Informed Consent (HRPP 5.1)

Description:

This policy describes UNMC's requirements for the process and documentation of informed consent.

GENERAL REQUIREMENTS:

- **The PI is ultimately responsible** for ensuring that valid informed consent is obtained and documented
- The PI may authorize other study personnel to participate in obtaining consent if they have adequate knowledge of the study
- Consent must be documented using an informed consent form unless a waiver is approved
- **Language must be understandable to the subject:**
  - Consent materials **must use language understandable to an 8th grade reading level,** using layman's terms where appropriate
- Informed consent must begin with a concise (two pages or less), focused summary including:
  - *Statement of voluntary research participation*
  - *Purpose and expected duration*
  - *Description of the procedures*
  - *Foreseeable risks/discomforts*
  - *Expected benefits*
  - *Alternatives to participation*

NOTE: The summary's contents need not be repeated in the rest of the consent form

- No exculpatory language is allowed; subjects cannot waive legal rights or release liability
- The consent process must minimize coercion or undue influence
- Special rules apply for certain vulnerable populations:
  - **Pregnant women/fetuses/neonates:** follow HRPP Policy 4.2
  - **Prisoners:** follow HRPP Policy 4.3

- **Children** *(parental permission and minor assent required):* follow HRPP Policy 4.4
- **Decisionally impaired** *(requires LAR permission and subject assent)*: follow HRPP Policy 4.6

Elements of Informed Consent:

Required Basic Elements:

- Purpose, duration, procedures, and risks
- Benefits and alternatives
- A statement describing the extent, if any, to which the confidentiality of records identifying the subject must be maintained
- Injury compensation details (for **greater than minimal risk studies**)
- For **research involving the collection of identifiable private information or biospecimens:**
    - Statement that identifiers might be removed and that after, the information/biospecimens could be used for future research studies without additional informed consent (if this might be possible), OR
    - Statement that the subject's information/biospecimens, even if identifiers are removed, will not be used or distributed for future research
- Who to contact for:
    - Study questions, concerns, complaints
    - Subject rights
    - Research-related injury
- Contact information for the IRB and Research Subject Advocate
- Voluntariness of participation and right to withdraw without penalty or loss of benefits
- Disclosure of third-party access to data *(IRB, FDA, etc.)*
- Clinicaltrials.gov listing for FDA-regulated/federally funded studies

Additional Elements (*When Applicable*):

- Unforeseeable risks
- Pregnancy risks
- Investigator-initiated withdrawal
- Additional costs to subject

- Consequences that may result from subject's decision to withdraw
- Early termination procedures
- Explanation whether the data already collected will be retained and analyzed if the subject withdraws from the research
    - The ICF cannot give the option of having the existing data removed from future analysis
- Statement that significant new findings developed during the research will be provided if they may relate to the subject's willingness to participate
- Approximate number of subjects involved in the study
- Commercial profit from biospecimens
- Disclosure of individual results
- Whole genome sequencing (if the research involves biospecimens)
- Compensation details
- Ongoing data collection after withdrawal
- Department-specific requirements *(ICH, GCP, DoD, DOJ)*

Process of Informed Consent:

- Must be obtained from subjects with legal and mental capacity *(or LAR if not)*
- Provide adequate time and privacy for decision-making
- Should be obtained in a **private and quiet location**
- Preferably conducted **in person**, but remote methods allowed if approved
- Must fully explain all elements of informed consent as described above
- Must take necessary steps to **minimize possible coercion or undue influence**
- Consider **additional protections** who make lack decision-making capacity or are especially at risk for exploitation. Consider the following:
    - Appointment of a subject advocate
    - Involvement of subject's friends and/or family
    - Use of a short form
    - Reading of the consent form to the subject
    - Use of teaching aids
- Must fully explain the rights of research subjects and provide a copy of the **"Rights of Research Subjects"**

- Must provide a written copy of **"What do I need to know before being in the research study?"**
- **Check for subject comprehension;** consider the following:
    - Asking questions about the consent form
    - Teach-back method (asking subjects to explain the research in their own words)
- In certain studies, consider verbal re-consent/reaffirmation on a routine basis

NOTE: the subject must be given a copy of the signed and dated consent form after signing. If the IRB has approved a waiver of signed consent, the subject must be offered a copy of the unsigned consent form.

Documentation of Informed Consent:

- Must use an IRB-approved ICF
- **Personnel authorized to document** consent must be:
    - *Authorized by the PI*
    - *Listed by name to document consent on the IRB application and consent form*
    - *Approved by the IRB*
- Must verify personnel have:
    - *Sufficient knowledge of the protocol*
    - *Sufficient knowledge of UNMC HRPP policies*
    - *Licensure and institutional authorization (if applicable)*
- ICF must be signed and dated by the subject, PI (or other person authorized to document consent), and the witness (if required) in the physical presence of each other *(unless waived)*
- Signature of a **witness required for:**
    - Research involving populations where the IRB determined a witness provides additional protection
    - The witness should NOT be listed as study personnel
- **Studies involving FDA unapproved drugs, biologics, and devices**: only licensed physicians or dentists may obtain and document consent for

Documentation in Research and Medical Records:

- Original signed ICF must be in the research record (*even if obtained electronically*)
- For billable interventions, a copy must also go in the medical record unless waived
- For **greater than minimal risk studies:** process of consent must be documented in the medical or individual subject study record (if applicable), or in a separate consent log
    - This should include names of the individuals involved in the process of consent

Re-Consent Requirements:

- **Minor changes** don't require formal re-consent (can be shared verbally at next study visit)
- **Significant changes or new findings** DO require full re-consent using an IRB-approved revised ICF or addendum
- Immediate notification required for information that could impact the subjects health and welfare
    - Can be done in person or by telephone, videoconferencing, etc.
    - Must be followed up as soon as possible by an updated consent process and form
    - PI must notify the ORA when all subjects have been contacted
        - This should include the identification of subjects by number and the date they were contacted
- If a modification of consent forms/information sheets are made by the investigator at the **time of continuing review**, obtaining additional consent of currently enrolled subjects is NOT required, unless it's a significant change or could impact the health and welfare of the subjects
- Investigators should regularly verbally affirm a subject's willingness to continue participation
- Upon withdrawal, subjects may be asked to allow continued data use *(must be documented if they agree)*