CARILION CLINIC
Institutional Review Board

INVESTIGATOR GUIDANCE: Electronic Informed Consent			
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HRP-804	**001**	**20JUN2020 23NOV2021 (rev) 18OCT2023 (rev)**	**Page 1 of 16**

Background

Electronic informed consent (eConsent) refers to the use of electronic systems and processes to convey information related to a research study and to obtain and document informed consent. It is important to note that the process of obtaining informed consent does not change regardless of the media used to obtain consent.

The eConsent must contain all elements of informed consent required by HHS regulations (45 CFR 46.116). The information must be in language understandable to the potential subject or the subject's LAR and conveyed in a manner that minimizes the possibility of coercion or undue influence regarding the subject's decision to participate in a study. Understandable means that the information presented to subjects is in a language and at a level the subject can comprehend, including an explanation of scientific and medical terms. Any eConsent should be easy to navigate, allowing the user to proceed forward or backward within the system, the ability to change responses within the eConsent form before submitting, and to stop and continue at a later time.

NOTE: This guidance is not applicable for studies where the IRB waives the requirement for written signature (waive "documentation") of consent (e.g. minimal risk online or phone survey studies) and Protected Health Information is not collected. For studies where a waiver of documentation of consent is approved, the subject would "Proceed to Provide Consent for Participation" for the survey within REDCap and a signature would not be required. If PHI is being collected for purposes of the research, then written consent should be obtained.

1. What is eConsent?

Electronic Informed Consent (eConsent) is a method for obtaining informed consent from research subjects using a computer-based consent form rather than traditional paper documentation.

Subjects will 'sign' their consent electronically by:

- typing their name AND date
  AND
- by utilizing a 'Signature' field type, which uses a stylus, mouse, or finger to "write" their signature on the form.

Please note that the eConsent process must be requested in the IRB application and approved by the Institutional Review Board as part of the approval of the consent process. The option to obtain eConsent is determined by the type of study conducted.

2. Obtaining eConsent from Research Subjects

Obtaining written consent is a critical step in the clinical research process, but managing paper forms can be cumbersome.

Carilion is using REDCap to offer a digital method to acquire and store subject consent forms through an e-Consent Framework and PDF Auto-Archiver. This functionality provides the ability to consent subjects remotely or consent subjects in clinic via computer, mobile phone, or tablet. Subjects will have the capability to sign electronically with a stylus, mouse, or finger.

3. Can eConsent be used on all projects?

The IRB must ensure that the consent process and documentation is appropriate for the risk level of the proposed research. In some cases, the IRB may decide that informed consent must be obtained face-to-face, which may preclude the use of a remote eConsent process.

In addition, the IRB must approve the use of eConsent for the study before it will be implemented in REDCap. The research protocol must outline the consent process, and how eConsent will be used to obtain consent for the study. Researchers may use an electronic version of the consent to document the consent process and store the signed consent without utilizing a remote consent process. The eConsent process requires that the HART Team assist in setting up the consent form in REDCap on a per project basis.

REDCap is currently the only approved method of obtaining an electronic signature for Investigator Initiated studies. Sponsored studies may have a different method of obtaining eConsent which may be permitted by the IRB if the sponsor provides documentation that their system is Part 11 compliant.

REDCap eConsent module is 21 CFR Part 11 ready and may be utilized for FDA regulated studies at Carilion. REDCap's eConsent module must be used according to

the procedures outlined in this document by qualified personnel to maintain compliance with 21 CFR Part 11.

Some minimal risk studies, such as online surveys not asking sensitive information or anonymous surveys, may qualify for a waiver of documentation of consent. For these studies, a consent form is still required, but it may be appropriate for subjects to consent through "Proceed to Provide Consent to Participate", which means subjects will consent to the research by proceeding through the consent form and answering the survey questions. Signatures are not required for these studies so eConsent is not applicable.

4. What eConsent materials should the investigator submit to the IRB?

The IRB will require a WORD document of each consent document to be uploaded into the study application, just like with any other submission. In addition, the investigator must submit to the IRB all informational materials, including any videos (a link would be acceptable because video files are not an accepted format in PRIS3M IRB) and web-based presentations, which the subject will receive and view during the eConsent process. The research protocol will need to explain the consent process, which includes how eConsent will be used (e.g. Carilion or the participant's personal computer, electronic tablet, smart phone), signature method (stylus, mouse, or finger), and the mechanism for authentication as described later in this document, if required. Questions or methods to gauge subject comprehension of key study elements must also be submitted to the IRB. The IRB will approve the use of the eConsent and then HART will build the eConsent in REDCap.

If there is a modification to the consent language, this must be reviewed and approved by the IRB, before HART will implement a change to the eConsent in RedCap. The investigator must obtain IRB approval for any subsequent modifications to the study-related information, whether electronic or in hard copy.

While WORD document copies of the consent will be stamped and finalized in the IRB system, eConsents will not have that same IRB stamp. The approved, stamped consent documents will be used by HART to create the eConsents in REDCap to ensure the final eConsent document in REDCap is consistent with the language the IRB has approved.

5. Should a signature section for the person obtaining consent be included on the eConsent form?

Yes. Consistent with signed consent obtained on paper, the person obtaining consent will be required to document that he/she obtained consent from the subject/subject's legally authorized representative. The person obtaining consent will be required to initiate the eConsent process from within REDCap in order for their name and a timestamp to appear on the study subjects signed consent form.

If a subject has limited English proficiency, the use of these methods would require a qualified interpreter and the use of a short form or a translated informed consent form previously approved by the IRB. The signature of a witness is required.

If a subject is unable to read, a witness must be present for the entire consent discussion and their signature is required.

6. How should information in the eConsent be presented to the subject?

The eConsent form should be easy to navigate, allowing the user to proceed forward or backward within the system, the ability to change responses within the eConsent form before submitting, and to stop and continue at a later time. The eConsent should be broken into pages that the subject must click through to promote understanding and easier reading of the information.

The eConsent should incorporate electronic strategies to encourage subjects to access and read all of the consent material before documenting their consent. This should include requiring subjects to answer multiple choice questions about the research study at the end of each page or at the end of the consent in order to document their understanding before signing.

eConsents may be used to either supplement or replace paper-based informed consent processes in order to best address the subject's needs throughout the course of the study. For example, some subjects may prefer one method over another. Other subjects may have difficulty navigating or using electronic systems because of, for example, a lack of familiarity with electronic systems, poor eyesight, or impaired motor skills. It is important to consider the population under study,and whether eConsent is a good option for the study population. In such cases, the eConsent process may not be appropriate for these subjects. In addition, if there are technical difficulties with the platform or internet connection, paper-based consent processes may be needed as a back-up. Therefore, subjects must have the

option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process.

It is important to document how consent was obtained and the process of obtaining consent in the research record to ensure an accurate representation of the consent process used to obtain consent with each subject.

7. How and where may the eConsent process be conducted?

The consent process may take place at the study site when both the investigator and subject/subject's legally authorized representative are at the same location, or it may take place remotely (e.g., at the subject's/subject's legally authorized representative home or another convenient venue). The eConsent materials may be used for both on-site and remote access.

Informed consent discussions that are occurring remotely may only take place via phone, or using Microsoft Teams or Vidyo, as these are approved by Carilion TSG. Other platforms are not permitted without a Vendor Risk Assessment performed by TSG.

In some cases, the link to the eConsent can be emailed or texted to the potential subject/subject's legally authorized representative to allow review in advance of the consent process. The email/text must not include PHI. The subject line and email body should not contain specific information about the study or the disease status of the potential participant. Instead the study information provided in the body of the email should remain generic (ex: research study survey). Emails must only be sent using Carilion email addresses, and if needed, the clinical department may create a generic department email for research communications to potential participants (ex: surgeryresearch@carilionclinic.org). The link to the consent form will be sent through REDCap.

The study team must obtain verbal permission to send the eConsent via REDCap or text to the potential participant. The permission should be documented in the research record. Verbal permission should state:

"Carilion Clinic cannot control the security of email or text messages once we send them, therefore we need your permission to text or email you the link to the eConsent form for the study we discussed. Please be aware that while the

email title will not include your [disease status], the body of the email will contain the link to the study. Someone else accessing your email/text messages could click on the link and read the consent, and therefore learn about your [disease status], which you may consider to be of a private or sensitive nature. Do you still wish to receive the link to the eConsent via email/text?"

Regardless of where the eConsent process is conducted, the process must still be approved by the IRB and include adequate time to review the consent materials, the opportunity for the subject/subject's legally authorized representative to have the research explained, and for questions to be asked and answered.

8. How do you authenticate that the individuals signing (subject/subject's legally authorized representative) is that person?

A study's data validity or reliability could be questioned without verifying subjects' identities. If any or all of the consent process takes place remotely and is not personally witnessed by a member of the research team, the process must include a method for identity verification to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study (or the subject's legally authorized representative). The IRB application or protocol must include a plan for verification of the identity of the participant if the consent process is occurring in a remote fashion, such as over the phone, Microsoft Teams or Vidyo.

Real-time identity verification prior to the remote consent discussion and eConsent signature can be conducted in ways described below. The creation of a passcode can occur during an in-person meeting, but may occur through a telephone or Microsoft Teams call using information already known by both parties. Researchers must make note in the research record of the additional steps they took to remotely verify the identity of the person having the consent discussion and signing study documentation.

The potential subject will then be prompted to reply with the appropriate passcode in order to access the consent form, and then provide the passcode again with their signature.

Verification with an Established Passcode: In this approach, an agreed passcode is communicated between the subject/subject's legally authorized representative and the study team. This passcode is saved as part of the subject's record for verification use later. The subject/subject's legally authorized representative must

enter the passcode at the time of accessing the survey/eConsent and must also enter the passcode with their signature. This method would require manual passcode/pin entry by the study staff in REDCap prior to the potential subject accessing the consent form.

Verification with a Passcode Based on Known Information: In this approach, a study team who has collected sufficient demographic data can verify authentication without agreeing to a prior known passcode by simply informing the subject/subject's legally authorized representative that a combination of their demographic data will be used as their passcode. This is a more robust form of authentication in the sense that no transmission of information between the subject and study team is required, because the information should already be known by both. For example, when obtaining eConsent a study coordinator who has collected or has access to the subject's date of birth, middle name, and street name may choose a combination of these variables to represent the passcode, which the subject/subject's legally authorized representative would then be prompted to answer when accessing the eConsent and at time of signing consent. This method would require manual passcode/pin entry by the study staff in REDCap prior to the potential subject accessing the consent form.

9. How and when should questions from subjects be answered?

The Investigator should follow the IRB-approved consent process, and as such have methods in place to ensure that the eConsent process allows subjects the opportunity to consider whether or not to participate and to ask questions. This may be accomplished by in-person discussions with study personnel or through a combination of telephone calls or video conferencing with a remotely located investigator or study personnel.

10. How can electronic signatures be used to document eConsent?

Carilion Clinic and HHS regulations permit the use of electronic signatures when written informed consent is required, if such signatures are legally valid within the jurisdiction where the research is to be conducted. For example, they are acceptable in the United States, but may not be acceptable internationally.

Subjects can 'sign' their consent electronically by:

- typing their name AND date
  AND

- by utilizing REDCap's 'Signature' field type on the survey, which uses a stylus, mouse, or finger to "write" their signature on the form.

The process of obtaining consent should be documented by the person obtaining consent in the research record. This process note should include statements about:

- the method that was used to discuss the study with the potential subject (discussion happened over the phone, Microsoft Teams, etc.);
- the questions that the potential subject asked;
- the time the potential subject was given to make their decision;
- how long the conversation lasted;
- the process of verifying the individual's identity over the phone and then with the eConsent signature, as described above.

11. Should subjects have access to the consent form before the consent process and should subjects then receive a copy of their signed eConsent?

Yes. HHS regulations require that the subject/subject's legally authorized representative be provided a copy of the consent form. The HIPAA regulations require that the subject/subject's legally authorized representative receive a signed copy of the consent form with authorization. The IRB application or protocol should include a plan for providing copies of the consent to participants.

When the study team will not physically interact with the subject/subject's legally authorized representative, REDCap should be set up to display a button for the subject/subject's legally authorized representative to download the signed consent form. If this is not possible for the subject (ex: they are using a public computer), other methods need to be used to provide the subject/subject's legally authorized representative a signed copy (e.g. paper copy through the mail, emailed PDF).

When the study team will physically interact with the subject/subject's legally authorized representative, REDCap can be set up to send the subject/subject's legally authorized representative an email with a PDF attachment of the signed consent form, if an email address is provided, or a signed paper copy can be provided to the subject/subject's legally authorized representative.

Once the consent form is signed and submitted, subjects will be able to receive a print out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form. If the participant selected that they wish to receive an email copy of the signed consent, they should be presented with the

following statement and confirm that they wish to receive via email.

> ***"Carilion Clinic cannot control the security of email messages once we send them, therefore we need your permission to email you the copy of your signed consent. Please be aware that while the email title will not include your [disease status], the attachment to the email will contain study consent. Someone else accessing your email messages could click on the attachment and read the consent, and therefore learn about your [disease status], which you may consider to be of a private or sensitive nature. By providing your email address, you are authorizing Carilion Clinic to email you a copy of your signed form.***

If a signed copy of the consent will be emailed to the subject using REDCap, the subjects must provide their e-mail address on the completion page, and the following statement must be included in the field where the email address is requested:

> ***Enter your email to receive confirmation message?***
> *A confirmation email is supposed to be sent to all respondents that have completed the survey, but because your email address is not on file, the confirmation email cannot be sent automatically. If you wish to receive it, enter your email address below.*

12. Can HIPAA authorizations for research, which are frequently combined with informed consent documents, be obtained electronically?

Yes. HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject's personal representative) is a valid electronic signature under applicable laws and regulations. The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a subject (or a subject's personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.

13. What other measures can researchers implement to ensure the consent process is robust and that participants are truly informed when using eConsent remotely?

- Ensure the potential participant is comfortable using an eConsent

process and has access to the necessary technology to do so (ex: internet and email)

- Use Microsoft Teams or Vidyo calls to permit better assessment of participant comprehension, answer questions, and verify identity; if video calls are not possible due to technology limitations, phone calls should occur
- To ensure that patients are approached in a consistent fashion, a standard process should be used that includes the following:
    - Identification of who is on the call and creation of the passcode
    - Review of the informed consent with the patient by the investigator (or their designee) and response to any questions the patient may have.
    - Presence of an impartial witness to the consent process (Note: it is strongly advised to have a witness for eConsent, but not required unless the patient is non-English speaking or is unable to read). If an impartial witness is involved, obtain confirmation by the witness that the patient's questions have been answered.
    - Confirmation by the investigator that the patient is willing to participate in the study and sign the informed consent document while in live communication with the subject
    - Verbal confirmation by the subject that they agree to participate in the trial and that they have signed and dated the informed consent document that is in their possession

14. What special considerations should be given to the use of eConsent for pediatric studies?

When approving an assent process, an IRB considers whether the study population has the ability to provide assent, this is regardless whether assent is obtained by paper or electronically. The method used to obtain assent (paper or eConsent) should not impede the child's capability to provide assent.

15. What materials or documents will OHRP require during an inspection?

During inspections of clinical investigation sites, OHRP regulations require that OHRP be granted access to records and reports made by the investigator, including site- specific versions of the eConsents, the materials submitted to IRBs for review and approval, all amendments to the site-specific eConsents, and all subject-specific signed eConsents. These should be available at the site either in electronic or paper form. OHRP reserves the right to review the content of the eConsent program or informed consent document and the corresponding informed consent of the subject/subject's authorized representative and the signature of a witness, where applicable, along with the date that the eConsent was signed. Any updates to the documentation should also be available for review.

16. What do I need to do if I want to use REDCap to obtain eConsent?

The Carilion Clinic IRB must approve consent form and description of the eConsent process, and confirmed that it meets all local and federal consenting requirements. Please read this entire guideline carefully to ensure you are familiar with the requirements for eConsent.

- The research protocol will need to explain the consent process, which includes how eConsent will be used (e.g. computers, electronic tablets, smart phones) and the mechanism for authentication, if required.
- Create WORD versions of all consent documents and submit your study application to the IRB as usual.
- Keep in mind that the questions to assess the subjects' understanding will be built in at the end of the consent document in REDCap. Therefore, the questions asked to assess participants understanding should be described in the IRB application or protocol.
- Once your IRB application and consent documents are IRB approved, the watermarked version of your consent form with signature boxes (in case a subject requests a paper consent) and without signature boxes (to be uploaded into REDCap) will be available in PRIS3M under your newly approved study.
- After IRB approval, to get the eConsent creation process started, the PI/Study Contact will need to submit the IRB approval letter and approved consent form with and without signature boxes to HART at HART@carilionclinic.org and the HART REDCAP Administrator will work with the study contact to set up the eConsent form.

17. What if I need to revise my consent form, and I'm using the REDCap eConsent system?

You should first submit your modification to change the WORD consent document in PRIS3M. Once your modification is approved, you will need to work with HART to update your eConsent(s) in REDCap. REDCap has versioning control built into the technology to allow for versioning control.

Appendix 1

eConsent Research Protocol Template Language

The below template text that can be used in a research protocol to describe the specific steps for obtaining eConsent. This language should be modified to describe the study-specific eConsent process:

The consent document will be created using a REDCap-based electronic consent form. The IRB-approved consent form will be developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users.

*Subject signatures will be obtained using a (**select method: typed signature, written signature – via stylus/cursor, etc.**). Once the consent form is signed and submitted, subjects will be able to receive a print out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form. They will also be able to request that a paper copy of the signed consent form be mailed to their home address.*

*Potential subjects will participate in the consent process by (**select method**):*

1.) ***eConsent Obtained in Person** – Subject/Subject's legally authorized representative is approached in-person at (INSERT) and accesses the REDCap eConsent via a Carilion Clinic portable electronic device. During the in-person consent process…(Describe the consent process and how the signed consent will be provided to the subject/subject's legally authorized representative)*

and/or

2.) ***eConsent Obtained Remotely with Required Remote Consent Process (e.g. video/telephone)** – The eConsent form will be accessed on the potential subject's personal electronic devices (e.g., computers, portable tablets, smart telephones). During the remote consent process … (Describe the consent process that occurs remotely between the subject/subject's legally authorized representative and the study team member, the identity authentication method, and how the signed consent will be provided to the subject/subject's legally authorized representative). The study team will request verbal permission to send the eConsent via a REDCap link. The email/text must not include PHI. The request will state: "Because Carilion Clinic can't control the security of email or text messages once we send them, we need your permission to text or email you. Do you want to receive the link to the eConsent via text or email?" The permission will be documented.*

and/or

3.) ***eConsent Obtained through the "Proceed to Provide Consent for***

Participation" method (e.g., link provided using posted QR codes, web-links on study posters, brochures, or websites; email link) *– The eConsent form will independently be accessed on the potential subject's personal electronic devices (e.g., computers, portable tablets, smart telephones). The study team provides contact information (email and phone) for prospective subject within the consent form to contact a study team member with questions, if any. (Describe the process in detail and any authentication method, if required).*

Most studies in this category would be determined to be exempt research under Category 2 by the IRB and would not have a requirement for signed consent. This is not the recommended method for studies that are collecting PHI.

Appendix 2

A complete example of a response for the Informed Consent for Adult Subjects section in PRISM:

The consent document will be created using a REDCap-based electronic consent form. The IRB-approved consent form will be developed in REDCap, a secure, web-based, HIPAA-compliant, data collection platform with a user management system allowing project owners to grant and control varying levels of access to data collection instruments and data (e.g. read only, de-identified-only data views) for other users.

The investigator will reach out to the participant to schedule time to talk over the phone or through Microsoft Teams. The study team will request verbal permission to send the eConsent via email or text so that the participant will be able to review before the call. The email/text will not include PHI. The investigator will first state:

"Carilion Clinic cannot control the security of email or text messages once we send them, therefore we need your permission to text or email you the link to the eConsent form for the study we discussed. Please be aware that while the email title will not include your [disease status], the body of the email will contain the link to the study. Someone else accessing your email/text messages could click on the link and read the consent, and therefore learn about your [disease status], which you may consider to be of a private or sensitive nature. Do you still wish to receive the link to the eConsent via email/text?"

The permission will to send the consent form via text or email will be documented in the individual's research record.

Once the investigator is on the phone or Microsoft Teams call with the potential participant, the investigator will ask the individual to verify their identity by using a combination of questions, including name, date of birth, and their specialist provider name. A passcode will be created from the first 3 letters of the subject's last name and their provider's last name. The link to the eConsent form will sent to the participant and will be accessed on the potential subject's personal electronic devices (e.g., computers, portable tablets, smart telephones). The investigator will enter the passcode in REDCap and the potential participant will enter the passcode in order to access the consent. The investigator and potential participant will discuss the study and review the consent form page by page. If there is another study team member available, or the participant has a family member nearby, they will be asked to observe as a witness. The investigator will encourage the participants to follow along in the document and ask questions. The investigator will give the potential participant as much time as they would like either on the phone or after the call before the signing the consent. The participant will be told they can call the investigator with any follow-up questions. The investigator will document on the form by signing their name that they reviewed the consent with the participant and will document the date of this discussion.

The participant will also be required to answer multiple choice questions to demonstrate their understanding of the study before they sign the document. The questions will include: 1. Please

describe the purpose of the study. 2. Please describe your responsibilities in the study 3. Please describe what you should do if you think you are injured by your participation in the study 4. Please describe what you should do if you wish to stop being in the study. The questions must be answered correctly before the participant may proceed to the next page. The investigator will ensure the code is accurate when reviewing the participant's signature. When the individual is ready to provide consent, they will type their name and then sign their name using their finger or stylus and will also be required to type the date of signature. They will be asked to provide their passcode number. They will then be asked how they would like to receive a copy of their signed consent. Once the consent form is signed and submitted, subjects will be able to receive a print-out of the paper copy, download a pdf, and/or receive an email with a PDF attachment of the signed consent form. If the participant selected that they wish to receive an email copy of the signed consent, they should be presented with the following statement and confirm by providing their email address that they wish to receive via email.

"Carilion Clinic cannot control the security of email messages once we send them, therefore we need your permission to email you the copy of your signed consent. Please be aware that while the email title will not include your [disease status], the attachment to the email will contain the study consent you have signed. Someone else accessing your email messages could click on the attachment and read the consent, and therefore learn about your [disease status], which you may consider to be of a private or sensitive nature. By providing your email address, you are authorizing Carilion Clinic to email you a copy of your signed form.

The process of obtaining consent will be documented within a process note by the person obtaining consent in the research record. This process note will include statements about:

- *the process of verifying the individual's identity over the phone and then with the eConsent signature;*
- *the method that was used to discuss the study with the potential subject (discussion happened over the phone, Microsoft Teams, etc.);*
- *the questions that the potential subject asked;*
- *whether a witness was required and present, and who the witness is;*
- *the time the potential subject was given to make their decision;*
- *how long the conversation lasted;*
- *how the participant received a copy of their signed document.*