISIONS FROM PREVIOUS VERSION
Addition of references to FDA regulations, requirements specific to clinical trials and determinations required for waivers

POLICY
Informed Consent/Assent/Permission: Process and Documentation

A major requirement of research involving human subjects is that researchers must obtain the informed consent of prospective subjects before they include these subjects in research. Informed consent is an ongoing educational process that takes place between the researcher and prospective subject, 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 subjects. 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.

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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 subject 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.

Waiver of Informed Consent Process

The IRB has the authority to approve a consent procedure that does not include or which alters some or all of the federally mandated elements of informed consent provided the approved procedure meets applicable federal regulations. The FDA and DHHS requirements for waiver differ. Consequently, the investigators and IRB must comply with the applicable regulations, which differ depending upon study sponsor or regulatory status of the proposed research. A summary of applicable waiver requirements is as follows:
1. **Non-FDA regulated studies:** to waive informed consent requirements, the IRB must find and document that the study meets the requirements in 45 CFR 46.116(c)(d). These include:
   - The research 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 cannot practicably be carried out without the waiver or alteration.
   - When appropriate, the participants will be provided with additional pertinent information after participation.
   - The research is not FDA-regulated.

2. **FDA regulated studies:** the IRB approves exceptions for informed consent requirements if the study meets all of the requirements specified in 21 CFR Subpart B 50.24 and/or 45 CFR 46.101(i).

3. **Waiver of parental or guardian permission:** when consent of parents or guardians is not a reasonable requirement because it poses additional risk to the potential subject 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.

**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.

- 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.
- When granting waivers of the requirement to obtain written documentation of the consent process, the IRB considers requiring the researcher to provide participants with a written statement regarding the research.
- **FDA regulated studies:** the IRB may waive documentation for some or all of the subjects if the study meets the conditions listed in 21 CFR 56.109(c).
- **Non-FDA regulated studies:** the IRB may waive requirements to obtain a signed consent form for some or all of the subjects if the study 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 submits a proposed informed consent procedure and written form with his/her IRB application prior to initiation of research, unless the study meets exemption criteria (although informed consent(s) may be included). The PI indicates in Project Team form which study personnel will participate in 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 subjects.

3. At a minimum, the proposed consent process and form include the following federally required elements:
   - **Research statement**: a statement that the study 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.
   - **Reasonably foreseeable risks or discomforts**: a statement that describes foreseeable risks or discomforts associated with the research, the likelihood 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 subjects or others**: a statement that describes benefits to subjects 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 remuneration 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 subject. If no alternatives exist, the consent form must 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 subject (e.g. law requires reporting child abuse, etc.) and describes how the research team will protect subjects’ private records during and after the conclusion of proposed research studies. Any research that is subject to audit or inspection must identify who will have access to the subject’s record (e.g. FDA, National Science Foundation (NSF), National Institutes of Health (NIH), UNM or sponsors).
   - **Compensation or treatment for injury**: for studies with greater than minimal risk and potential for physical harm, a statement explaining any compensation and an explanation of any medical treatments available if injury occurs or where the subject may obtain further information. The IRB informed 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 subjects’ 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 subject is otherwise entitled, the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

4. IRB requires the additional elements unless the item(s) does not apply given the nature of the research or the proposed procedures (e.g. subjects will not receive remuneration for participation).
• **Unforeseeable risks to subjects, embryos, or fetuses:** a statement warning subjects that some risks are currently not known or foreseeable, when applicable;

• **Investigator-initiated termination of participation:** a statement that describes the instances in which an investigator may terminate a subject’s participation (e.g. subject noncompliance, subject not benefiting from research, etc.);

• **Additional costs:** a statement that describes any additional costs a subject may encounter such as transportation, time away from work, parking, health costs, etc.;

• **Early withdrawal/procedures for termination:** a statement that describes a subject’s right to withdraw from the study and any procedures that may be necessary after an early withdrawal;

• **Significant new findings:** a statement that subjects will be told of any new findings which may affect willingness to continue in the research;

• **Approximate number of subjects:** a statement that explains the approximate number of subjects to be enrolled in the study, nationwide and locally;

• **Management and Disposal of subject’s biospecimens:** DNA testing, cell lines, development of future products;

• **Payment:** a statement which includes all information concerning the amount and schedule of payment for participation.

5. If the research involves vulnerable populations or sensitive issues, the investigator addresses additional regulatory and/or institutional requirements. The investigator 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 involving collection of criminal behavior information;
   • Research involving prisoners.

6. The investigator also must address the following issues, if applicable to the proposed research:

   • Any waiting period between informing the prospective participant and obtaining consent;
   • DHHS/NIH-sponsored multicenter clinical trial: the investigator must include a copy of the DHHS/NIH-approved sample informed consent document in the application. The investigator must justify in writing any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document, and the IRB must approve these deletions or modifications;
   • 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 will included;
   • Additional requirements as required by the Sponsor.

7. Investigational drugs, devices, or biologics: In the IRB approved consent form, the investigator must inform the subject in the purpose that the study includes evaluation of both safety and 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 subject that the clinical trial will be entered into a national clinical trial registry data bank;
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 study, the data collected on the participant to the point of withdrawal remains part of the study 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 study. Under this circumstance, the discussion with the participant distinguishes 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, 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 study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, 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 subject or subject’s legally authorized representative; be in language understandable to the subject; be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate and that minimize coercive influences; does not include language through which the subject is made to waive his/her 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. When the IRB approves a study, OIRB staff affix an approval stamp to every page of the approved informed consent and recruitment document(s), which includes the approval and expiration dates. OIRB staff then forwards the form to the researcher. Researchers may only enroll subjects using informed consent/assent forms which have a valid “IRB approval” stamp unless the IRB grants a waiver from the requirement for informed consent or documentation.

14. The researcher is responsible for ensuring that informed consent is obtained from each research subject or his/her LAR after the subject or the subject’s LAR has had an adequate opportunity to read the form and prior to subject participation in any part of the study, using the process and form approved by the IRB.
15. The subject or the subject’s LAR and the researcher providing the information to the subject sign and date the informed consent document at the time of consent. Only researchers authorized (in the IRB approved protocol) to obtain informed consent sign on the line entitled “Name of Researcher.” The subject or LAR signing on the subject’s behalf receives a copy of the signed form.

16. 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 study and obtained informed consent must be qualified and approved by the IRB.

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: Policy on Protection of Vulnerable Subjects; 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, if applicable, the assent form to ensure compliance with IRB guidance and federal requirements.

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 he/she 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 Subjects

1. Researchers must deliver all information regarding informed consent/assent to potential subjects or their LAR in the subject’s native language(s) or one that the subject understands. The researcher must provide the IRB and prospective subjects 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 study and informed consent/assent document 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 subjects, the need for protection of vulnerable subjects, 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 of subjects, surveys of subjects, 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