**Issuing Department:** Human Subjects Protection Program
**Policy Number:** 2011-008.1
**Policy Title:** Informed Consent Process

## *Purpose*

The purpose of this policy is to describe the informed consent process and provide examples of acceptable methods for obtaining informed consent as well as examples of activities that may occur without informed consent of the subject or a waiver of the requirement to obtain consent.

## *Definitions*

See policy 2011-007.0 for definitions of the following terms:

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| Coercion | Informed Consent Process | Informed Consent Form |
| Legally Authorized Representative | Undue Influence | |

## *Policy*

For purposes of this policy the term subject is inclusive of the subject or the subject's legally authorized representative when applicable and the term investigator is inclusive of the principal investigator, co-investigator, study coordinator, consenter or data manager.

The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruitment or determining the eligibility of prospective subjects without the informed consent of the prospective subject (and without the need for waivers or alterations), if either of the following conditions is met:

- The investigator will obtain information related to screening, recruiting or determining eligibility through oral or written communication with the prospective subject.
- The investigator will obtain identifiable private information or identifiable biospecimens for the purpose of screening, recruiting or determining eligibility by accessing records or stored identifiable biospecimens.
    - In order to access records or specimens for such purposes, there must be an established relationship between the investigator and the individuals whose records /specimens will be reviewed.
        - The investigator may delegate the review to designated UConn Health research staff.
        - Appropriate measures must be in place to protect the confidentiality of the data being utilized.

When obtaining information or biospecimens for the purpose of screening, recruitment or determining the eligibility of prospective subjects without the informed consent of the prospective subject, the protocol and/or supporting research documents must address plans to protect the confidentiality of the information/specimen during this process.

Unless waived by the Institutional Review Board (IRB), the IRB-approved informed consent process must be conducted with a potential subject prior to any involvement of the subject in non-exempt research to ensure that the subject has an appreciation for the study (e.g., understanding of the purpose, risks, benefits) in which they may enroll. The process of consent should continue throughout the study,

for example by explaining each visit as it occurs and ensuring the subject is still willing to participate, or by providing new information to subjects as it is learned to ensure they are still willing to participate.

Consent can be sought only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and to ask and obtain answers to questions, and that minimize the possibility of coercion or undue influence. The consent process must also be conducted in a setting that affords sufficient privacy to the potential subject and the information that is given to the subject shall be in language understandable to the subject. As necessary, the Principal Investigator (PI) must address other special provisions required by the subject, e.g., hearing impaired individuals may want a sign language interpreter present or individuals with dyslexia may prefer to have the document read to them.

Exculpatory language which releases or appears to release the institution, sponsor or investigator from liability or which makes or appears to make subjects waive any legal rights cannot under any circumstance be included in the informed consent process.

Individuals conducting the consent process must have in depth knowledge of the research protocol and the ability to answer questions that may be posed by the potential subject. The individual obtaining consent is required to have completed education in the protection of human subjects in research.

Unless documentation of consent has been waived by the IRB, the informed consent process is documented by use of an IRB approved informed consent form. Documentation of the initial informed consent process may be supplemented by notes in a research chart that indicate on-going discussions with the subject at subsequent study visits.

Consenting a subject, is a process that should occur in person whenever feasible. When it is not feasible, the IRB may approve other methods of consent such as e-consent, or consent by phone or videoconference. The IRB may require a consent process for exempt research. The IRB may impose additional protections as part of the consent process. For example, the IRB may require observation of the consent process, the use of the consent feedback form, the use of a consent process checklist, a witness to the consent process or videotaping the consent process.

With the exception of the short form consent process, obtaining consent from illiterate subjects, and obtaining consent by phone/fax, the consent process generally does not have to be witnessed but the IRB may require this. When an individual is signing the form as a witness they must indicate whether they are a witness to the signature only or a witness to the entire consent process. The IRB reserves the right determine who may serve as the witness.

Subjects in long-term follow-up must be informed of outcome data and safety related information. The PI will determine the mechanism of communication, giving consideration to the subject's underlying conditions, available support systems and the nature of the information being conveyed. They do not have to be re-consented regarding changes to the protocol if they are no longer in the active phase of the study.

Techniques that may be used in the consent process included but are not limited to, the following:

*Observation:* The consent process may be observed by the Research Compliance Monitor or other representative of the HSPP or IRB. The observation will be done to ensure compliance with regulations and policy, for quality improvement and/or for educational purposes. Verbal consent of the subject may be sought prior to the observation.

*Waiting Period Requirement:* The IRB may require a waiting period between the time that a study is explained to a potential subject and the time that consent is sought from the potential subject or representative. Situations when this option may be exercised include, but are not limited to, studies that involve vulnerable populations or studies that are of high-risk.

*Staged Consent Process:* The IRB may require a staged consent process whereby consent is obtained at various points in the study to ensure that the subject is still willing and / or still able to provide consent. Situations when this option may be exercised include, but are not limited to, studies that involve vulnerable populations, for example populations with diminishing capacity, or studies that are of high-risk.

*Summary of Information:* The IRB may require that an individual obtaining consent also ask the subject to provide a summary of the study after the initial discussion occurs as a means of evaluating their level of understanding of the study. The IRB may require that the individual obtaining consent ask the subject to explain in their own words the purpose of the study, the risks involved, the potential benefits, the alternatives available etc. and may require that the responses be documented. If the potential subject is unable to demonstrate an understanding of the study, either consent from a legally authorized representative must be obtained or the subject may not be enrolled into the study. The IRB may provide the questions to be used to solicit feedback or may require the PI to develop the questions and submit them to the IRB for review/approval.

## *Procedure*

**General:**

Details of the informed consent methods and documentation must be described to and approved by the IRB. When submitting an application to the IRB, the PI must respond to questions within the IRB application regarding the process for obtaining and documenting initial and on-going consent from subjects, including the names of the individuals authorized to obtain consent and identification of who will be providing consent (i.e., subject or legally authorized representative). Once the consent materials are approved, the investigator must obtain prospective IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy.

Unless waived by the IRB, the process of consent will be documented on an IRB approved consent form to be signed and dated by the subject (or legally authorized representative) and the person obtaining consent.

- For embryo donation both the egg and sperm donor must sign the consent form.
- The person obtaining consent must provide the subject (or the subject's legally authorized representative) with a copy of the signed and dated document, including any relevant addendums, appendices, attachments etc.
- An emancipated subject must provide proof of emancipated status. The person obtaining consent must attach this proof to the informed consent form.

- A legally authorized representative, other than a parent of a minor child or next of kin, must provide proof of such status. The person obtaining consent must attach this proof to the informed consent form. When the LAR is next of kin the affirmation of the LAR will be accepted and it is recommended that a note be made to file.

Standard screening and review procedures are used as described in the procedures for Expedited and Full Board reviews.

**Consent by Phone / Fax**

Procedure 1:

- the potential subject must be given a copy of the approved, IRB-stamped consent document (either by mail, fax or e-mail of scanned document) prior to the phone conversation and with enough time allowed to read the document prior to the conversation;
- the PI ensures the individual obtaining consent is approved by the IRB to consent and has sufficient knowledge of the study to conduct the conversation and to answer any questions;
- a witness must be present for the entire conversation;
- the subject must be informed that the witness is present and consent to the witness listening to the entire conversation (via speaker or extension phone);
- the consent conversation includes an in-depth review of the consent document allowing sufficient time for questions to be asked and answered;
- the subject must be instructed that if they agree to participate, they must return the signed and dated consent document (either by mail, fax or e-mail of scanned signed document); and
- the individual obtaining consent and the witness must sign, and date the IRB approved consent document upon completion of the phone conversation;
- the two forms are joined together upon receipt
- research can begin after the forms are joined; or

Procedure 2:

- the investigator requests a waiver of the requirement to document consent at the time of initial application or via a request for modification using the form to request such a waiver;
- an IRB approved script incorporating the elements of consent is presented over the phone to the subject;
- the IRB may require that the investigator provide subjects with a copy of the script (via mail, e-mail or fax) regarding the research.

**Consent by Videoconference (e.g., WebEx, Zoom)**

- the potential subject must be given a copy of the approved, IRB-stamped consent document (either by mail, fax or e-mail of scanned document) prior to the consent conversation and with enough time allowed to read the document prior to the conversation;
- the PI ensures the individual obtaining consent is approved by the IRB to consent and has sufficient knowledge of the study to conduct the conversation and answer any questions
- the consent conversation includes an in-depth review of the consent document allowing sufficient time for questions to be asked and answered
- when documenting consent on the paper consent form:
    - the subject must be instructed that if they agree to participate they must return the signed and dated consent document (either by mail, fax or e-mail of scanned signed document);

    - the individual obtaining consent must sign, and date the IRB approved consent document during the videoconference;
    - the two forms are joined together upon receipt
    - research can begin after the signed forms are joined.
- when documenting consent electronically:
    - the subject must be instructed that if they agree to participate, they will electronically sign and date the consent document and return it by e-mail or through the electronic platform being used (e.g., RedCap, Qualtrics) to the study team for consenter signature.
    - the individual obtaining consent will apply their signature and date to the consent document signed by the subject;
    - when the consent document is fully-signed and a copy has been provided to the participant, the research can begin.
- a copy of the informed consent signed and dated by both the person providing consent and the consenter must be provided to the person signing the form.

**Electronic Documentation of Consent**

The IRB may approve an electronic method to capture the signature of the subject or the subject's LAR when written informed documentation of consent is required (i.e., documentation of consent has not been waived). When proposing to use electronic methods to document consent, the PI is responsible to ensure electronic signatures are legally valid within the jurisdiction where the research is to be conducted. For FDA-Regulated research, the PI is responsible to ensure documentation of consent is compliant with regulations at 21 CFR part 11 and 21 CFR part 50 and to provide the IRB with confirmation that the electronic systems used to obtain consent and electronic signature meet the relevant regulatory requirements in 21 CFR part 11.

The subject/LAR must be instructed that if they agree to participate they will electronically sign and date the consent document and return it by e-mail or through the electronic platform being used (e.g., RedCap, Qualtrics) to the study team for the individual conducting the consent meeting (consenter) to sign. The consenter will apply their signature and date to the consent document signed by the subject. After the consent document is fully-signed by the subject and consenter, a copy of the signed informed consent will be provided to the person signing the form and the research can begin.

**Electronic Informed Consent (eIC) Process** ***(When Consent is not Witnessed by Study Personnel)***

The investigator should discuss plans for using eIC with the IRB before finalizing development of the eIC to ensure that the IRB agrees that such a format may be used for obtaining informed consent for the applicable research. When eIC is proposed subjects must still be provided the option of the consent process occurring in person and/or using a paper-based consent form. For FDA-Regulated research, the PI is responsible to ensure consent procedures and documentation are compliant with regulations at 21 CFR part 11 and 21 CFR part 50. The PI must provide the IRB confirmation that the electronic systems used to obtain consent and electronic signature meet the relevant regulatory requirements in 21 CFR part 11.

When eIC is proposed subjects must still be provided the option of the consent process occurring in person using a paper-based consent form.

The IRB should receive copies of all informational materials including any videos and web-based presentations which the subject will receive and view during the eIC process. If the program uses hyperlinks to convey study-related information, the contents to which subjects are referred should be provided for the IRB to determine if the study-related information is accurate and appropriate.

The IRB should be given access to the e-consent platform to review the usability of the eIC materials to ensure that they are easy to navigate and that the user may navigate forward or backward within the system, or stop and complete the process at a later time. The investigator must also provide the IRB with a hard copy version of the Web site information that contains the study-related information that the IRB will review and approve. The investigator must ensure the eIC process provides sufficient opportunity for the subject to consider whether to participate and that a mechanism is in place whereby subjects may ask and obtain answers to questions before signing consent.

In FDA regulated research, if any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject's LAR (see 21 CFR 11.100(b)). This is encouraged for non-FDA regulated studies as well.

**Other Methods:**
Other methods of consent, for example processes in accordance with new guidance issued by a regulatory agency, should be described to the IRB as applicable such that the IRB can determine whether the consent process is appropriate in the context of the research.

## *Related Policies*

2011-007.0 – Definitions Applied to Policies
2011-008.0 – Informed Consent - Forms
2011-008.2 – Informed Consent – Waivers and Alterations
2011-008.5 – Informed Consent – Providing and Obtaining Informed Consent
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by Convened Board
2011-013.0 – Translation Policy
2011-023.0 – Educational Requirements

## *Basis*

45 CFR 46.
21 CFR 50
FDA Guidance on eIC

## *Document Attributes*

**Date Effective: 6/9/2023**

**Replaced Version:** 5/11/2020

**Reviewed and Approved By:**

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| *Richard H. Simon* | *6/8/2023* |
| **Richard Simon, MD**<br>**Director Human Subjects Protection Program** | **Date** |