

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 responsible for the informed consent process.
- The PI may authorize other study personnel to participate in obtaining consent as long as they have adequate knowledge of the study.
- Informed consent must be documented by use of an informed consent form unless a waiver is approved.
- **Language must be understandable to the subject:**
 - 8th grade reading level
 - Layman's terms should be used
- **No exculpatory language** may be used.

Basic Elements of Informed Consent:

The informed consent must begin with a concise summary of key information (no more than 2 pages). **The summary must include at least the following:**

- A statement that **consent is being sought for research** and that **participation is voluntary**.
- The **purpose and expected duration** of the subject's participation.
- A description of the **procedures**.
- Foreseeable **risks and discomforts**.
- **Benefits** the prospective subject and others may expect.
- Available **alternative procedures** or courses of treatment, if any, that might have more advantages to the subject.

The consent process and form **must also provide the following** information:

- A statement describing the extent, if any, to which the **confidentiality of records identifying the subject must be maintained.**
- For **greater than minimal risk research**, an explanation of the available medical treatment in case of a **research-related injury**, including who will pay for treatment and whether other financial compensation is available.
- For any **research involving the collection of identifiable private information or biospecimens**:
 - A statement that identifiers might be removed and that after such removal, the information or biospecimens could be used for future research studies without additional informed consent (if this might be a possibility), OR
 - A statement that the subject's information or biospecimens, even if identifiers are removed, will not be used or distributed for future research.
- **Who to contact** for answers to pertinent questions, concerns, or complaints about the research, or in case of a research-related injury.
- **Contact information** for the **IRB and Research Subject Advocate.**
- A statement that **participation is voluntary and refusal to participate will not involve penalty or loss of benefits** to which the subject is entitled and that the subject may discontinue participation at any time.
- A statement that the IRB, institutional officials, OHRP, FDA, NIH, etc. will as necessary have access to research records containing PHI.
- A statement that FDA-regulated clinical trials and federally funded interventional and observational trials must be listed on ClinicalTrials.gov.

Additional Elements of Informed Consent:

The consent process and form must include the following, when appropriate:

- A statement that a particular treatment/procedure may involve risks to the subject, (or embryo or fetus if the subject is or may become pregnant, which are currently unforeseeable.
- The anticipated circumstances that would necessitate **subject withdrawal by the investigator.**
- Any **additional costs** to the subject.
- The consequences that may result from the **subject's decision to withdraw** from the research.
- Procedures for **early termination** of subject participation from the research.
- An explanation whether already collected data about the subject will be retained and analyzed if the subject chooses to withdraw.
 - The ICF cannot give subjects the option of having the existing data removed from future analysis.
- A statement that significant new findings developed during research that may affect the subject's willingness to participate will be provided to the subject.

- The approximate number of subjects involved in the study.
- A statement that the subject's biospecimens may be used for commercial profit and whether the subject will share in the profit.
- A statement regarding whether clinically relevant research results will be disclosed to subjects.
- For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.
- If the subject withdraws from the interventional portion of the study, ask if they want to continue with the follow-up/data collection portion of the study.
 - If this is not in the original consent form, the subject must provide additional written consent for this limited part of the study.
 - If the subject withdraws from ALL parts of the research, the research team must not access for the purposes of the study their medical record or other confidential records.

Process of Informed Consent:

- Subjects should be **approached sufficiently far in advance** of their involvement.
- Should be obtained in a **private and quiet location**.
- Should occur by **face-to-face contact**. However, depending on circumstances, the IRB may permit a remote consent process (HRPP Policy 5.3).
- Must take all necessary steps to **minimize coercion or undue influence**.
- Consider **additional protections for prospective subjects who may 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 written copy of the **"Rights of Research Subjects"**.
- Must provide a written copy of **"What do I need to know before being in a research study?"**.
- Must **ensure subjects comprehend** all elements of informed consent. Consider the following:
 - Asking questions about the consent form
 - Teach back method (asking the subjects to explain the research in their own words)
- In certain studies, consider verbal re-consent/reaffirmation on a routine basis.

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 be documented by use of a written or electronic consent form approved by the IRB.
- 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
- Individuals documenting consent must have:
 - Sufficient knowledge of the protocol
 - Sufficient knowledge of UNMC HRPP policies
 - Required licensure to perform procedures described in the protocol, as applicable.
 - Authorization per hospital policy to perform procedures in a non-research context, as applicable.
- Once the subject proves to fully understand elements of consent and voluntarily agrees, the subject, PI (or other person authorized to document consent), and the witness (if required) sign and date the consent form in the physical presence of each other.
- Signature of a witness is required for:
 - Research studies involving populations where the IRB determined a witness provides additional protection. The witness should NOT be listed as study personnel.
- Only licensed physicians or dentists are authorized to obtain and document consent for studies involving FDA unapproved drugs, biologics, or devices.

Documentation in Research and Medical Records:

- The research record must contain the original signed ICF, even if it's obtained electronically.
- The medical record must contain a copy of the signed ICF if the research may result in a billable charge from the hospital/clinic.
 - The IRB or Executive Chair/designee may waive this requirement with justification from the investigator.
- For studies **greater than minimal risk**, the 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.

Additional consent of Subjects:

- Obtaining additional consent is NOT required for minor changes. Minor changes:
 - Don't alter the risk-benefit relationship and a reasonable person wouldn't consider it justification for withdrawing.

- Must be presented through a verbal exchange at the earliest convenience (i.e. next study visit).
- Obtaining additional consent IS required for significant changes in a protocol or consent form or new substantive information.
 - Requires the same process as the initial consent as well as full documentation in the medical and research record.
- If new information emerges that could potentially impact the health and welfare of the subjects, the subjects should be notified immediately.
 - Can be notified in person or by telephone, videoconferencing, etc.
 - Notification must be followed up as soon as possible by an updated consent process and form.
 - The 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 or 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.
- Subjects withdrawing consent to participate may be asked to allow continued follow-up of clinical outcomes to be used for research purposes. This should be documented.