Using eConsent: Overview and General Instructions

Boston University Medical Campus
Boston University Charles River Campus
Boston Medical Center

Electronic consent (eConsent) involves use of an electronic or digital format to provide the required elements of consent; the information needed for the research participant to make an informed decision about taking part in the research study. eConsent formats also have the capability for obtaining valid and legal electronic signatures.

eConsent uses an electronic digital platform to fulfill the same requirements as a paper consent:

- Ensure the protection of the rights, safety, and welfare of human participants
- Facilitate the participant's comprehension of the information
- Ensure that appropriate documentation of consent is obtained

Per the shared FDA/OHRP 2016 guidance *Use of Electronic Informed Consent in Clinical Investigations*, "electronic informed consent [eConsent] refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent."

eConsent can be used for *in-person* (participant and researcher sharing the same physical location) or *remote* consent (participant and researcher are not in the same physical location) processes. It's important to think about all of the steps included in the eConsent guidance and instructions in relation to whether or not the consent is being conducted *in-person* or *remotely*.

The eConsent process may or may not involve obtaining electronic signatures of the participant or researcher based on the IRB-approved study plan and HRPP policies. (As applicable, see BMC/BUMC HRPP policies on consent documentation and BU CRC HRPP policies on consent documentation.)

Study teams are recommended to review the shared FDA/OHRP 2016 guidance *Use of Electronic Informed Consent in Clinical Investigations* in full prior to implementing eConsent as it contains best practices and current thinking of the federal government on the use of electronic formats for consenting. The end of this guidance document contains links to further guidance related to eConsent, electronic signatures, and FDA Part 11 requirements.

This overview is designed to provide broad information about using eConsent at Boston Medical Center, Boston University Medical Campus, and Boston University Charles River Campus. There may be additional nuances or guidelines depending on the study's primary location or needs. Study teams should contact the resources listed below under *General Contact Information* as necessary if there are questions about specific policies or procedures. Many of the links in this document guide researchers to the Boston University Medical Campus HRPP policies, but teams should review their specific IRB-of-record's policies on eConsent and consent in general before proceeding.

Scenario examples to show the wide range of studies that can utilize eConsent are provided in Appendix A.

Advantages of Using an eConsent Process

Presenting the consent document in an electronic format has benefits for the study team and the participant. Study teams should think carefully about operationalizing this process and be sure to include all appropriate steps in their IRB application.

Helps in conducting a remote consent process

A remote consent process is when the researcher conducting the consent discussion is in a different physical location than the participant. Different physical locations could be different rooms in the same building or completely different locations including different cities or states. Remote consent may be appropriate and advantageous for many reasons. For example, the research study is conducted remotely; participants are not able to easily get to the clinic to meet in-person; or participants may have a communicable disease and study staff want to lessen the possibility for transmission, etc. A remote consent process could be conducted using a paper form or using an eConsent form. If using a paper form, a witness would be needed to sign the paper form on behalf of and at the direction of the participant. The eConsent process allows the participants to sign for themselves, on their own devices, or with a tablet or similar device supplied by the research team or the hospital.

Flexibility in providing information to participants

eConsent has the functionality for links that can be embedded directly into the consent for definitions, videos, or images, and other information that could improve the participant's understanding of the research. Study teams should think about how the use of embedded links can be applicable for their particular study or patient population. As with all participant-facing materials or content, these embedded links must be approved by the IRB.

Increases compliance with documentation requirements

Depending on the platform used, an eConsent can be programmed to capture the actual date and time of signatures to facilitate compliance with documentation requirements. The eConsent platform will also maintain an audit-trail to document changes.

Streamlines maintenance of the informed consent form

eConsent platforms typically provide the capability to automatically archive PDF copies of completed eConsent documents. Maintaining signed consent forms in this way helps to ensure that researchers comply with the policy to retain research study documents for a minimum of seven years.

Systems for eConsent at BUMC and BMC

Study teams can use sponsor-provided systems for eConsent. The use of this should be explained in, as appropriate and applicable, the IRB application or protocol, contracts, or other documents and submissions. Study teams have two other options for eConsent.

REDCap

REDCap is a software system developed by Vanderbilt University to enable clinical researchers at licensed non-profit organizations to create research databases. When enabled, the REDCap eConsent Framework provides standardized settings and security, including a consenting certification screen and storage of the auto-generated PDF of the signed consent. REDCap can be used when HIPAA-regulations apply and, with specific procedures set up, when FDA Part 11 regulations apply. Further information on using REDCap when FDA Part 11 regulations apply is provided below in the section titled *eConsent when FDA 21 CFR Part 11 Regulations Apply*.

Study teams electing to use REDCap for eConsent should use the REDCap eConsent Framework. Please contact REDCap help for more information regarding the eConsent Framework settings and integrated REDCap functionality.

The eConsent Platform in REDCap can be used for a number of consent process and signature documentation scenarios:

- *Exempt study* utilizing an Exempt Information Sheet
    - Consent contains no HIPAA language: Neither participant nor researcher signature required.
    - Consent contains HIPAA language: Participant signature is required for HIPAA authorization only and researcher signature is not required. As appropriate for the study, the researcher may request a Waiver of HIPAA Authorization.
    - Use Guidance on Building REDCap eConsent for Minimal risk or Exempt Research Not Requiring Signatures or Exempt Research that Includes HIPAA authorization.
- *Non-Exempt study* utilizing either an Exempt Information Sheet with an Alteration of Consent approved by the IRB or a full Consent with a Waiver of Documentation of Consent approved by the IRB
    - Neither participant nor researcher signature is required but a memo or note-to-file should be written to document the consent process. These memos can be written within REDCap or some other external electronic or paper process.
    - In some cases, a participant signature may still be required for HIPAA Authorization unless the IRB has also approved a Waiver of HIPAA Authorization.
    - Use Guidance on Building REDCap eConsent for Minimal risk or Exempt Research Not Requiring Signatures or Exempt Research that Includes HIPAA authorization.
- *Non-Exempt study* utilizing a full Consent and requiring signatures of either the participant or researcher
    - Note that some minimal risk studies may not require the signature of the person conducting the consent discussion, but this must be approved by the IRB.
    - Use Guidance on Building a Non-exempt eConsent from a Pre-Built REDCap Template.
- *Study that will enroll participants with Limited English Proficiency.*
    - REDCap has a Multi-Language Management (MLM) module, allowing creation and configuration of multiple display languages for the project. This module should be used when enrolling participants with Limited English Proficiency. Use of the MLM module can give researchers the capability to use branching logic to accommodate multiple consent scenarios in a single e-consent instrument (for example, toggling between consent form language translations, accommodating short form consent documentation, etc.) For assistance on these features, please contact REDCap help.

To get started with REDCap, an account can be created by completing the End User Agreement. If joining an existing study, the new user should be added to the IRB application through INSPIR before being added to the REDCap project. Training videos and FAQs are available once logged in. Additional REDCap guidance can be requested.

It is important to utilize the guidance documents in the above examples when you develop your consent forms in REDCap as there are special requirements for consents for non-exempt studies. These are available on the CRRO website.

DocuSign Life Sciences

BMC IT offers licenses to a 21 CFR Part 11 compliant DocuSign Life Sciences account as a HIPAA compliant platform for electronic signatures on consents. DocuSign will only be available for FDA-regulated research studies that require 21 CFR Part 11 compliance.

The general process is as follows:

1. The participant will receive an email from DocuSign. After selecting "Review Document" the participant will follow the steps to authenticate their identity.
2. Authentication Method: Account Login
    1. If the participant does not already have a DocuSign account, they will be prompted to create one and set up a password.
    2. Once the participant is granted access to the envelope, they will navigate to the fields on the document to take action (skip to #5).
3. Authentication Method: SMS
    1. The participant will enter the last four digits of their phone number and the code they received via SMS.
    2. Once the participant is granted access to the envelope, they will navigate to the fields on the document to take action.
4. The participant will click the signature field to sign. Per FDA regulations, when clicking each signature or initial field, the participant must select a reason for signing from the list provided.
5. The participant will click Sign, then click Continue to authenticate their identity. They will either be redirected back to the login page where they will have to enter their username and password (Account Login method) or enter their last four digits of their phone number and code received via SMS (SMS method).
6. Once the participant has completed all of the required fields, they will click Finish and authenticate their identity if prompted to complete the signing process.
7. The participant will receive a completed envelope email with the signed document once all recipients have signed.

A video on signing a 21 CFR Part 11 DocuSign envelope is available here.
To get started with DocuSign Life Sciences, access BMC's ServiceNow's Service Catalog. Under Research Technology Program (RTP), choose "RTP Request>RTP Inquiry" and complete the form, including study name, IRB number and names of users that need licenses. A member of RTP will reach out to you to provide next steps for your requested DocuSign accounts.

Remote Consent and Using eConsents

As noted above, a remote consent process is when the researcher conducting the consent discussion is in a different physical location than the participant. Different physical locations could be different rooms in the same building or completely different locations, such as different cities or states. The eConsent process allows the participants to sign for themselves, on their own devices or with a tablet or similar device supplied by the hospital or research team, rather than using a witness signing the paper consent form on behalf of the participant.

eConsent when FDA 21 CFR Part 11 Regulations Apply

As part of the overall requirements for FDA-regulated research, there is a sub-set of regulations called Part 11. These regulations specifically apply to records in electronic form that are created, modified, maintained, archived, retrieved, or

transmitted as part of a study that is FDA-regulated. When an electronic or digital format is used to provide the required elements of consent or to obtain signatures, Part 11 applies. Researchers should carefully review the FDA Guidance Document on Part 11 when using eConsent in an FDA-regulated study. Additional general, non-institutional guidance on REDCap's compliance with Part 11 is also available.

Researchers should also review the BMC/BUMC HRPP Policy on Part 11. For FDA-regulated drug or device studies conducted by the Principal Investigator at Boston Medical Center or Boston University Medical Campus under an IND or IDE, it is the responsibility of the Principal Investigator to ensure compliance with 21 CFR Part 11 requirements for electronic records and electronic signatures if the study uses an electronic system managed by Boston Medical Center or Boston University for electronic records and documentation of electronic signatures. This responsibility also extends to studies that are not conducted under an IND or IDE, but that involve study data that will be submitted to FDA.

DocuSign may be used for FDA-regulated research that is subject to Part 11 requirements.

Boston University's instance of *REDCap* may be used for FDA-regulated research that is subject to Part 11 requirements for researchers at either BUMC and BMC. The BU REDCap Part 11 Request Form must be completed to initiate the process. Review REDCap Part 11 Process & Training for full details on setting up REDCap for Part 11 compliance.

To be compliant with Part 11 regulations, two distinct components must be used to verify the identity of the participant when signing an eConsent. These components could be a unique identifier and generated code. One example is an email address and password. For more information, refer to the Joint guidance issued by the FDA and OHRP, which provides further detail.

Acceptable Signatures for eConsent

Joint guidance issued by the FDA and OHRP permits the use of electronic signatures when written informed consent is required; see Question 6 entitled "How can electronic signatures be used to document eIC?".

FDA 21 CFR Part 11 regulation provides the criteria needed for FDA to consider electronic signatures to be "trustworthy, reliable and generally equivalent to handwritten signatures on paper." To be equivalent, electronic signatures must comply with all applicable requirements under 21 CFR Part 11.

OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted.

A legally valid signature can be one of the following:

- Wet signature: signed with pen on paper
- Electronic signature: typed name and date or signed name and date using mouse, finger, or stylus
- Digital signature: typed name and date with authentication code or key
- Biometric signature: biological signature including DNA, fingerprint, or face recognition (note this is not an available function in REDCap)

Signature Process for Witnesses and Interpreters When Enrolling Participants Who Are Limited Readers or Have Limited English Proficiency

The process and requirements for enrolling limited readers and participants who have limited English proficiency are the same regardless of if it is completed within an eConsent system or on paper. The researcher should determine in advance who needs to be involved in the consent process for a particular potential participant. Depending on the study and the study participant, it is possible that the following individuals may be involved: family members, interpreter, an impartial witness for limited/non-readers, or a witness to the short form process. Researchers must account for these additional individuals when implementing an eConsent process and these details must be described in the INSPIR application.

Researchers are directed to review HRPP Policies on Witnesses and Interpreters for Non-English Speaking Subjects and Informed Consent for Limited- and Non-Readers for more information.

IRB Submission Requirements for eConsent

Very specific information is required to be provided to the IRB for approval prior to implementation. This should be submitted during the initial application but can also be added as an amendment later. This information is required to be submitted regardless if the study is exempt or non-exempt. The IRB must approve the eConsent process before it can be used in any study. All details should be included in the consent section of the IRB application. Either the IRB or CRRO can be contacted for guidance on completing the application for eConsent procedures.

As with a paper consent used in-person, the IRB will want to know details on who will lead the consent discussion, how long the potential participant has to decide to enroll in the study, and in what setting the consent will take place. While outside the scope of this guidance, study teams should also include information in the IRB application on screening questions and the use of Brief Screening Agreements if these will also be done remotely or electronically.

When completing the IRB application, study teams should ensure that the signature boxes they are including in the paper consent align with what is required for all of their processes, including eConsent or remote procedures. This includes processes such as consent with Decisionally-impaired participants using a Legally Authorized Representative, consent with participants with limited English proficiency, or consent involving other populations that could impact processes around documentation and signatures.

If using REDCap and doing non-exempt research, the IRB requires that a PDF of the IRB-approved and stamped consent form be displayed with all applicable electronic signature sections and checkboxes. Historically, IRB-approved and stamped consent forms were displayed in REDCap via multiple single inline images; the new and preferred REDCap functionality allows a multi-page PDF to be displayed inline. For exempt research when using an Exempt Information Sheet, the wording from the information sheet can be pasted directly into REDCap rather than a PDF. These steps of either using a PDF or pasted text should be included in the INSPIR application.

The IRB will also want to know specifics in regards to the eConsent process itself, including but not limited to the following:

- What is the system being used for eConsent? This will either be REDCap, DocuSign, or sponsor-provided system.
- If a Waiver of Documentation of Consent, Waiver or Alteration of Consent, or HIPAA Waiver of Authorization is needed.

- How will the eConsent discussion take place? Will it be in-person or remote? If remote, will the discussion take place via telephone, Zoom or other videoconferencing technology? Both in-person and remote discussions can be used with eConsent and sometimes it's important to provide potential participants with options. If conducting both in-person and remote eConsent processes, the INSPIR application should be clear on which steps apply to which process.
- How will the eConsent form be provided to the potential participant *before* the consent discussion? Examples could include via tablet for an in-person eConsent, or provided in a link sent to the individual in an email or text.
- Will a password for accessing the eConsent be provided to the participant? If so, how?
- How will the signed eConsent form be provided to the participant *after* the consent has been signed? Examples could include printing out the signed form and either directly providing it to the participant if in-person or sending in the postal mail. This could also mean emailing a PDF copy to the participant.
- For FDA regulated research, what methods will be used to verify the identity of the participant when signing an eConsent?
- Details will need to be provided for studies enrolling any of the following. These details should specifically address any required signatures or special processes for witnesses or interpreters, if applicable.
    - Limited or non-readers
    - Non-English speaking individuals including the use of full translated consents or short form consents
    - Legally Authorized Representatives (LARs) for those who are decisionally-impaired
- Details will need to be provided about the confidentiality of the eConsent document and process. These details should specifically address confidentiality of the communication method including email or texting. For example, if eConsent links are provided in an email, the IRB application should include information in the consent and email script that emails are not necessarily secure.
- If audio-visual recordings of the consent process will be made and kept by the researcher for documentation purposes, this must also be described in the IRB application including plans for disclosure to participants, how and where recordings will be securely stored, and deletion from the original recording device.

Storage Requirements for eConsent Files After Study Closure

Institutional HRPP Policy is that all study records including signed consent forms must be stored for a minimum of 7 years after the end of the study. All retention and storage requirements included and approved in a study-specific IRB application must be followed.

REDCap

The REDCap project status can be changed to reflect the project lifecycle stage via the "Other Functionality" tab on the Project Setup screen. Move the project to Analysis/Cleanup status when data collection has ended, and cleaning and analysis have begun. Many features will be disabled, such as surveys, Alerts & Notifications, Automated Survey Invitations, and other features typically used during data collection.

If you are finished with a project, it can be marked as Completed to take it offline and hide it from access. This status ensures that the project and its data remain intact for a certain amount of time, but accessibility is no longer needed. Only REDCap administrators may undo the Completion status and return the project to an accessible state for all project users.

DocuSign

Signed envelopes/documents within an account are never removed. Draft envelopes are stored in your account for 30 days from the date they were created.

Additional Resources and Information

CRRO eConsent Guidance

OHRP and FDA Resources

- OHRP and FDA Joint Guidance: Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers, December 2016
- FDA Regulations: 21 CFR Part 11 Electronic Documents and Signatures
- FDA Guidance: Part 11, Electronic Records; electronic Signatures – Scope and Application, September 2003

Relevant BMC/BUMC HRPP Policies

- 8.4.1 Written Consent
- 8.4.2 Waiver of Documentation of Consent
- 8.4.3 Waiver or Alteration of Consent
- 8.5.1 Authorization to Use and Disclose PHI
- 8.5.2.2 Waiver or Alteration of Authorization for Use and Disclosure of PHI

Educational Resources

- Clinical Research Seminar - December 2020: Remote and E-consent (including REDCap)
- RPN Workshop - December 2020: Remote and E-consent: Lightning Talks and Group Discussion
- RPN Workshop - March 2023: eConsent: Benefits, Challenges, and Considerations

Boston Medical Center Guidance *(only accessible with BMC account)*

- HIPAA Information
- Record Retention

REDCap and Part 11 Compliance for FDA-Regulated Research

- BU REDCap Part 11 Request Form
- REDCap Part 11 Process & Training

General Contact Information

- Clinical Research Resources Offices
- Boston University Medical Campus and Boston Medical Center IRB
- Boston University Charles River Campus IRB
- REDCap Help

Appendix A: Scenarios

These examples are intended to provide researchers with an understanding of the wide range of studies that can benefit from using eConsent and to help illustrate the difference between eConsent and remote consent. These scenarios do not address all of the necessary steps in eConsent but are provided as short examples only.

Researchers are advised to contact the CRRO for a consultation and/or to contact REDCap help (if using REDCap) prior to implementing to discuss any of these scenarios further or to discuss other scenarios, such as utilizing eConsent in a multicenter study, eConsent in decentralized clinical trials, and utilizing the REDCap multi-language (MLM) module.

For more detail on building eConsent forms and processes within REDCap, including information on the MLM module, the multi-signature consent module and more, please refer to the two additional CRRO eConsent guidance documents on developing eConsent using REDCap.

Study involving only one electronic survey in REDCap

- A link to an electronic survey is sent by the researcher to the participant. Before the survey there is an Exempt Information Sheet or Consent that the participant must review prior to answering the survey questions. This would be a fully remote study with an eConsent.
- The electronic survey can be done on a tablet handed to the participant during a clinic visit or other in-person visit. The Exempt Information Sheet is included in the beginning of the survey and is reviewed prior to answering the questions. This would be an in-person study with an eConsent.

Study taking place at a community health center with all procedures including consent, blood draw, physical exams, and surveys completed in person

- The researcher and the participant complete the consent discussion in person at the community health center using an eConsent form on a tablet. The participant then signs the eConsent form by typing in their name with the date being auto-completed with the researcher signing the same eConsent. The signed eConsent is emailed to the participant or if they do not have an email address, the consent is printed and given directly to the participant. These two different methods of providing the consent were included in the INSPIR application and approved by the IRB. The researcher uses a Consent Checklist to document which method is used. This is an in-person study with an eConsent.

Study involving a blood draw for research with IRB approval for a waiver of documentation of consent

- The researcher sends the consent form to the potential participant via email or postal mail and then conducts the consent discussion over the phone or Zoom. The consent discussion is done prior to the participant's next clinic visit, at which they will have blood drawn for research purposes. This would be a remote eConsent even if other procedures are done in-person. Although signing the consent is not necessary, the researcher should document that the consent discussion was completed. This can be done in a progress note or the CRRO Informed Consent Documentation template tool.
- The researcher meets with the potential participant at their clinic visit and provides them with the eConsent on a tablet to review. The participant verbalizes their consent to participate in the research. The researcher uses the Documentation of Informed Consent tool to document the consent discussion. At this clinic visit, blood is drawn for research purposes. This would be an eConsent done in person.

Study that is designed so that most or all procedures can be done remotely including ongoing data collection from participants using personal monitoring devices to collect things like blood pressure, heart rate, and step count

- The participant is sent the eConsent link in an email and a password is provided verbally during a remote consent discussion conducted over Zoom. The participant then signs the eConsent form in REDCap by typing in their name with the date being auto-completed with the researcher signing the same eConsent. The signed copy of the eConsent is then emailed to the participant. The participant is then shipped the monitoring devices, instructions on how to use, and will be emailed links to complete surveys in REDCap.

Inpatient study when the researcher cannot enter the hospital room due to possible infectious disease transmission

- The researcher will conduct the consent discussion remotely and signatures will be collected remotely. When doing this type of study or with a participant with an infectious disease preventing in-person consent, researchers should contact BMC CTO for guidance. These procedures were originally developed for COVID-19, but could be implemented for any in-patient infectious disease study requiring remote procedures.
- The IRB has approved two methods for consent for this situation:
    - The participant and researcher each have a paper consent form. The consent discussion takes place by phone, Zoom, or other approved method. When it is time to sign the form, the researcher uses the "Remote Consent Signature page" provided by the IRB. The participant directs a witness to sign and date the consent form on their behalf. The participant signs their own copy of the consent form. The researcher then signs the same form that the witness signed. It is the researcher and witness signed version that is kept for research records.
    - An eConsent form can be used that will be signed remotely by the participant and researcher. The participant is sent the eConsent link and a password in separate emails. The researcher conducts a remote consent discussion with the participant by telephone or zoom call. The participant then signs the eConsent form by typing in their name with the date being auto-completed with the researcher signing the same eConsent. The signed copy of the eConsent is then emailed to the participant.

Inpatient study with a potential participant who is not able to consent for themselves and their Legally Authorized Representative (LAR) is not available for an in-person consent discussion at the hospital

- With approval from the IRB for the Legally Authorization Representative process, the consent discussion can be remotely conducted for this study using either a paper consent form or an eConsent form. The researcher will speak with the LAR over the telephone or meet with them over teleconferencing like Zoom and conduct the consent discussion. Signatures can be obtained several different ways, any of which require IRB approval:
    - Using a paper consent with a witness who will sign the consent on behalf of the LAR.
    - A paper consent form that is signed by the LAR after the consent discussion and postal mailed or scanned and emailed to the researcher who will then sign the form.
    - An eConsent that will be signed by the LAR and the researcher.