

Section 5:

Informed

Consent

- 5.1 Obtaining Informed Consent From Research Subjects
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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 of the research, and a brief 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 (permission of the LAR and assent of the subject) 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 .
- 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. A description of whether collection of clinical outcome information through review of medical or other records will continue if a subject withdraws from the interventional portion of the study, and a statement that the subject may refuse to allow this on-going data collection.
- 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).

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 (English or Spanish)

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

- 5.2. Humanitarian Use Device template (as per [HRPP Policy 6.3](#))
- 5.3. Emergency Treatment Consent Form (as per [HRPP Policy 6.4](#))
- 5.4. Narrative Consent Form and/or Cover Letter

- 5.5. 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 consent conversation 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 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" in the subject's language as available.
- 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?" in the subject's language as available.

- 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, they 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 them 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. For example, a prospective subjects' comprehension may include questioning the individual concerning their understanding of all the elements of informed consent, or 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 subject's 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 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. 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 policy 1.21 (Post-Approval Monitoring of Research) and HRPP Policy 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 IRB Application as authorized to document informed consent, and in the 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 ICF.
 - 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 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, licensed dentists, or Advanced Practice Professionals (including Certified Nurse Midwives, Certified Registered Nurse Anesthetists, Nurse Practitioners, Physician Assistants) acting within their scope of practice 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 above, 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.
 - 10.4. 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.
 - 10.5. 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.
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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

? Revised 1/8/2025 – clarified information which must be included in “concise and focused summary” [excluded “duration of participation”, and specified “brief” description of procedures] in section 3.7.1; revised section 4.2.14 to delete information present in other sections, or not relevant to this policy; simplified and clarified list of “types of consent forms” (section 5.0); revised section 6.4 to delete information already present in other policies; revised sections 6.8 and 6.9 to require provision of “Rights of Research Subjects” and “What Do I Need to Know before being in a Research Study?” in the subject’s language as available; added that documentation of consent for studies involving an FDA unapproved product may also be provided by Advanced Practice Professionals (including Certified Nurse Midwives, Certified Registered Nurse Anesthetists, Nurse Practitioners, Physician Assistants) acting within their scope of practice (section 7.7); deleted requirement that PI must notify the ORA when all subjects have been contacted due to new information could potentially have a significant impact on the health and welfare of subjects (section 10.3.2); revised to delete redundant references to changes made at Continuing Review (section 10.4); stylistic changes. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

5.2 Waiver or Alteration of Informed Consent and HIPAA Authorization

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for granting a waiver or alteration of informed consent with or without waiver of HIPAA authorization in research.

2.0 Policy

It is the policy of the Organization that:

- 2.1. Waiver or alteration of the requirement for informed consent may be approved, provided that the IRB finds and documents the criteria specified in 45 CFR 46.116(f) have been met.
- 2.2. Waiver of authorization under the HIPAA Privacy Rule may be approved, provided that the IRB (acting as the Privacy Board) finds and documents the criteria specified in 45 CFR 164.512(l)(2)(ii) have been met.
- 2.3. Waiver of the requirement for informed consent from parents of minor subjects (parental permission) may be approved provided that the IRB finds and documents the criteria specified in 45 CFR 46.408(c) or 21 CFR 50.55 have been satisfied.
- 2.4. Waiver or alteration of the requirement for informed consent for FDA regulated clinical investigations may be approved, provided the IRB finds and documents the criteria specified in 21 CFR 50.22 have been met.
- 2.5. The IRB will acknowledge an exception to FDA's general requirements for informed consent for emergency use of a test article in accordance with 21 CFR 50.23(a), and HRPP policy 6.4 (Emergency Use of a Test Article).

- 2.6. Exception from informed consent requirements for emergency research involving an FDA regulated test article must be in full compliance with the requirements of 21 CFR 50.24, and [HRPP policy 5.6](#) (Exception from Informed Consent Requirements for Emergency Research).
 - 2.7. Complete waiver of informed consent is not allowed for research involving subjects who are prisoners. The Organization will allow the alteration of informed consent provided the criteria at 45 CFR 46.116(f) and 45 CFR 164.512(l)(2)(ii) are met, and prisoners are clearly informed in advance that their participation in research will have no effect on their parole, if such notification is relevant [45 CFR 46.305(a)(6)].
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3.0 Criteria for Waiver or Alteration of Consent under HHS regulations and HIPAA regulations

- 3.1. The IRB may allow a waiver or alteration of informed consent and HIPAA authorization provided the requirements of 45 CFR 46.116(f) (and 45 CFR 164.514(l)(2)(ii) if applicable) are met; specifically:
 - 3.2.1. The research involves no more than minimal risk to the subjects (45 CFR 46.116(f)(3)(i)).
 - 3.2.1.1. For research subject to the HIPAA Privacy Rule, criterion the IRB must find that the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: (1) An adequate plan to protect the identifiers from improper use and disclosure; (2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and (3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity (45 CFR 164.512(l)(2)(ii)(A))

Note: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological

examinations or tests (45 CFR 46.102(j)). The Organization interprets “daily life” to be the “daily life of the average person in the general population” as opposed to the daily life of the subject.

- 3.2.2. The research could not practicably be carried out without the requested waiver or alteration (45 CFR 46.116(f)(3)(ii)); (45 CFR 164.512(l)(2)(ii)(B)).

In some research projects it would not be practicable to perform the research if informed consent was required. For example:

1. The sample size required is so large (for example, with epidemiological studies) that including only those samples/records/data for which informed consent could be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
2. The subjects for whom records would be reviewed may be lost to follow-up. Individuals likely to have relocated or died may be a significant percentage of the proposed subject population, thus decreasing the statistical power of the study if informed consent was required.
3. Disclosure of the study purpose would bias the research subjects so that study results are not meaningful.
4. There is a risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek informed consent.
5. There is a risk of inflicting psychological, social, or other harm by contacting individuals or families with particular conditions.

Finally, it should be noted that, in general, investigator inconvenience or cost does not determine “impracticability” and there should be a clear rationale why the research could not be conducted with a population from whom informed consent could be obtained.

- 3.2.3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format (45 CFR 46.116(f)(3)(iii)).
 - 3.2.3.1. For research subject to the HIPAA Privacy Rule, the IRB must find that the research could not practicably be conducted without access to and use of the protected health information (45 CFR 164.512(l)(2)(ii)(C)).
- 3.2.4. The waiver or alteration will not adversely affect the rights and welfare of the subjects (45 CFR 46.116(f)(3)(iv)).

Note: This justification should be based on the “reasonable person” standard; that is, whether or not a reasonable person in the subject’s position would consider the waiver as adversely affecting his/her rights and welfare. For example, a reasonable person would probably not object to innocuous identifiable medical information, such as height or weight being entered into a database without their knowledge or informed consent. The same reasonable person might, however, object

if the identifiable information was sensitive (e.g., previous psychiatric treatment, HIV status, age at first pregnancy). It should also be recognized that in some cultures any waiving of informed consent may well be interpreted by the community as adversely affecting the rights and welfare of members of that community.

It should also be noted that the Family Education Rights and Privacy Act (FERPA; 20 U.S.C. §1232g; 34 CFR 99) protects the privacy of personally identifiable information contained within a student's educational record. FERPA applies to all schools (K-12 and postsecondary institutions) that receive funds under various programs from the U.S. Department of Education. Generally, schools must have written permission from the student (or parent if the student is a minor) in order to release any information from a student's education record unless it meets some of the specified criteria for which release is allowed.

- 3.2.5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation (45 CFR 46.116(f)(3)(v)).

Note: In general, this criterion is designed to address de-briefing after research is conducted. In these situations, it may be ethically required or determined to be respectful to provide the subject with pertinent information pertaining to their participation in research under the waiver of informed consent/authorization granted by the IRB. When this is the case, the subject must be presented with an ICF (ICF) for continued participation in the research. The ICF must include a provision for the subject to withdraw their data and/or samples from use in research should they choose not to continue participation.

4.0 Criteria for Waiver of Parental/Guardian Consent (Permission) under HHS regulations at

45 CFR 46.408(c)

- 4.1. The IRB may allow a waiver of parental/guardian consent (permission) provided the requirements of 45 CFR 46.408(c) are met; specifically;
 - 4.1.1. The research must be designed for conditions or for a subject population for which parental/guardian permission is not a reasonable requirement to protect the subjects.

The following are considerations which may justify a waiver:

1. Informing parents or guardians may result in harm to the child. For example, the study involves STD testing of 15-18 year old females which is permitted by state law without parental/guardian permission.
2. The research is important to the health and well-being of adolescents and the subjects are capable of understanding informed consent at an adult level. For example, the research involves asking 15-18 year old females about their sexual practices, prescribing contraception in accordance with described sexual practices and an annual follow up for three years. The questions are reasonably commensurate with questions asked during gynecologic services which the adolescents are permitted by law to receive without parental permission and the prescribed contraceptive methods are also permitted by state law without parental/guardian permission.

It should also be noted that the Family Education Rights and Privacy Act (FERPA; 20 U.S.C. §1232g; 34 CFR 99) protects the privacy of personally identifiable information contained within a student's educational record. FERPA applies to all schools (K-12 and postsecondary institutions) that receive funds under various programs from the U.S. Department of Education. Generally, schools must have written permission from the student (or parent if the student is a minor) in order to release any information from a student's education record unless it meets some of the specified criteria for which release is allowed.

- 4.1.2. There is an appropriate mechanism in place for protecting the children who will participate as subjects in the research.

Note: The choice of an appropriate mechanism depends upon the nature and purpose of the research activities, the risks and anticipated benefit to the subjects, and their age, maturity, status, and condition. For example, the appointment of an advocate, provisions for referral to counseling or other safeguards may be necessary.

5.0. Criteria for Waiver or Alteration of Consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials

- 5.1. The IRB may allow a waiver or alteration of informed consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials provided the requirements of 45 CFR 46.116(e) are met; specifically;
 - 5.1.1. 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:
 - 5.1.1.1. Public benefit of service programs
 - 5.1.1.2. Procedures for obtaining benefits or services under those programs
 - 5.1.1.3. Possible changes in or alternatives to those programs or procedures
 - 5.1.1.4. Possible changes in methods or levels of payment for benefits or services under those programs.
 - 5.1.2. The research could not practicably be carried out without the waiver or alteration.
 - 5.1.3. The research is not regulated by the FDA.
-

6.0. Criteria for Waiver or Alteration of Consent for FDA Regulated Minimal Risk Research

- 6.1. The IRB may allow a waiver or alteration of informed consent in FDA regulated research provided the requirements of 21 CFR 50.22 are met; specifically

- 6.1.1. The clinical investigation involves no more than minimal risk to the subjects;
 - 6.1.2. The clinical investigation could not practicably be carried out without the requested waiver or alteration;
 - 6.1.3. If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;
 - 6.1.4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
 - 6.1.5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
-

7.0. Responsibilities of IRB/ORA

- 7.1. For research which does not involve PHI, the IRB will review the proposed waiver or alteration of informed consent in accordance with HRPP policy 2.2 (Full Board Review) or HRPP policy 2.3 (Expedited Review).
 - 7.2. Research which involves PHI may only be reviewed by the convened IRB, unless the research represents no more than minimal risk to the privacy of the individuals who are the subject of the PHI, in which case it may qualify for expedited review.
 - 7.3. The Checklist for Waiver or Alteration of Informed Consent and HIPAA Authorization in Research will be used to determine whether or not a waiver can be granted in accordance with the federal regulations.
 - 7.4. Documentation and justification for IRB approval of waiver or alteration of informed consent and HIPAA authorization will appear in the IRB review letter and in the meeting minutes.
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? Revised: 3/17/2023 – stylistic revisions {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised 2/7/2024 – sections 2.4 and 6 revised to allow for waiver or alteration of consent for FDA regulated research as per revised 21 CFR 50.22 (final rule January 22, 2024). {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

5.3 Use of a Remote Consent Process

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for use of remote informed consent process. For the purpose of this policy remote consent includes telephone, video-conferencing, or use of desktop, mobile or web-based applications or similar technologies.

2.0 Policy

It is the policy of the Organization that

- 2.1. Remote consent may be used in both clinical and non-clinical research, provided such communication satisfies requirements of HHS regulations at 45 CFR 46.116 and 45 CFR 46.117 and FDA regulations at 21 CFR 50.20 and 21 CFR 50.27, and satisfies the additional requirements in the policy.
 - 2.1.1. The convened IRB or a qualified expedited reviewer (if the research or change in protocol qualifies for expedited review) may authorize use of remote consent or documentation for new subjects, or re-consent for current subjects.
 - 2.1.2. If the convened IRB or a qualified expedited reviewer has not previously authorized the use of remote consent, the IRB Executive Chair or designee may authorize use of remote consent or documentation for a single subject if:
 - 2.1.2.1. Direct face-to-face contact with the research staff would place an unreasonable burden on the subject (for example, because of distance), OR
 - 2.1.2.2. Requirement for direct face-to-face contact would prohibit enrollment of a potential subject in research with the prospect of direct benefit, OR
 - 2.1.2.3. Provision of new information to the subject would be inappropriately delayed by requiring direct face-to-face contact with the research staff.

3.0 Process for Utilizing Remote Consent

- 3.1. Enrollment of new subjects
 - 3.1.1. The informed consent form (as well as all protocol related ancillary materials) and a copy of “The Rights of Research Subjects” and “What Do I Need to Know?” must be provided to the subject for review prior to the remote consent process. These items can be provided to the subject in paper form by mail or fax, in PDF or equivalent form electronically, or through RSS or another desktop, mobile or web-based application remotely.
 - 3.1.2. The process of consent will be conducted as per the requirements of HRPP policy 5.1 (Obtaining Informed Consent from Research Subjects), HHS regulations (45 CFR 46.116(a)) and FDA regulations (21 CFR 50.20).
 - 3.1.2.1. For research posing greater than minimal risk, if remote consent is utilized and the research interventions take place on the premises of the Organization, the investigator must also obtain in-person written informed consent at the first opportunity (ideally prior to any intervention involving greater than minimal risk).
 - 3.1.2.2. For research posing greater than minimal risk, if remote consent is utilized and the research interventions do not take place on the premises of the Organization, the consent process must utilize a video component, except when specifically authorized by the IRB or by the Executive Chair or designee.
 - 3.1.3. If the subject agrees to participate in the research:
 - 3.1.3.1. If the ICF is supplied in paper form the subject is instructed to sign and date the ICF and return the signed document to the investigator by mail, fax or a scanned copy via email.
 - 3.1.3.2. If the ICF is supplied in PDF or equivalent form the subject is instructed to print, sign and date the ICF and return the signed document to the investigator by mail, fax or a scanned copy via email.
 - 3.1.3.3. If the ICF is supplied remotely through RSS or another desktop, mobile or web-based application, the subject is instructed to sign through that application.
 - 3.1.3.4. If the signed ICF (noted in sections 3.1.3.1.or 3.1.3.2 above) cannot be collected by the investigator, the subject may supply a photograph of the ICF, OR a dated attestation by a witness who participated in the call and by the investigator that the subject confirmed that he/she agreed to participate in the study and signed the informed consent.
 - 3.1.3.5. In all cases, the investigator must verify the identity of the person signing the form or providing the electronic signature. Verification of identity and signature can be accomplished by direct (or video) observation of the process of signing, or by using information from some form of official

identification, such as a birth certificate, a government-issued passport, or a driver's license, or via security questions, or via a digital signature (per FDA regulations at 21 CFR part 11, and OHRP guidance), or by the written attestation of a witness to the signature.

- 3.1.3.6. No research interventions constituting greater than minimal risk can be conducted until a signed copy of the ICF has been received by the investigator electronically, or by email, fax or mail except when specifically authorized by the IRB or by the Executive Chair or designee.
- 3.1.3.7. When the ICF has been signed by the subject in paper format it must also be signed and dated by the investigator upon receipt of the document with a note added on the form which explains the lapse in time between signatures (for example, "received in the mail 10/30/2018; remote consent obtained 10/27/2018").
- 3.1.3.8. A copy of the ICF signed by the investigator must be provided to the subject (unless the subject has the ability to print the signed ICF through the desktop, mobile or web-based application).
- 3.1.4. If the research satisfies the requirement for waiver of documentation of informed consent under 45 CFR 46.117(c) the ICF does not need to be signed and returned by the subject to the investigator and research interventions may begin as soon as verbal consent is obtained. In addition, ICF does not need to be signed and dated by the investigator.
- 3.1.5. The process of remote consent must be documented in the medical or individual study subject record, if applicable, or in a separate consent log. The documentation must include:
 - 3.1.5.1. The date and time of remote consent.
 - 3.1.5.2. Identification of all personnel involved in obtaining and documenting informed consent.
- 3.2. Re-consent to disclose new information or protocol changes
 - 3.2.1. Remote Consent may be utilized for the purpose of disclosing new information which may relate to the subject's willingness to continue participation in the research, or protocol changes that may affect the subject directly.
 - 3.2.2. Procedure will be as per sections 3.1 above.
 - 3.2.3. If new information requires immediate verbal transmission to the subject (for example, a serious adverse event, or significant change in protocol which is required immediately) the subject may be notified by phone prior to supplying the revised ICF. The phone conversation between the investigator and the subject should be witnessed by a member of the Organization not associated with the research. Written re-consent as per section 3.1 should follow promptly.
- 3.3. Enrollment of decisionally impaired subjects whose LAR is unavailable in person
 - 3.3.1. Remote Consent may be utilized for the purpose of enrolling decisionally impaired subjects whose LAR is unavailable in person.
 - 3.3.2. Procedure will be as per section 3.1 above.
 - 3.3.3. The phone conversation between the investigator and the LAR should be witnessed by a member of the Organization not associated with the research.
 - 3.3.4. Assent of the decisionally impaired person must be obtained as required in HRPP policy 4.6 (Research Involving Subjects with Impaired Decision-Making Capacity).

? Written: 1/12/2016 (Approved: 1/12/2016) - original author not documented

? Revised: 7/27/2018 - revision not documented

? Revised: 6/11/2020 - previously titled policy: Use of a Telephone Consent Process

? Revised: 1/19/2021 - clarify authority of convened IRB, expedited reviewer and IRB Executive Chair in authorizing use of remote consent (sections 2.1.1 and 2.1.2)

? Revised 2/9/2024 - Revised to allow use of remote consent for all research (regardless of level of risk); revised to delete difference in requirements for clinical vs non-clinical research; added requirement that for research posing greater than minimal risk, the investigator must also obtain in-person written informed consent at the first opportunity if the research interventions take place on the premises of the Organization (section 3.1.2.1), or must utilize video remote consent if the research interventions do not take place on the premises of the Organization (section 3.1.2.2); clarified research interventions may begin immediately when remote consent is obtained electronically (sections 3.1.3.6 and 3.1.3.7); deleted requirement to document the rationale for use of remote consent. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

5.4 Waiver of Requirement to Obtain Signed Consent Form

1.0 Purpose

The purpose of this policy is to describe the Organization's process for waiver of the requirement to obtain a signed Informed Consent Form (ICF).

2.0 Policy

It is the policy of the Organization that:

- 2.1. A waiver of the requirement to obtain a signed ICF for some or all subjects may be approved provided that the IRB finds and documents the criteria specified in 45 CFR 46.117(c) are satisfied.
 - 2.2. A waiver of the requirement to obtain a signed ICF for some or all subjects may be approved for FDA regulated research only provided that the IRB finds and documents the criteria specified in FDA regulations at 21 CFR 56.109(c) are satisfied.
 - 2.3. For research where the IRB has waived the requirement to obtain signed informed consent, the PI/authorized study personnel must still perform an adequate informed consent process in accordance with [HRPP policy 5.1](#) (Obtaining Informed Consent from Research Subjects).
-

3.0 Criteria for IRB Approval of a Waiver of Requirement to Obtain a Signed ICF

- 3.1. The IRB may waive the requirement for the investigator to obtain a signed ICF for some or all subjects if it finds any of the following:
 - 3.1.1. The only record linking the subject and the research would be the ICF and the principal risk would be potential harm resulting from a breach of confidentiality (45 CFR 46.117(c)(1)(i)).
 - 3.1.1.1. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
 - 3.1.1.2. This justification for waiver applies only to non-FDA regulated research.

- 3.1.2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (45 CFR 46.117(c)(1)(ii)), or 21 CFR 56.109(c)).
 - 3.1.2.1. For research regulated by FDA, the subject will be provided with a written statement regarding the research. This statement can be in the form of an informed consent form without signature blanks, or a narrative.

Note: Examples of procedures that might meet the requirements of 45 CFR 46.117(c)(1)(ii) and/or 21 CFR 56.109(c) include (but are not limited to) interviews and on-line or in person surveys, routine venipuncture, vital sign measurements as well as some routine diagnostic procedures such as magnetic resonance imaging without contrast and electrocardiography.

- 3.1.3. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm and the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained (45 CFR 46.117(c)(1)(iii)).
 - 3.1.3.1. Application must describe an appropriate alternative mechanism for documenting that informed consent was obtained.
 - 3.1.3.2. This justification for waiver applies only to non-FDA regulated research.
- 3.2. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

Note: The existence of a written summary or an unsigned ICF could potentially present a risk to the subject if someone else gains access to the summary or ICF and can link the subject with the research. Therefore, it is unlikely that the IRB would require such a statement or ICF be provided to the subject when a waiver is granted under 3.1.1 above.

4.0 IRB and/or ORA Responsibilities

- 4.1. The IRB or expedited reviewer will review the proposed waiver in accordance with HRPP policies 2.2 (Full Board Review) or 2.3 (Expedited Review).

- 4.2. Documentation and justification for approval of waiver of requirement to obtain signed ICF will appear in the IRB review letter.
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? Revised: 1/25/2018 - revision not documented

? Revised 12/11/2024 – added (and clarified) types of procedures which might not require written consent outside the research setting (section 3.1.2); added requirement that application describe an appropriate alternative mechanism for documenting that informed consent was obtained under 45 CFR 46.117(c)(1)(iii) (section 3.1.3); minor stylistic changes. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

5.5 Use of the Short Form Consent Document

1.0 Purpose

The purpose of this policy is to describe the Organization's requirements for use of a short form written consent document for enrollment in research.

2.0 Policy

It is the policy of the Organization that:

- **2.1.** The use of a short form written consent document is permissible in accordance with HHS regulations at 45 CFR 46.117(b)(2) and FDA regulations at 21 CFR 50.27(b)(2) when:
 - **2.1.1.** A subject/LAR who cannot understand English is unexpectedly encountered.
 - **2.1.2.** There is not sufficient time to develop and obtain IRB approval for a complete ICF written in language understandable to the subject/LAR.
 - **2.1.3.** The research presents the prospect of direct therapeutic benefit to the subject.
 - **2.2.** The short form is not a substitute for a complete fully translated ICF when it is anticipated that a significant number of subjects will be non-English speaking. The IRB may require that a translated CF be prepared and used for research where it is reasonable to expect that a significant number of non-English speaking persons will participate.
 - **2.3.** Use of the short form is restricted to enrollment of no more than three subjects per language in a given protocol. In order to enroll more than three subjects, the PI is required to have the complete ICF translated into the appropriate language and reviewed and approved by the IRB.
 - **2.4.** Use of a short form written consent document is permissible when an external IRB acts as the IRB of record for clinical trials conducted on the premises of the Organization provided the IRB of record approves the use of the short form written consent document.
-

3.0 Definitions

- **3.1.** Qualified Interpreter: as defined in addendum B to [HRPP policy 5.7](#) (Obtaining Informed Consent from Non-English Speaking Persons, or Persons with Additional Needs or Vulnerabilities). Generally, it must be an individual fluent in English and in the spoken

language of the subject, and preferably who has a basic understanding of the medical or other scientific terminology related to the research.

4.0 Use of the Short Form

- **4.1.** The Short Form states that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's LAR
 - **4.1.1.** The short form will also state that a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research (as required by 45 CFR 46.116(a)(5)(i)) was presented first to the subject, before other information, if any, was provided.
 - **4.1.2.** IRB-approved short forms are available in a variety of languages on the IRB website, along with an English translation of the short form.
- **4.2.** Investigators must complete a Short Form Request within RSS, and the request must be approved by the IRB Executive Chair/designee prior to use of the requested short form.
- **4.3.** The approval to use the short form is valid for two weeks and may be used for one subject only. The approval period can be extended by the Executive Chair/designee with adequate justification.
- **4.4.** If an IRB-approved short form is not available in a language understandable to the subject/LAR, the investigator may develop an appropriate short form based upon the IRB-approved English version of the short form. The completed Short Form Request and the translated Short Form must be submitted to ORA for expedited review and approval before use.
- **4.5.** A Qualified Interpreter who is fluent in both English and the language of the subject/LAR must be identified.
 - **4.5.1.** If a prospective subject/LAR/parent wishes to designate his/her own interpreter a Qualified Interpreter must also be present to ensure the quality and accuracy of the interpretation and this must also be documented. A minor cannot be used as an interpreter.
- **4.6.** A witness who is fluent in both English and the language of the subject/LAR must be identified and must fill the same requirements as a qualified interpreter.
 - **4.6.1.** The Qualified Interpreter may also serve as the witness (with the exception that study staff may not serve as witness).
- **4.7.** The interpreter must be involved in the process of consent as follows:
 - **4.7.1.** The subject/LAR should be given a copy of the short form.
 - **4.7.2.** The person obtaining consent, with the assistance of the interpreter, should explain the use of the short form.
 - **4.7.3.** The person obtaining consent, with the assistance of the interpreter, must
 - **4.7.3.1.** Provide a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research (as required by 45 CFR 46.116(a)(5)(i)) before other information about the research.
 - **4.7.3.2.** Describe the research and the prospective subject's rights (including elements of consent required by 45 CFR 46.116), using the IRB-approved English version of the complete ICF as a guide. As long as the above

information is provided, the complete ICF need not be translated word-for-word.

- **4.7.4.** The complete ICF, which has been approved by the IRB, will serve as the summary required by 45 CFR 46.117(b)(2).
- **4.7.5.** Interpreters should be provided with a copy of the short form and the IRB-approved English version of the ICF. Whenever possible, these forms should be provided in advance of initiating the consent process with the subject/LAR.
- **4.8.** Upon conclusion of the consent process the subject/LAR, person obtaining consent, and the witness must sign the forms as follows:
 - **4.8.1.** The subject/LAR must sign and date the short form.
 - **4.8.2.** The person obtaining consent must sign and date the English version of the complete ICF.
 - **4.8.3.** The witness to the oral presentation of the ICF must sign both the Short Form, as well as the English version of the complete ICF.
- **4.9.** A copy of the signed and dated short form and the English version of the complete ICF must be given to the subject/LAR.
- **4.10.** Depending on the nature and duration of the research, the IRB Executive Chair/designee may determine that the English version of the complete ICF must be translated into a language understandable to the subject with a copy given to the subject as soon as possible after enrollment in the research using the short form. In general, this may be required for studies which are significant risk and of long duration.
- **4.11.** The process of consent must be documented in the medical or individual study subject record (if applicable). This documentation should include the names of the individuals involved in the process of consent, including the names and contact information of the interpreter and the witness.
- **4.12.** The enrollment of a minor under circumstances which satisfy the criteria specified above is permitted using the short form signed by the minor's parent/guardian. There is no requirement that the minor be provided with a study information sheet. However, minors, age 13 and above, must sign the short form. Minors between the ages of 7-12 must be verbally assented with documentation in the research or medical record.

DOCUMENT HISTORY:

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? Revised: 6/18/2018 - revision not documented

? Revised: 5/13/2021 - Revised to state request form available thru RSS; added BMC staff as eligible interpreter or witness; deleted list of short form available languages; deleted requirement to record time spent in the process of consent; deleted requirement that interpreter separately document the process of consent; corrected references to revised Common Rule; minor stylistic changes

? Revised 10/14/22 – added definition of “Qualified interpreter” to harmonize with HRPP 5.7; clarified that approval to use short form is only valid for 2 weeks and may only be used for one subject; stylistic changes; correction of typographic errors. {Approved Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board Notified: 11/29/2022

? Revised 11/30/2022 - corrected 4.1.2 from: "IRB-approved short forms are available in a variety of languages on the IRB website in the following languages, along with an English translation of the short form.", to: "IRB-approved short forms are available in a variety of languages on the IRB website, along with an English translation of the short form." (Robert Lewis - IRB Assoc)

5.6 Exceptions from Informed Consent Requirements for Emergency Research

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements for IRB review and approval of an exception from informed consent requirements for emergency research.

2.0 Policy

- **2.1.** It is the policy of the Organization that an exception from informed consent requirements for emergency research must be in full compliance with the requirements of 21 CFR 50.24 for FDA-regulated research.
 - **2.2.** It is the policy of the Organization that the informed consent requirements of 45 CFR 46.116 and 45 CFR 46.408 may be waived for emergency research not subject to 21 CFR 50, provided the IRB has approved both the research and a waiver of informed consent and has found and documented that conditions for emergency research contained in the Secretarial waiver document have been met [61 FR 51531, 1996].
-

3.0 Definition

- **3.1. *Emergency Research*** means a planned clinical investigation that requires prior written FDA authorization to proceed and involves subject(s) who are in a life-threatening situation for which available treatments or in vitro diagnostic tests are unproven or unsatisfactory
-

4.0 Requirements

- **4.1.** For research which is subject to the FDA regulations at 21 CFR 50.24, the IRB may approve the investigation without requiring that informed consent for all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is an IRB member or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents that each of the conditions under Section 4.3 below

have been satisfied.

- **4.2.** For research not subject to FDA regulations, the IRB may approve the research without requiring that informed consent for all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the research) finds and documents 1) that the research is not subject to regulations codified by the FDA at 21 CFR Part 50, and (2) that the conditions under Section 4.3 below have been satisfied. In addition, this documentation must be submitted to OHRP.
- **4.3.** Conditions for granting an exception from informed consent for emergency research are as follows:
 - **4.3.1.** The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
 - **4.3.2.** Obtaining informed consent is not feasible because:
 - **4.3.2.1.** The subjects will not be able to give their informed consent as a result of their medical condition, and
 - **4.3.2.2.** The intervention under investigation must be administered before informed consent from the subjects' legally authorized representatives is feasible, and
 - **4.3.2.3.** There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation or research.
 - **4.3.3.** Participation in the research holds out the prospect of direct benefit to the subjects because:
 - **4.3.3.1.** Subjects are facing a life-threatening situation that necessitates intervention, and
 - **4.3.3.2.** Appropriate animal and other pre-clinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects, and
 - **4.3.3.3.** Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
 - **4.3.4.** The clinical investigation could not practicably be carried out without the waiver.
 - **4.3.5.** The protocol defines the length of the potential therapeutic window based on scientific evidence.
 - **4.3.6.** The PI will attempt to contact a LAR for each subject within the therapeutic window and, if feasible, ask the LAR for informed consent within that window rather than proceeding without informed consent.
 - **4.3.7.** The PI will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review.
 - **4.3.8.** The IRB has reviewed and approved informed consent procedures and an ICF consistent with 21 CFR 50.25/45 CFR 46.116 and 46.117. These procedures and the ICF are to be used with subjects or their LAR in situations where use of such procedures and documents is feasible.
 - **4.3.9.** The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation.

- **4.3.10.** Additional protections of the rights and welfare of the subjects will be provided, including, at least:
 - **4.3.10.1.** Consultation (including, where appropriate, consultation carried out by the IRB), with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn.
 - **4.3.10.2.** Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits.
 - **4.3.10.3.** Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.
 - **4.3.10.4.** Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation.
 - **4.3.10.5.** If obtaining informed consent is not feasible and a LAR is not reasonably available, the PI has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a LAR, and asking whether he or she objects to the subject's participation in the clinical investigation.
 - **4.3.10.6.** The PI will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
- **4.4.** The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the ICF.
 - **4.4.1.** The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
 - **4.4.2.** If a LAR or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible.
 - **4.4.3.** If a subject is entered into a clinical investigation with waived informed consent and the subject dies before a LAR or family member can be contacted, information about the clinical investigation is to be provided to the subject's LAR or family member, if feasible.
- **4.5.** Protocols subject to FDA regulations and involving an exception to the informed consent requirement must be performed under an FDA approved separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols as protocols that may include subjects who are unable to informed consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists.
- **4.6.** If the IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception, or because of other relevant ethical concerns, the IRB will document its findings and provide these findings promptly in writing to the PI and to the sponsor of the clinical investigation.
- **4.7.** The IRB determinations are to be retained by the IRB for at least 7 years after completion of the clinical investigation, and the records shall be accessible for inspection

and copying by FDA.

DOCUMENT HISTORY:

? Written: 1/8/2016 (Approved: 1/8/2016) - original author not recorded

? Revised: 3/5/2018 - revision not documented

5.7 Obtaining Informed Consent from Non-English Speaking Persons, or Persons with Additional Needs or Vulnerabilities

1.0 Purpose

The purpose of this policy is to describe the Organization's 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. For general considerations of informed consent see [HRPP policy 5.1](#) (Obtaining Informed Consent from Research Subjects).

2.0 Policy

It is the policy of the Organization that:

- 2.1. Non-English speaking persons, or persons with additional needs or vulnerabilities will be offered accommodations and additional protections regarding the process and documentation of informed consent.
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3.0. Specific Protections and Requirements for Non-English Speaking Subjects

- 3.1. Expected Enrollment of Non-English Speaking Subjects
For research where it is reasonable to expect that a significant number of non-English speaking persons will participate, the IRB may require that a translated CF be prepared and used.
 - 3.1.1. Consent forms must be prepared by a qualified translator, as defined in the addendum A to this policy.
 - 3.1.2. A Qualified Interpreter, as defined in addendum B to this policy, must be identified.
 - 3.1.3. Interpreters should be provided with a copy of the IRB-approved ICF. Whenever possible, the ICF(s) should be provided in advance of initiating the

consent process with the subject.

- 3.1.4. Upon conclusion of the consent process the subject must sign and date the non-English version of the ICF.
 - 3.1.5. The person obtaining consent must sign and date the English version of the ICF.
 - 3.1.6. The process of consent must be documented in the medical or individual study subject record (if applicable). This documentation should include the names of the individuals involved in the process of consent, including the name or other identifying information (such as employee number) of the interpreter.
 - 3.2. Unexpected Enrollment of a Non-English Speaking Subject
If a non-English speaking prospective subject is unexpectedly eligible to enroll in research and there is no IRB-approved translated ICF, the following requirements apply:
 - 3.2.1. If the research offers no prospect of direct therapeutic benefit the person can only be enrolled a) after the IRB has reviewed and approved a translated ICF, and b) an interpreter who is fluent in both languages is used during the process of consent. The PI or other study personnel may serve as the interpreter.
 - 3.2.2. If the research offers the prospect of direct therapeutic benefit, the person can be enrolled using the IRB-approved short form as per the requirements of HRPP policy 5.5 (Use of the Short Form Consent Document).
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4.0. Specific Protections and Requirements for Visually Impaired or Blind Subjects

- 4.1. For research where it is reasonable to expect that a significant number of blind or low vision subjects will participate, the investigator must describe a plan to assure that materials are available to assist the prospective subject in the process of consent. This may include large font (electronic or paper) consent forms, audio version of consent form, Braille consent form, or other technology as appropriate.
 - 4.2. If Braille CF is utilized, the IRB may require a transcription into print text or review of the document by a qualified person who reads Braille in order to ensure that a Braille ICF is accurate.
 - 4.3. If an unexpected blind or visually impaired subject is encountered, the IRB Executive Chair or designee may authorize use of any of the above methods or technologies as appropriate.
 - 4.4. If possible, the subject should sign or make an X to signify consent. A witness unaffiliated with the research team must observe the consent process, and witness the signature or mark. The witness must sign the consent form attesting that the information in the consent document and any other written information was accurately conveyed.
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5.0. Specific Protections and Requirements for Hearing Impaired or Deaf Subjects

- 5.1. For research where it is reasonable to expect that a significant number of hearing impaired or deaf subjects will participate, the investigator must describe a plan to assure that the process of consent can be conducted in an appropriate manner. This may include

use of an American Sign Language (ASL) interpreter, or appropriate assistive technologies.

- 5.2. If an unexpected deaf or hearing impaired subject is encountered, the IRB Executive Chair or designee may authorize use of any of the above methods or technologies as appropriate.
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6.0. Specific Protections and Requirements for Illiterate or Low Literacy Subjects

- 6.1. For research where it is reasonable to expect that a significant number of illiterate or low literacy subjects will participate, the investigator must describe a plan to assure that the process of consent can be conducted in an appropriate manner. This may include reading the CF to the subject, use of a pre-recorded audio version of consent form, use of other technology as appropriate, or use of a Short Form (per [HRPP policy 5.5](#) Use of the Short Form Consent Document).
 - 6.2. If an unexpected illiterate subject is encountered, the IRB Executive Chair or designee may authorize use of any of the above methods or technologies as appropriate.
 - 6.3. If possible, the subject should sign to signify consent. If the subject is unable to sign, they may make an X to signify consent. A witness unaffiliated with the research team must observe the consent process, and witness the mark. The witness must sign the consent form attesting that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject and that consent was freely given.
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Addendum A: Minimal Requirements for Translation of Informed Consent Documents

Translation of Consent forms into a language other than English must be performed by qualified persons, with adequate competence in English and the language of the translation, and preferably with knowledge of research methodology.

A. For research conducted solely within the Organization acceptable translation by a “qualified” translator includes, in order of preference:

1. Translation provider by a translator certified by The American Translators Association (<https://www.atanet.org/>)
2. Translation provided by a translator certified by any other non-profit organization, or Federal, State or Municipal government agency
3. Translation provided by a professional translation service that will certify the accuracy of the translation
4. Translation by a person deemed “competent to translate” and accompanied by a certification statement that the document translation is complete and accurate (see <https://www.atanet.org/client-assistance/what-is-a-certified-translation/>). A person deemed “competent to translate” includes (a) foreign language instructors employed by an accredited university or college; or (b) graduate students in foreign language currently in training at an accredited university or college; or (c) a bilingual person able to write in two languages with equal fluency (including members of the research team). For research

involving greater than minimal risk (per 45 CFR 46.102(j)), translation by someone other than a certified translator (categories 1 and 2) or a professional service (category 3) must be accompanied by a back-translation by a different person or group, preferably of categories 1, 2 or 3. B. For Multi-institution research where the Organization is a participating site, translation must be accompanied by documentation that the translation was performed by a “qualified” individual, as defined above.

Addendum B: Minimal Requirements for Interpretation

Interpretation must be performed by qualified persons, who are fluent in both English and the language of the subject, and preferably with knowledge of research methodology.

Qualified interpreters include, in order of preference:

1. A person holding certification by the National Board of Certification for Medical Interpreters, the Certification Commission for Healthcare Interpreters, or any similar credentialing body, or certified by any other non-profit organization, or Federal, State or Municipal government agency.
2. A person employed by, or contracted by, the Organization to provide interpretation services in a clinical context. This includes commercial interpretation services (such as CyraCom).
3. UNMC, Nebraska Medicine, CH&MC, BMC, UNO or study site staff who are fluent in both English and the language of the subject.
4. Study personnel who are fluent in both English and the language of the subject.
5. Other persons, including (a) foreign language instructors employed by an accredited university or college; or (b) graduate students in foreign language currently in training at an accredited university or college; or (c) a bilingual person; specifically, a person using or able to speak in two languages with equal fluency.

If a prospective subject wishes to designate his/her own interpreter, a Qualified Interpreter must also be present to ensure the quality and accuracy of the interpretation. A minor cannot be used as an interpreter.

DOCUMENT HISTORY:

? Written: 11/2/2022 - Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair), {Approved: 11/8/2022 Chris Kratochvil (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Board notified: 12/2/2022

? Revised: 1/27/2023 - updated hyperlinks for HRPP references 5.1, 5.3, and 5.5 (Robert Lewis, IRB Assoc)

? Revised: 3/7/2023 – deleted requirement for signature of interpreter when obtaining informed consent using a translated ICF (section 3.1.1.4); revised Addendum A to explicitly state use of a professional translation service is acceptable {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised: 2/7/2024 – add use of Short form to section 4.4.1. {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

? Revised - 11/12/2024 – allowed for recording or employee number of interpreter (rather than name) (section 3.1.6); revised numbering {Approved Russell McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}