

Informed Consent	Effective Date	8.8.2001
	Revisions Date	2.29.2024

- 1.0 Purpose:** The purpose of this standard operating practice (SOP) is to provide guidance for preparing, obtaining, documenting, and ensuring the ongoing informed consent of individuals participating in human research overseen by the University and Medical Center Institutional Review Board (UMCIRB).
- 2.0 Persons Affected:**
- 2.1 Principal investigators (PI) and research team members
 - 2.2 UMCIRB members
 - 2.3 UMCIRB office staff members
- 3.0 SOP:** Informed consent is one of the basic ethical obligations for researchers and is the embodiment of the ethical principle of respect for persons. Prior to involving any individual in research, investigators or their designated research personnel must obtain effective informed consent from the participant or their legally authorized representative (LAR). The IRB has the authority to waive documentation of consent and in some cases, when the federal criteria are met, can authorize waiver of the consent process (see separate SOPs regarding the use of an LAR and consent waivers). Any individuals on the research team who will be involved in the consent process must have received appropriate training and be approved by the UMCIRB.
- 4.0 Definitions:**
- 4.1 **Adult:** an individual who has achieved the legal age for consent (18 years or older in NC).
 - 4.2 **Informed Consent:** an individual’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. Prospective participants must be given sufficient information about the research and its risks and benefits in order to reach an informed decision as to whether they will voluntarily participate. Informed consent is prospectively obtained prior to enrolling a participant in human research and is an ongoing process throughout the duration of the research.
 - 4.3 **Informed Consent Document:** a document that embodies the elements of informed consent.
 - 4.3.1 This document may be read to the participant or their LAR, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it and ask questions before it is signed.
 - 4.4 **Legally Authorized Representative (LAR):** an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective research participant to the individual’s participation in the procedure(s) involved in the research
 - 4.5 **Essential elements of informed consent:**
 - 4.5.1 A statement that the study involves research, an explanation of the purposes of the research and expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
 - 4.5.2 A description of any reasonably foreseeable risks or discomforts to the subject.
 - 4.5.3 A description of any benefits to the subject or to others that may reasonably be expected from the research.

- 4.5.4 A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
- 4.5.5 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. The possibility that the Food and Drug Administration (FDA) may inspect the records should be noted for FDA regulated research.
- 4.5.6 For research involving more than minimal risk, an explanation as to whether there is any compensation for injury, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- 4.5.7 An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and who to contact in the event of a research related injury to the subject.
- 4.5.8 A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- 4.5.9 One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
 - 4.5.9.1 A statement that identifiers might be removed from the identifiable private information or identifiable biospecimen 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 or the LAR, if this might be a possibility; or
 - 4.5.9.2 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 studies.
- 4.5.10 If study is a clinical trial, include the following FDA element of consent: "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web Site will not include information that can identify you. At most, the Web Site will include a summary of the results. You can search this Web site at any time."
- 4.6 **Additional elements of informed consent to be provided to potential participants, or their LAR, when appropriate:**
 - 4.6.1 A statement that the particular treatment or procedures may involve risks to the subject (or the embryo or fetus if the subject is or may become pregnant), which are currently unforeseeable.
 - 4.6.2 Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR's consent.
 - 4.6.3 Any additional costs to the subject that may result from participation in the research.
 - 4.6.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

- 4.6.5 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.
- 4.6.6 The approximate number of subjects involved in the study.
- 4.6.7 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.
- 4.6.8 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- 4.6.9 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- 4.7 **Exceptions to informed consent requirements:** the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent
- 4.8 **Documentation of informed consent:** the requirement that informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the participant or their LAR. The consent form may be either of the following:
 - 4.8.1 A written consent document that embodies the elements of informed consent. This form may be read to the potential participant or their LAR, but in any event, the investigator shall give either the potential participant or their LAR adequate opportunity to read it before it is signed; or
 - 4.8.2 A "short form" written consent document stating that the elements of informed consent have been presented orally to the potential participant or their LAR and that key information was presented first to the subject, before other information, if any, was provided. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the potential participant or their LAR. Only the short form itself is to be signed by the participant or their LAR. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or their LAR, in addition to a copy of the short form.
- 4.9 **Waiver of written consent:** an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all research participants.
- 4.10 **Practicable:** feasible; capable of being effected, done or put into practice; and that may be practiced or performed; capable of being done or accomplished with available means or resources.
- 4.11 **Vulnerable population:** groups of individuals that are considered to be particularly susceptible to coercion or undue influence in a research setting. These groups include children, prisoners, pregnant women and fetuses, persons who are mentally disabled or otherwise cognitively impaired, and economically or educationally disadvantage persons, although there may be others depending on the situation.

4.12 Short Form: written consent document stating that the elements of informed consent have been presented orally to the participant or the participant's LAR and that required key information was presented first to the participant, before other information, if any, was provided.

4.12.1 Interpreter: a person known by the PI or study team to be bilingual in order to communicate with the study team and the non-English speaking participant or their LAR. In addition to a professional interpreter, this could be a family member, friend or study team member.

4.12.2 Witness: a person fluent in both English and the language of the participant or their LAR. The interpreter may serve as a witness (unless they are a member of the study team or are obtaining the consent), or a family member or friend may serve as a witness.

5.0 Responsibilities:

5.1 UMCIRB office staff will

5.1.1 Perform a pre-review of the consent information provided by the investigator.

5.1.1.1 For consent changes that are made after initial approval, UMCIRB office staff will review plans for re-consent of existing participants which is necessary when there are changes to procedures, risk information or other element that may affect the participants decision to continue in the study.

5.1.2 Communicate with the PI or appropriate research personnel on any changes that might be needed to the consent documents or consent process, as required by federal regulations.

5.1.3 Stamp each page of the UMCIRB approved consent document and return that stamped document to the investigator.

5.1.3.1 If a study is no longer recruiting, consent documents will not be stamped at subsequent reviews.

5.2 Investigators have the responsibility to

5.2.1 Conduct the consent process and obtain documentation of consent from participants of their LAR before any research procedures are implemented.

5.2.2 Provide the prospective subject or their LAR sufficient opportunity to discuss and consider whether or not to participate and

5.2.3 Conduct the consent process in a manner that minimizes the possibility of coercion or undue influence.

5.2.4 Ensure that all federally required elements are included in the consent document or submit a request for alteration of the consent document.

5.2.5 Use only the most currently approved consent document. The approval dates will be stamped on the document and will reflect either the initial approval period, the last approved continuing review approval period, or the date of the most recently revised document through the end of the approval period.

5.2.6 Continue the consent process at each subsequent visit and document the discussion in the participant's research records.

5.2.7 Ensure only those individuals properly trained and approved by the UMCIRB are delegated to obtaining informed consent.

5.2.8 Ensure the consent document contains all of the required and additional elements as appropriate to the study.

5.2.8.1 If the study is externally funded, the use of a sponsor’s consent document is allowed if all required ECU language is included.

5.2.8.2 For non-funded or ECU funded studies, the appropriate consent template from the UMCIRB website can be used.

5.3 UMCIRB

5.3.1 Reviews each consent document to determine that it contains required information in sufficient detail to protect the rights and welfare of human research participants.

5.3.2 Reserves the option for 3rd party witness of the consent process.

5.3.2.1 Primarily employed for concerns regarding the conduct of the consent process. The primary purpose of a 3rd party witness by the UMCIRB is to ensure there is an adequate informed consent process.

5.3.2.2 The UMCIRB committee may assign the Chair, another IRB member, or a member of the UMCIRB office staff to perform the 3rd party witness to the consent process. The observer is expected to prepare a summary of the observations, which will be documented and stored with the study material. The evaluation will be shared with the committee, the investigator, and any other relevant institutional bodies.

6.0 Procedures:

6.1 The amount of information that needs to be presented both in writing (i.e., the consent document and related materials) and verbally is directly related to the research risk and complexity of the study(ies).

6.2 The prospective subject or the LAR 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 an opportunity to discuss that information.

6.3 For studies conducted, supported, or funded by a Federal department or agency, informed consent must begin with 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. This part of the informed consent must be organized and presented in a way that facilitates comprehension and should include information such as:

6.3.1 The purpose of the study and why it’s relevant to a potential participant.

6.3.2 Main reasons someone may or may not want to join the study.

6.3.3 The aspects of research participation or this particular study that are likely to be unfamiliar to a prospective subject, diverge from a subject’s expectations, or require special attention.

6.3.4 Major requirements or types of activities that someone will do as part of the study.

6.3.5 Description of information being collected as part of this research.

6.3.6 Description of impact of participating in this research on the participant outside of the research (i.e., will it reduce options for standard treatments?).

6.3.7 How participants’ experiences in this study differ from treatment outside of the study.

6.3.8 The most important risks and/or benefits.

6.3.9 Other alternatives to participating, if appropriate.

- 6.3.10** Time commitment.
- 6.4** Informed consent 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 or LAR's understanding of the reasons why one might or might not want to participate.
- 6.5** Documents for written and oral communication involving the research study should be in a language understandable to the participant and others involved in the consent process.
- 6.6** There must be no coercion or undue influence on participants when being asked to enroll or to continue in a research study; e.g., participants' entrance into or continuation of the research study must be totally voluntary.
- 6.7** Individuals must have sufficient time to decide whether they want to participate in a research study and should be encouraged to consult with family and/or others as needed.
- 6.8** Participants should feel free to ask questions at any time. The participant or the Legally Authorized Representative (LAR), if applicable, should have all questions answered to their satisfaction prior to signing the consent document.
- 6.9** No informed consent may include any exculpatory language through which the subject or their LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
- 6.10** Documentation of consent must be sought prior to any research activities occurring. Additionally, the consent document must be signed prior to any screening tests that otherwise would not be performed.
- 6.11** A copy of the approved consent document, along with other written research-related materials must be given to the participant or his/her Legally Authorized Representative.
- 6.12** Additional safeguards for vulnerable populations should be built into the informed consent documents and processes to add further protections.
- 6.13** The UMCIRB or sponsors may require additional information to be included in the consent document above that required in the basic and/or additional elements of consent.
- 6.14** The information included in the consent document must be consistent with the research protocol and the information provided to the UMCIRB.
- 6.15** All consent documents in FDA regulated trials must also contain wording related to the purpose of evaluating a test item in terms of safety and efficacy.
- 6.16** Research studies that follow Good Clinical Practices should also contain the required elements, which may otherwise be considered optional elements under other regulations or guidance. Some of the additional elements are as follows:
- 6.16.1** An explanation of the probability for random assignment to each study arm.
 - 6.16.2** The research participant's responsibilities as related to the research study.
 - 6.16.3** The important potential benefits and risks for alternative procedures or options that might be available.
 - 6.16.4** The anticipated, prorated payment if any as a result of participating in the trial.
- 6.17** Non-English Speaking Subjects:
- 6.17.1** When the study subject population includes non-English speaking people, or the clinical investigator or the UMCIRB anticipates that the consent interviews will be conducted in a language other than English, the UMCIRB expects a consent document be translated accordingly. The UMCIRB requires that all non-English

consents be submitted for review and approval. The investigator should provide the UMCIRB with the name and credentials for the individual performing the consent document translation, and describe safeguards to ensure the accuracy of the translation given the target population.

6.17.1.1 The PI and study team should consider the need for an interpreter for ongoing study related communication, procedures, and follow-up.

6.17.2 All materials the participant may be required to complete should be evaluated for need for translation into a language understandable by the participant and these documents should also be submitted for UMCIRB review and approval.

6.17.3 The UMCIRB cannot provide financial assistance to the investigator for the translation process.

6.17.4 If a non-English speaking research participant is encountered, and investigators do not have a written translation of the consent document, an alternative means of consent and documenting consent may be used. The regulations governing human research permit investigators to utilize an oral translation of the informed consent information used in conjunction with an approved “Short Form” written consent document and a written summary of what is presented orally. This process is allowed as long as the PI is able to retain translation services and the protocol does not prevent enrolling non-English speaking participants. IRB approval is required before using the Short Form process. Use of a UMCIRB approved written translation of the entire consent document is always preferred.

6.17.4.1 There is an English version of the Short Form template on the UMCIRB website that may be used to translate into other languages (a Spanish version of the Short Form template is available on the UMCIRB website). Short Form templates from other places may also be utilized. A witness to the oral presentation is required and the Short Form written document should be in language understandable to the participant or their LAR and should be presented by an interpreter who is known by the PI to be bilingual.

6.17.4.2 The UMCIRB-approved English language informed consent document should be utilized as the study summary when presenting to the participant/LAR.

6.17.4.3 The participant or their LAR should be encouraged to ask questions to the study team with the interpreter’s assistance.

6.17.4.4 At the time of consent, the Short Form document must be signed by the participant or their LAR; the summary must be signed by the person obtaining consent; the Short Form document and the summary must be signed by the witness.

6.17.4.5 The participant or their LAR gets a copy of the summary document and signed Short Form.

6.17.4.6 If, in the future, the consent form is translated into the language of the participant or their LAR, an unsigned copy of the translated consent forms should be provided, when possible, to the participant or their LAR as a courtesy.

6.18 Limited or Low Literacy Subjects:

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- 6.18.1 A person that speaks and understands English, but does not read and write, can be enrolled in a study by signing and dating or by "making their mark" on the consent document.
 - 6.18.1.1 The principal investigator or his/her designee is responsible for determining whether a potential participant is able to read the consent document or other materials discussed during the consent process. If the principal investigator or his/her designee has any doubt regarding the literacy of a potential participant, then additional protections should be put in place consistent with consenting participants of limited or low literacy under this section.
 - 6.18.2 An impartial third party witness should be present during the entire consent discussion and verify the contents of the informed consent document were orally presented and explained. The witness must then sign the consent document signature page attesting that the consent document contents and other materials were accurately explained, that the participant appears to have understood the discussion, and that the consent was freely given.
 - 6.18.3 Investigators should carefully formulate plans to ensure additional safeguards are in place for this vulnerable population. The investigator or research personnel should be sensitive to the increased difficulties in understanding complex study schematics and designs when presented orally. Liberal use of drawings and other such tools may prove beneficial for this group, and other groups may benefit from this strategy as well. These subjects may require more frequent reiteration of the informed consent document contents, and when possible, a significant other should be included in the research process.
- 6.19 Subjects Unable to Speak or Write:
- 6.19.1 A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. A competent individual may be enrolled into the research if they are able to evaluate the study concepts and risks and indicate approval or disapproval for enrollment.
 - 6.19.2 The consent form should document the method used for communication with the prospective participant and the specific means by which they communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document. It is recommended to have the witness confirm what type of response was given. A video tape recording of the consent interview may be useful.
- 6.20 Remote consent, eSignature and eConsent for non-Exempt human research:
- 6.20.1 Remote consent is permitted for studies unless otherwise determined at a convened meeting of the UMCIRB or via expedited procedures to be inappropriate.
 - 6.20.2 Unless a waiver or alteration of informed consent, or waiver of documentation of consent, is granted, the required elements of informed consent outlined in this SOP will need to be satisfied in any remote consenting process.
 - 6.20.3 Investigators intending to use remote consent, eSignatures and eConsent will need to provide robust plans detailing the methods to be used.
 - 6.20.4 Remote consent may occur via telephone, conference call, video conferencing, telemedicine or other methods.
 - 6.20.5 The subject or their LAR must be provided with a copy of the consent form prior

- to engaging in the informed consent conversation.
- 6.20.6** The consent form can be provided to the participant via postal mail, email, fax, or another method. If mailed, two copies must be mailed so the participant or LAR is able to retain a copy for reference when their signed consent form is returned to the site and they are waiting to receive the final copy with all necessary signatures back from the site.
 - 6.20.7** The individual obtaining consent must discuss the study with the potential participant via telephone, conference call, video conferencing, telemedicine, or other methods as dictated by local institutional policy.
 - 6.20.8** The individual obtaining consent must have the same informed consent discussion that they would have had with the participant or LAR during an in-person meeting.
 - 6.20.9** The individual obtaining consent must implement a method to ensure the identity of the participant or LAR (e.g., verification of state identification or other identifying documents or use of personal questions or visual methods).
 - 6.20.10** The consent form must be signed by both the participant or LAR and the individual obtaining consent.
 - 6.20.10.1** If the participant or LAR agrees to participation after the consent discussion, they must sign and date the consent form and return it to the investigator. An electronic system or method may be used, including scanning or photographing the signed consent form and emailing it to the investigator. If postal mail is used, a pre-paid, self-addressed envelope should be provided to the participant or LAR to mail the signed consent form back to the investigator.
 - 6.20.10.2** Once the research team receives the signed consent form from the subject or LAR, the individual obtaining consent who conducted the consent process must sign and date the document using the current date.
 - 6.20.10.3** Under the signature line, the individual obtaining consent must document the way remote consent was conducted, the date of the informed consent discussion, and the date the signed consent form was received. For example, “Discussed with [subject or LAR name] via [telephone or videoconferencing] on [insert date] and received signed consent form on [insert date].” Include a brief reason for performing the informed consent discussion over the telephone/videoconferencing.
 - 6.20.10.4** The date the individual obtaining consent signs the consent form, not the date the consent discussion with the subject or LAR took place, is the official date of informed consent for the participant on the trial.
 - 6.20.11** The final consent form must be filed in the designated investigator/site regulatory file location.
 - 6.20.12** A copy of the final consent form, signed by the subject or LAR, the investigator, and the witness (if applicable), must be sent back to the subject via email/scan, fax, or postal mail.

Revision History:

Date	Change	Reference Section(s)
1.22.2015	Updated to stand-alone document.	All
11.04.2015	Updates sections; clarifies statements	3.0; 5.2.4, 5.2.6; 5.3.2.2.; 6.1-6.3, 6.7-6.10
1.27.2016	Included required wording for clinical trial consents and a description of when re-consent is necessary.	4.5.9; 5.1.1.1
1.21.2019	Updated to reflect revised regulations regarding process and elements of consent.	2.0-6.0
4.27.2020	Updated Short Form procedures secondary to guidance from NCI CIRB.	6.17; 4.12
1.15.2021	Corrected hyperlink to SACHRP's letter to the HHS Secretary; added new footer	References; all
2.29.2024	Updated with language on remote consent procedures	6.2

References:

DHHS, OHRP. Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

FDA. Code of Federal Regulations:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50> and

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>

NC General Statutes, Chapter 48A:

http://www.ncga.state.nc.us/EnactedLegislation/Statutes/PDF/ByChapter/Chapter_48A.pdf

Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP Letter to HHS Secretary. January 31, 2008: <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2008-january-31-letter/index.html>

International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice e6(r1). Current *Step 4* version dated 10 June 1996. Section 4.8.

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf