

5.1 Obtaining Informed Consent From Research Subjects

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for the process and documentation of informed consent.

2.0 Policy

It is the policy of the Organization that:

- **2.1.** The process of informed consent obtained from subjects, their Legally Authorized Representatives (LARs), or a minor subject's parents or legal guardians will be conducted in accordance with, and to the extent required by HHS regulations at 45 CFR 46.116, FDA regulations at 21 CFR 50.20 (as applicable) and UNMC HRPP policies.
 - **2.2.** Informed consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117, 21 CFR 50.27 (as applicable) and UNMC HRPP policies.
 - **2.3.** For this policy reference to "subject" also refers to a subject's LAR, or a minor subject's parent or legal guardian, as appropriate.
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3.0 General Requirements

- **3.1.** No human being may be enrolled as a subject in research unless the PI or authorized designee has prospectively obtained the legally effective informed consent of the subject unless a waiver or alteration of informed consent has been approved by the IRB in accordance with [HRPP policy 5.2](#) (Waiver or Alteration of Informed Consent and HIPAA Authorization).
- **3.2.** The PI, in accordance with [HRPP policy 1.26](#) (PI Qualifications and Responsibilities), is ultimately responsible for the obtainment, and documentation of valid informed consent from the subject prior to participation in the research, unless these requirements have been waived by the IRB.
- **3.3.** The PI may authorize other study personnel (secondary investigator, participating personnel or research coordinator) to participate in the process of consent, providing those persons have adequate knowledge of the research protocol, of HRPP policies, and

of their responsibility to protect the rights and welfare of subjects.

- **3.4.** Except as provided in HRPP policy 5.4 (Waiver of the Requirement to Obtain Signed Consent Form), informed consent must be documented by the use of a written informed consent form (ICF), or through an electronic signature process approved by the IRB. The PI (or authorized designee) shall seek such consent only under circumstances that provide the prospective subject (or LAR) sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- **3.5.** The information contained in the ICF and conveyed to the subject during the process of consent shall be in language understandable to the subject. To the extent possible, the language should be understandable by a person who is educated to the 8th grade level and, where appropriate, layman's terms shall be used in the description of the research.
- **3.6.** The subject must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and must be provided with an opportunity to discuss that information.
- **3.7.** Informed consent must begin with a concise and focused presentation (summary) of the key information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
 - **3.7.1.** The summary must include at least the following information:
 - **3.7.1.1.** A statement that consent is being sought for research, and participation is voluntary.
 - **3.7.1.2.** The purpose and expected duration of the subject's participation, and a description of the procedures to be followed.
 - **3.7.1.3.** The reasonably foreseeable risks and discomforts to the subject. This section should only include the most important reasonably foreseeable risks.
 - **3.7.1.4.** The benefits to the prospective subject or to others that may reasonably be expected.
 - **3.7.1.5.** Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective subject.
 - **3.7.2.** The summary should not exceed two pages in length.
 - **3.7.3.** Information included in the summary need not be repeated later in the body of the informed consent form.
- **3.8.** Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's understanding of the reasons why one might or might not want to participate.
- **3.9.** No ICF or process may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the PI or other study personnel, the sponsor, the institution, or its agents from liability for negligence.
- **3.10.** The consent process must minimize the potential for coercion and undue influence.
- **3.11.** The obtainment of consent for the participation of pregnant women, fetuses and neonates (nonviable or uncertain viability) in research must be conducted in accordance with this policy and HRPP policy 4.2 (Research Involving Pregnant Women, Human Fetuses, and Neonates-Nonviable or of Uncertain Viability).
- **3.12.** The obtainment of consent for the participation of prisoners in research must be conducted in accordance with this policy and HRPP policy 4.3 (Research Involving Prisoners).

- **3.13.** The obtainment of parental permission (consent) for participation of children in research must be conducted in accordance with this policy and HRPP policy 4.4 (Research Involving Children).
 - **3.14.** The obtainment of assent for the participation of minors in research must be conducted in accordance with HRPP policy 4.4 (Research Involving Children).
 - **3.15.** The obtainment of consent for the participation of decisionally impaired individuals in research must be conducted in accordance with this policy and HRPP policy 4.6 (Research Involving Subjects with Impaired Decision-Making Capacity).
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4.0 Elements of Informed Consent

- **4.1. Basic Elements of Informed Consent**
 - **4.1.1.** The consent process and form must provide the following information, in accordance with Federal Regulations at 45 CFR 46.116 and 21 CFR 50.25, other laws and regulations, and/or HRPP policy. This requirement is satisfied by utilizing the appropriate ICF.
 - **4.1.1.1.** A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the subject.
 - **4.1.1.2.** A description of any benefits to the subject or to others which may reasonably be expected from the research.
 - **4.1.1.3.** A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 - **4.1.1.4.** A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained.
 - **4.1.1.5.** For research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of research-related injury, including who will pay for the treatment and whether other financial compensation is available.
 - **4.1.1.6.** For any research that involves the collection of identifiable private information or identifiable biospecimens:
 - **4.1.1.6.1.** A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject authorized representative, if this might be a possibility; OR
 - **4.1.1.6.2.** A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research.
 - **4.1.1.7.** An explanation of whom to contact on the research team for answers to pertinent questions about the research or to voice concerns or complaints about the research, and whom to contact in the event of a research-related injury to the subject.

- **4.1.1.8.** Provision of contact information for the IRB and Research Subject Advocate (as applicable) in the event the subject wishes to talk to someone other than the research staff or to obtain assistance in the event the research staff cannot be reached. The subject may wish to obtain answers to questions about the research or their rights as a research subject, or for resolution of problems, concerns, complaints or offer input about the research.
- **4.1.1.9.** A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- **4.1.1.10.** A statement which indicates that the IRB, institutional officials designated by the IRB, OHRP, and, as appropriate, FDA, NIH, sponsors/CROs, other institutions and investigators, third party payers, the FPBCC SRC, or others will, as necessary, have access to research records containing PHI.
- **4.1.1.11.** A statement that FDA-regulated clinical trials and federally funded interventional and observational trials must be listed on [ClinicalTrials.gov](https://clinicaltrials.gov).
- **4.2. Additional Elements of Informed Consent** [45 CFR 46.116(b), 21 CFR 50.25(b)]
When appropriate, the consent process and form must provide some or all of the following information, in accordance with Federal Regulations at 45 CFR 46.116 and 21 CFR 50.25, other laws and regulations, and/or HRPP policy. This requirement is satisfied by utilizing the appropriate ICF template available in RSS.
 - **4.2.1.** A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable (for example, when the research involves investigational test articles or other procedures in which the risks to the subject are not well known).
 - **4.2.2.** A statement that if the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable (for example, when the research involves pregnant women or women of childbearing potential and the risks to the fetus or embryo associated with the drugs, devices, or other procedures involved in the research are not well known). Where appropriate, a statement regarding unforeseeable teratogenic risk transferred to females from male subjects should be included.
 - **4.2.3.** Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent (for example, when there are medical circumstances or compliance requirements that would necessitate involuntary withdrawal of the subject from the research).
 - **4.2.4.** Any additional costs to the subject that may result from participation in the research.
 - **4.2.5.** The consequence(s) of a subject decision to withdraw from the research (for example, when withdrawal from the research is associated with adverse medical consequences, such as an interruption of treatment).
 - **4.2.6.** Procedures for orderly termination of the subject's research participation (for example, voluntary notification of the PI, follow up and treatment substitution).
 - **4.2.7.** An explanation whether already collected data about the subject will be retained and analyzed even if the subject chooses to withdraw from the research. The ICF cannot give the subject the option of having the existing data removed from future analysis.
 - **4.2.8.** A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will

be provided to the subject.

- **4.2.9.** The approximate number of subjects involved in the study. It may be appropriate to inform subjects when there is a small number of participants or a large number of subjects.
 - **4.2.10.** A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
 - **4.2.11.** A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions
 - **4.2.12.** For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing.
 - **4.2.13.** The amount and schedule for compensation of subjects.
 - **4.2.14.** When a subject withdraws from the interventional portion of the study, ask if the subject wishes to continue into the follow-up portion of the study where there are no direct study interventions. This portion of the study involves collection 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.
 - **4.2.14.1.** If this is not in the original consent form, the subject must provide additional written consent for this limited participation in the study.
 - **4.2.14.2.** If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up collection 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.
 - **4.2.15.** For research subject to ICH GCP, a description of the additional elements for informed consent are found in [HRPP policy 1.13](#) (Compliance with ICH Guidelines).
 - **4.2.16.** For Department of Defense research, a description of the additional elements for informed consent are found in [HRPP policy 1.14](#) (Research Subject to Department of Defense Regulatory Requirements).
 - **4.2.17.** For Department of Justice research, a description of the additional elements for informed consent are found in [HRPP policy 1.15](#) (Research Subject to Department of Justice Regulatory Requirements).
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5.0 ICF and Information Sheet Templates

All investigators are required to utilize one or more of the templates in RSS as applicable:

- **5.1.** ICF template
- **5.2.** ICF template - Spanish
- **5.3.** Humanitarian Use Device template
- **5.4.** Emergency Treatment Consent Form
- **5.5.** Narrative Consent Form

Note: the ICF template may be used to document consent (or permission) from an adult, parent or guardian, or LAR.

- **5.6. Information Sheet**

Note: the Information Sheet template may be used for Child, Youth or Decisionally Impaired Subjects.

6.0 Process of Informed Consent

- **6.1.** Informed consent may only be obtained from subjects who have the legal and mental capacity to give consent. For subjects without that capacity, consent must be obtained from an LAR, as described in HRPP policy 4.6 (Research Involving Subjects with Impaired Decision-Making Capacity).
- **6.2.** Prospective subjects should be approached sufficiently far in advance of their involvement in research to enable them to have time to make an informed decision whether or not to participate in the study.
- **6.3.** The environment where informed consent will be obtained should be a private and quiet location, conducive to discussion and thoughtful consideration by the prospective subject with consideration given to the need to minimize the possibility of coercion or undue influence.
- **6.4.** The process of informed consent can be described as the transmission of relevant information to the prospective subject. The exchange of information between the PI/designee and the prospective subject should occur by face-to-face contact. However, depending upon the nature and risks of the study or other factors, the IRB may permit a process including remote consent, as described in HRPP policy 5.3 (Use of a Remote Consent Process).
- **6.5.** The PI/designee must fully explain all elements of informed consent (as described in sections 4.1 and 4.2 above) to the prospective subject.
- **6.6.** The PI/designee involved in the process of consent should take all necessary steps to minimize the possibility of coercion or undue influence. In addition, no exculpatory language should be used which suggests or implies in any way that the subject is waiving any of their legal rights or appears to release the investigator, sponsor, or the institution from liability for negligence.
- **6.7.** The PI/designee will consider additional protection for prospective subjects who may have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity or situational circumstances, or because they are especially at risk for exploitation. Such additional protections may include but are not limited to appointment of a subject advocate, involvement of the subject's family or friends, use of a short form consent, reading the consent to the subject, and use of teaching aids.
- **6.8.** The PI/designee must fully explain the rights of research subjects and provide the prospective subject with a written copy of the "Rights of Research Subjects" or "Los Derechos de los Participantes de Investigaciones" (Spanish version).
- **6.9.** The PI/designee must provide the prospective subject with a written copy of "What Do I Need to Know before being in a Research Study?" to use as a guide for questions to be answered before agreeing to participate in the study.
- **6.10.** The prospective subject must be given sufficient time and opportunity to read the ICF and to ask questions, which must be fully answered. In some cases, the consent process should be extended over several days and involve other individuals such as the prospective subject's family members, clergy, nurses, and others. In all cases, if at any

time the prospective subject is uncomfortable making a decision, he/she should be encouraged to consult with family members or other individuals of their choosing.

- **6.11.** The PI/designee have a legal and an ethical obligation to ensure that the prospective subject has sufficient knowledge and comprehension of all of the elements of informed consent to enable him/her to make an informed and enlightened decision whether or not to participate in research.

Note: The fact that an individual is prepared to sign the ICF and has no unanswered questions does not necessarily represent sufficient evidence of an adequate level of comprehension. A prospective subjects' comprehension may be assessed by: a) questioning the individual concerning his/her understanding of all the elements of informed consent, or b) asking the individual to describe the research in sufficient detail whereby the subject demonstrates an acceptable level of comprehension of all of the elements of consent.

- **6.12.** In certain studies, it may be appropriate to seek active re-consent from subjects. A subject's preferences and interests may change over time, even in the absence of material changes in the research protocol. Therefore, investigators should consider obtaining re-consent, or at least reaffirmation of the willingness to continue participation, on a routine basis. In most cases, such re-consent need only be a verbal agreement on the part of the subject after questioning by the investigator or research team member. In some cases, more formal re-consent (for example, quarterly or at the time of each research intervention) may be appropriate. Re-consent whether verbal or written should be documented in the research record.
- **6.13.** Each subject must be given a copy (paper or electronic) of the signed and dated ICF after signing. If the IRB has approved a waiver of signed informed consent, each subject must be offered a copy (paper or electronic) of the unsigned ICF.
- **6.14.** The IRB is authorized to randomly audit any on-going process of informed consent, as per HRPP policies 1.21 (Post-Approval Monitoring of Research) and 8.4 (Review of Noncompliance Involving the PI and Study Personnel).

7.0 Documentation of Informed Consent

- **7.1.** Unless a waiver of the requirement to obtain signed consent in accordance with HRPP policy 5.4 (Waiver of the Requirement to Obtain Signed Consent Form), informed consent must be documented by the use of a written or electronic ICF approved by the IRB.
- **7.2.** Study personnel who are permitted to document informed consent must be:
 - **7.2.1.** Authorized by the PI.
 - **7.2.2.** Listed by name in the documentation of consent section of the IRB Application and consent form.
 - **7.2.3.** Approved by the IRB.
- **7.3.** Individuals authorized to document consent must have the:
 - **7.3.1.** Sufficient knowledge of the protocol.
 - **7.3.2.** Sufficient knowledge of UNMC HRPP policies and of their responsibility to protect the rights and welfare of subjects.
 - **7.3.3.** Required licensure to perform the procedures described in the protocol, as applicable.
 - **7.3.4.** Authorization per hospital policy to perform the procedures in a non-research context, as applicable.

- **7.4.** Once it is determined the prospective subject has fully understood all of the elements of the consent, has no further questions, and has voluntarily (without coercion or undue influence) agreed to participate in the study, the subject should sign and date the current IRB-approved and stamped ICF at the time of consent.
 - **7.5.** Provided the IRB has not approved an alternate method of communication and consent (per [HRPP policy 5.3](#) Use of a Remote Consent Process) the subject, PI (or other person authorized to document consent), and the witness (if required per section 7.6 below) must sign and date the ICF in the physical presence of each other. The PI (or other person authorized to document consent) must be present at this time to certify that the subject provided valid informed consent.
 - **7.6.** The signature of a witness is required for all research studies involving populations where the IRB has determined that a witness provides additional protection. The witness should be someone who is not listed on the IRB Application and ICF as study personnel.
 - **7.7.** For studies involving an FDA unapproved drug or biologic, or an FDA unapproved significant risk device, only licensed physicians or dentists are authorized to obtain and document consent.
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8.0 Documentation in the Research and Medical Records

- **8.1.** The research record must contain the original signed ICF. If signature is obtained electronically, then the research record must either include a printed copy of the electronically signed form, or an electronic copy of the form with the e-signature attached.
 - **8.2.** For any protocol where a research procedure or intervention may result in a billable charge from the hospital or clinic, the subject's medical record must contain a copy of the signed ICF.
 - **8.2.1.** The IRB or the Executive Chair/designee may waive this requirement with adequate justification from the investigator (for example, but not limited to, if inclusion of the CF in the medical record would represent a physical or financial risk to subjects if a breach of confidentiality occurred).
 - **8.3.** For all studies greater than minimal risk, the process of consent must be documented in the medical or individual study subject record (if applicable), or in a separate consent log. This documentation should include the names of the individuals involved in the process of consent.
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9.0 Special Consent Circumstances

- **9.1.** Additional requirements for the process and documentation of informed consent for non-English speaking persons, or persons with additional needs or vulnerabilities participating in human subject research are described in [HRPP policy 5.7](#) (Obtaining Informed Consent from Non-English Speaking Persons, or Persons with Additional Needs or Vulnerabilities).
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10.0 Requirements for Re-Consent of Subjects

- **10.1.** A formal re-consent procedure is not required for minor changes in protocol or the ICF.
 - **10.1.1.** Examples of “minor changes” are provided in [HRPP policy 2.4](#) (IRB Review of Changes in Previously Approved Research). In general, minor changes are those that do not alter the risk-benefit relationship and that a reasonable person would not consider justification for withdrawing from the research.
 - **10.1.2.** This new information may be presented, as necessary, through a verbal exchange between the subject/LAR and PI/designee), for example at the time of the next planned interaction with the subject.
- **10.2.** Changes in the protocol or in the ICF that are more significant than those described in section 12.1, or new information relevant to the subject, requires formal re-consent of the subject through the use of an IRB-approved revised ICF or an addendum to the ICF.
 - **10.2.1.** This process of re-consent must follow the requirements for the process of initial consent discussed above, as well as include full documentation in the medical and research record. Depending on the nature of the new information or changes, re-consent may occur at the time of the next planned interaction with the subject
- **10.3.** When new information could potentially have a significant impact on the health and welfare of subjects (for example, information concerning a serious adverse event), subjects should be notified immediately in person, or by telephone, video-conferencing, or use of desktop, mobile or web-based applications or similar technologies with the transmission of information documented and witnessed.
 - **10.3.1.** Notification of subjects must be followed up as soon as possible by re-consent using the IRB-approved revised ICF or addendum. This process of re-consent must follow the requirements for the process of initial consent discussed above, as well as include full documentation in the medical and research record.
 - **10.3.2.** The PI must notify the ORA when all subjects have been contacted. This notification should include identification of subjects by number and the date they were contacted.
- **10.5.** If modification of ICFs or information sheets are made by the investigator at the time of continuing review, re-consent of currently enrolled subjects is not required except as described in section 10.1, 10.2 or 10.3 above.
- **10.6.** Since consent must be an on-going process throughout the duration of the study, investigators should regularly verbally reaffirm the subject’s willingness to continue participation in the study as well as solicit and answer questions from the subject.
- **10.7.** Subjects withdrawing consent to participate in a study may be asked to allow continued follow-up of clinical outcomes to be used for research purposes. The subject’s agreement to use of clinical follow-up data must be documented in the research record or medical record.

11.0 Telephone Consent

Refer to [HRPP policy 5.3](#) (Use of a Telephone Consent Process).

12.0 Short Form

Refer to [HRPP policy 5.5](#) (Use of the Short Form Consent Document).

13.0 Waiver or Alteration of Informed Consent

Refer to [HRPP policy 5.2](#) (Waiver or Alteration of Informed Consent and HIPAA Authorization).

14.0 Waiver of the Requirement to Obtain a Signed ICF

Refer to [HRPP policy 5.4](#) (Waiver of the Requirement to Obtain Signed Consent Form).

DOCUMENT HISTORY:

? Written: 2/5/2016 (Approved: 2/5/2016) - original author not documented

? Revised: 1/26/2018 - revision not documented

? Revised: 5/24/2021 - Clarified that documentation of consent may be obtained thru an electronic signature per HRPP Policy 5.3, and made multiple revisions throughout concerning process of e-consent and e-signature; deleted requirement that only licensed physicians or dentists are authorized to obtain and document consent for “clinical studies involving significant risk”; clarified and simplified available informed consent and information sheet templates; clarified and expanded description of vulnerable subjects who may need additional protections during the consent process; expanded methods suitable for contact of subjects to disclose new information (and affirm willingness to continue); clarified situations where re-consent might be required; clarified that agreement for continued follow-up does not require written consent; deleted reference to LAR since section 2.3 states “For this policy reference to ‘subject’ also refers to a subject’s LAR, or a minor subject’s parent or legal guardian, as appropriate”.

? Revised 8/15/2022 - specifics concerning who constitutes as a qualified interpreter, addendum added - {Approved: 6/27/2022 Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 9/8/2022 – moved section 9 (Special Consent Circumstances...) to HRPP Policy 5.7 {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/9/2022

Revision #22

Created 24 October 2019 21:38:47 by Autumn M Eberly

Updated 7 September 2023 02:50:25 by Robert A Lewis