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| <b>SOP: Electronic Informed Consent (eIC) in Human Subjects Research</b> |             |               |                    |             |
| <b>NUMBER</b>  | <b>DATE</b> | <b>AUTHOR</b> | <b>APPROVED BY</b> | <b>PAGE</b> |
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# Obtaining Electronic Consent (eIC) in Human Subjects Research

## 1. Purpose

- 1.1 This procedure establishes that the informed consent process and documentation may be conducted utilizing an electronic platform and/or media in human subjects research. **Electronic informed consent (eIC)** is becoming increasingly more common and has been acknowledged by both the Department of Health and Human Services (HHS) Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) as an appropriate method to obtain voluntary, informed consent.
- 1.2 eIC employs the use of electronic systems and processes, whether remotely or in-person, to convey information to a participant and/or document research consent. The electronic media can vary depending on the type of system utilized and can include the use of applications, videos, graphics, interactive text, etc.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3 POLICY

- 3.1 The Spectrum Health IRB (SH IRB) must approve the eIC process and forms used during the informed consent process prior to implementation in the study. The methods to be utilized in the eIC process must be submitted to the SH IRB in a format that facilitates this review and includes a sufficient description of the eIC process and the platforms, systems, and/or media employed.
- 3.2 Any subsequent changes to the eIC process also require SH IRB approval prior to implementation, unless the proposed alteration is required to eliminate an immediate hazard to participants or staff.

## 4 REQUIREMENTS DURING eIC AND GUIDING PRINCIPLES

- 4.1 eIC presents an opportunity to assist investigators and study teams meet their enrollment goals and provide flexibility in the consent process. It provides an opportunity to improve the experience of consent and leverage technology to present information in a novel, informative way. As eIC opens the possibility to enhance understanding and retention by participants and to more easily document their consent, it is not the intention of the SH IRB to limit its use to specific electronic platforms or methods.
- 4.2 The principles that govern in-person informed consent still apply during an eIC process – The entirety of the current, approved SH IRB consent form must be presented, there must be ample time for the subject/Legally Authorized Representative (LAR) to review the information, ask questions and have them answered, and give their voluntary, informed consent.
- 4.3 eIC may be used in several different methods and time-points during the eIC process. For example:
  - 4.3.1 This process can take place at the research study site where both the investigator (or other authorized member of the research team) and the subject/LAR are at the same location (“**In-Person eIC**”); or
  - 4.3.2 Remotely where the subject reviews the consent information in the absence of the investigator/research team member (“**Remote e-IC**”).

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- 4.4 An **electronic signature** is:
- 4.4.1 an electronic sound, symbol, or process attached to, or logically associated with, a record and executed or adopted by a person with the intent to sign the record;
  - 4.4.2 is unique to one individual and shall not be reused by, or reassigned to, anyone else;
  - 4.4.3 is linked to the record to which it pertains to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record.
- 4.5 The platform for the eIC is to include a method to ensure that the person electronically signing the informed consent document, or providing their consent, is the subject who will be participating in the research study or is the subject's LAR. Appropriate methods for obtaining this verification are also available in the SH IC SOP 401. If requested, or required, the subject/LAR must have the option to use paper-based forms completely or partially.
- 4.6 Privacy measures require extra consideration during a remote eIC process. If during the eIC process the person obtaining consent is remotely located (i.e. the consent process is conducted via a call, video conferencing, or other e-messaging method) the subject should be reminded to find a private location to help ensure privacy of this discussion.
- 4.7 The system that supports e-IC must be secure, utilize restricted access (e.g. unique users and password protection) and store records of the subject's identity, study participation and personal information, so that subject confidentiality is protected.
- 4.8 Special attention is needed when vulnerable or special populations are included and there should be an adequate plan in place to obtain eIC for the needs of these populations.
- 4.8.1 *Non-English speaking subjects/LAR:*
    - 4.8.1.1 Investigators are to incorporate an interpreter into the eIC process. If a translated consent form will be utilized the principles for enrolling a Non-English speaking subject/LAR outlined in the SH IC SOP 401, or other applicable policies/procedures, are to be followed.
    - 4.8.1.2 Special attention is required when there is a need for a short-form in an eIC process. This may apply when the eIC process is conducted "in-person" or "remotely". At the time of consent, the investigator or designated study team member, are to be aware of this need for the addition of a translated short form to the eIC process/platform and include an interpreter for the Non-English speaking subject/LAR.
  - 4.8.2 *Legally Authorized Representatives for Adults*
    - 4.8.2.1 If an LAR is to provide consent for an adult subject, the principles for obtaining informed consent via the eIC platform still apply. The SH IRB may also make determinations that assent from the adult subject is needed. In these cases, this adult assent process is also to be incorporated into the eIC process.
    - 4.8.2.2 When possible, the eIC application/process should accommodate the special needs for adults that are visually or hearing impaired, or illiterate.
    - 4.8.2.3 During the eIC process the identity of the LAR and signature is to be confirmed and validated.
  - 4.8.3 *Children*
    - 4.8.3.1 When children are to be enrolled, the investigator will need to incorporate the SH IRB approved assent process in the eIC procedures/platform. If needed, assent can be obtained in the same way the parental permission was obtained.
- 4.9 An eIC process may also be utilized when the SH IRB has waived the requirement to obtain a signature on a consent form. With this waiver, the eIC process still includes an information sheet that is provided to the subject/LAR in its entirety. A checkbox response that states "I agree to participate" should be used to verify/confirm consent prior to initiating study procedures.

- 4.10 There are special considerations for studies that include an FDA-regulated drug, biologic, or device. The eIC platform/application must comply with the regulations outlined in 21CFR Part 11.
- 4.11 For studies in which HIPAA Authorization is required, this may be obtained utilizing an eIC platform to obtain an electronic signature. The HIPAA regulations also include that the subject/LAR's typed name is equivalent to an *electronic signature*.
- 4.12 The documentation of the consent process and signature(s) obtained is still applicable per best practices. Examples are provided in the SH IC SOP 401.
- 4.13 The subject/LAR must be provided a copy of the fully executed, signed informed consent/assent form either in hard copy or as an electronic file that can be stored on their own personal device of choice.

## **5 RESPONSIBILITIES**

- 5.1 The Principal Investigator (PI) is responsible for ensuring that legally effective informed consent is obtained prior to a subject taking part in the study unless a waiver is obtained from the SH IRB.
- 5.2 Procedures should be in place to regularly assess that the components of the eIC process are functioning properly. It is the responsibility of the PI to ensure that the IRB-approved eIC procedures meet all informed consent requirements as approved by the SH IRB.
- 5.3 It is the responsibility of the PI that the SH IC SOP 401, or applicable institutional policies/procedures, will be adhered to as applicable for their study and that the person obtaining consent is SH IRB approved prior to obtaining informed consent.
- 5.4 For FDA regulated studies, it is the PIs responsibility to provide documentation to the SH IRB that the proposed eIC complies with all applicable requirements under 21 CFR Part 11.
- 5.5 The PI is responsible for ensuring that all electronic documents can be stored and maintained according to record retention policies and can be accessed and retrieved easily. If an electronic system is used exclusively for storage of eIC forms, the PI is responsible to store records in accordance with the Spectrum Health Record Management, Retention and Destruction Policy (Reference #85).
- 5.6 The SH IRB will review the entire eIC process, including the usability of the eIC materials to ensure that they are easy to navigate and determine whether the process is adequate for obtaining and documenting informed consent, and HIPAA Authorization per SH IRB procedures and policies.
- 5.7 The PI is responsible for ensuring that all SH IS vetting, review, and approvals, as needed, are obtained prior to starting any study activities related to eIC.

## **6 PROCEDURE**

- 6.1 The PI/ delegated study team member is to submit to the SH IRB the following for the eIC process:
  - 6.1.1 Copies of all forms (electronic and paper) and informational materials, including any videos and Web-based presentations, which the subject/LAR will receive and view during the e-IC process. Screen-shots of web-pages may be provided, however, the SH IRB may require additional edits or revisions upon review of these documents.
  - 6.1.2 Consent documents on the SH IRB consent template(s) and/or separate HIPAA Authorization template.
  - 6.1.3 A description of how eIC will be conducted, including the electronic platforms/applications to be utilized.
  - 6.1.4 Information and documents related to any optional questions or methods used to gauge subject comprehension of key study elements. If the eIC program uses hyperlinks to convey study-related information, the contents to which subjects are referred is to be submitted for review to determine if the study-related information that has been supplied is accurate and appropriate.

- 6.1.5 Information on the security of the eIC platform/application and the process by which the study team will maintain confidentiality of all eIC records; including during access, use, and storage.
- 6.1.6 A description of who will have access to the eIC records.
- 6.1.7 A description of how subject/LAR privacy will be maintained during the eIC process.
- 6.2 If the study will include the recruitment of a vulnerable population, or children, the submission is to include:
  - 6.2.1 The process by which the assent of children or others will be obtained during eIC.
  - 6.2.2 Assent forms on the SH IRB template for review.
- 6.3 If the PI is requesting a waiver of the documentation of consent (i.e. waiver of obtaining an e-signature) the following is to be submitted to the SH IRB
  - 6.3.1 Information sheet that contains the required elements of consent.
  - 6.3.2 Documentation of why the waiver can be met using protocol-specific justification.
  - 6.3.3 Description of how the consent process discussion will be completed and consent obtained (e.g. “click to agree to participate”).

## **7 MATERIALS**

- 7.1 HRP-502 Informed Consent and HIPAA Authorization Template
- 7.2 HRP-310 HIPAA Authorization for Research Template
- 7.3 Assent for Children Template
- 7.4 HRP-508 Information Sheet Template

## **8 REFERENCES**

- 8.1 Informed Consent and Legally Authorized Representatives for Research – Policy #2053
- 8.2 Spectrum Health IRB SOP 401 for Informed Consent
- 8.3 21 CFR 50.20, 25 and 27; 312.60; 812.100
- 8.4 21 CFR Part 11
- 8.5 45 CFR 46.116 and 117
- 8.6 45 CFR 46.116(d)
- 8.7 E-sign Act; Public Law 106-229
- 8.8 Use of Electronic Informed Consent - <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/use-electronic-informed-consent-questions-and-answers/index.html>
- 7.9 FDA Guidance: Use of Electronic Informed Consent  
<https://www.fda.gov/media/116850/download>
- 8.10 FDA Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application <https://www.fda.gov/media/75414/download>
- 7.11 Uniform Electronic Transactions Act (UETA)  
[https://www.uniformlaws.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=2c38ee\\_bd-69af-aafc-ddc3-b3d292bf805a&forceDialog=0](https://www.uniformlaws.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=2c38ee_bd-69af-aafc-ddc3-b3d292bf805a&forceDialog=0)  
State of Michigan Bill  
[https://www.legislature.mi.gov/\(S\(0zwbyziic1r4x55w4a3hpno\)\)/documents/mcl/pdf/mcl-Act-305-of-2000.pdf](https://www.legislature.mi.gov/(S(0zwbyziic1r4x55w4a3hpno))/documents/mcl/pdf/mcl-Act-305-of-2000.pdf)