

Using E-consent at BMC and BU Medical Campus

(Note that when reading this guidance, use of the term “subject” below generally means “subject or LAR”.)

What is e-consent?

Per the shared FDA/OHRP 2016 guidance *Use of Electronic Informed Consent in Clinical Investigations*, “electronic informed consent [e-consent] 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.”¹

Practically speaking, e-consent is a digital platform that provides the [required elements of consent](#)^{2,3}, the information needed for the research subject to make an informed decision about taking part in the research study, in an electronic format, with the capability for obtaining valid, legal e-signatures. Instead of a hardcopy consent form, e-consent uses an electronic digital platform that enables the following:

- Ensuring protection of the rights, safety, and welfare of human subjects
- Facilitating the subject’s comprehension of the information
- Ensuring that appropriate documentation of consent is obtained

E-consent can be used for in-person (subject and investigator sharing the same physical location) or remote consent (where the subject and investigator are not in the same physical location). The e-consent process may involve obtaining the electronic signatures of the subject and investigator when documentation of informed consent is required. It might not involve obtaining the signatures of the subject or investigator if the IRB makes the appropriate determinations (i.e. exempt research with no PHI involved, waiver of documentation of consent, waiver of HIPAA authorization, etc.) that documentation of informed consent and/or HIPAA authorization is not required.

It is helpful to review [the 2016 joint FDA/ORHP guidance on e-consent](#). See also the end of this guidance for links to additional guidance related to e-consent, e-signatures, and FDA Part 11 requirements.

Why would I want to utilize e-consent?

There are several benefits to instituting an e-consent process.

- Flexibility and ease in providing information to subjects:
E-consent enables the functionality to be able to click on links that lead to definitions, videos or images, etc. that have the potential to improve the subject’s understanding of the research.
- Streamlines maintenance of informed consent forms:
E-consent can be programmed to capture the actual date and time that the subject and investigator signed the form, thus facilitating compliant consent documentation. The e-consent platform maintains an “audit trail” to show if/when changes were made. With the “e-Consent Framework” functionality of REDCap, completed e-Consent Documents will be automatically stored as a PDF in the project’s File Repository folder, simplifying ongoing maintenance of the documents.
- Helps in conducting remote consent:
Although e-consent can be used for consent discussions where the subject and investigator are in the same physical location and both sign the e-consent form using a shared touchscreen device, it

can be of especially great value in situations where such an “in-person” process is not possible. An example, of course, is conducting the consent process during a global pandemic, like COVID-19. COVID-19 inpatients will need a remote consent process to prevent transmission of the virus. The researcher is not able to enter the room to have an in-person consent discussion, and even if it were possible to do so, removing the hardcopy consent form from the patient’s room would not be permitted.

Thus, the consent process must take place “remotely” where the investigator is in a different physical location than the subject (even if just outside the patient's room). This is discussed in more detail later in this document. The e-consent process can allow the subjects to sign for themselves, on their own devices or with a tablet device supplied by the hospital, rather than having to utilize a witness who would sign the hardcopy consent form on behalf of and as directed by the subject.

What e-consent platforms are available here at BUMC and BMC?

There are currently two e-consent platforms available to BMC/BUMC researchers: 1) the e-consent platform within REDCap, and 2) DocuSign.

REDCap (Research Electronic Data Capture) is a software system developed by Vanderbilt University in 2004 to enable clinical researchers at member non-profit organizations to create research databases in a secure, HIPAA-compliant system. REDCap allows users great flexibility and functionality in creating data collection systems and is capable of compliance with HIPAA and FDA Part 11 requirements. In 2018, REDCap introduced an eConsent Platform that provides standardized tools to obtain consent and store consent documentation with a certification screen, and a storage function which automatically generates a “hard-copy” PDF of the signed form.

REDCap can be used as the e-consent platform for a wide range of e-consent scenarios, not just research requiring signed e-consent.

1. If exempt “Exempt Information Sheet” with no HIPAA language, no signature is required.
2. If exempt “Exempt Information Sheet” *with* HIPAA language, signature of subject (only) is required for HIPAA authorization.
3. If non-exempt and the IRB grants a waiver of documentation of consent under 45 CFR 46.117 (c)(1), then no signatures are required. The investigator may write a note-to-file documenting the consent process (see [Documentation of Informed Consent template](#)). HIPAA authorization may be required unless the IRB approves a HIPAA waiver, which is separate from a waiver of documentation of consent.
4. If non-exempt and does not meet waiver of documentation requirements, then signature/date by both the subject and investigator are required. The investigator sends the REDCap link to the subject via e-mail or text. The investigator provides a password to the subject via verbal communication, e-mail or text to be able to access the REDCap e-consent form. The subject signs the form by typing in the name and/or using a stylus or mouse to sign the form. REDCap will automatically provide the date and time of this signature (if programmed to do so). Then the investigator signs/dates the form. A copy of the signed consent form is emailed to the subject.

To get started with REDCap you should: 1) Submit end user agreement:

<https://redcap.bumc.bu.edu/surveys/?s=RYKEW4N4RX>; 2) Review training videos & FAQ:

<https://redcap.bumc.bu.edu/index.php?action=training>; 3) Request a REDCap consult: rchelp@bu.edu;

4) See below for the REDCap e-Consent Guidance link.

The CRRO has developed [REDCap e-consent guidance documents](#) that provide step-by-step instructions to create an e-consent form in REDCap for both non-exempt and exempt research. For non-exempt research the IRB requires that a PDF of the IRB-approved and stamped consent form be used. E-signature lines and applicable e-checkboxes will be added in REDCap as described within the guidance.

At this time REDCap e-consent should not be used for BU/BMC studies that are FDA regulated (i.e. studies testing drugs or devices). These studies are subject to FDA [21 CFR Part 11](#): Electronic Records; Electronic Signatures. REDCap does have the built-in controls needed for Part 11 but there is additional work at the institutional and site level that must be done to permit REDCap to be used for these studies.

DocuSign is a platform for electronic signatures. BMC Clinical Trials Office (CTO) has purchased a license for a limited number of consents using DocuSign. Although there may be exceptions to the rule, for the most part DocuSign will be available to FDA-regulated research studies (research testing drugs or devices) that are enrolling COVID-19 patients on the BMC medical units where a remote consent process is necessary. A DocuSign consent process will only be used for consent requiring signatures. The subject will receive an email from DocuSign sent on behalf of the investigator. The subject will agree to sign electronically, then starts the signing process. The first signature will require the subject to adopt their electronic signature by verifying their full name and initials. The subject will make any necessary changes and click “adopt and sign” to return to the consent document. The subject will then click all signature tags in the document and confirm signing by clicking finish. DocuSign will automatically provide the date and time of this signature. The investigator receives an email with the signed document attached, and the signed document appears in their DocuSign account. The Investigator will also sign the consent document and a copy of the signed consent form is emailed to the subject.

To get started with DocuSign log into ServiceNow’s [Service Catalog](#). Under Service Desk Requests, click [COVID-19 Request](#). Complete form and check the “Research” checkbox.

Can I use these e-consent options even if my research is subject to HIPAA and/or to FDA [21 CFR Part 11](#) regulations on electronic records and signatures?

HIPAA: Both DocuSign and REDCap may be used for research that is subject to HIPAA regulations.

FDA Part 11: At this time, only DocuSign may be used for FDA-regulated research that is subject to 21 CFR Part 11 requirements (any study testing a drug or device). There is an effort underway to perform the needed validation procedures that will allow REDCap to be used for FDA-regulated research here at BU Medical Campus and BMC. Even after the institution goes through the validation process, compliance must still be met on a per project level. When available, more information on this topic will be provided.

What do I have to tell the IRB regarding plans to use e-consent in my study?

If your study is not yet approved, you will need to include details about the e-consent process in the IRB application for both exempt and non-exempt research.

If your study is already approved, you will need IRB approval to implement an e-consent form and process for non-exempt research.

You will need to complete the consent section in the IRB application, describing in detail your plans for e-consent. For exempt research, typically an Exempt Information Sheet is all that is needed, and the wording from the information sheet can be pasted directly into REDCap rather than using a PDF of the Exempt

Information Sheet document. Signatures/dates for the Exempt Information Sheet are not necessary unless HIPAA authorization is needed. If you are adding e-consent to an exempt study, an amendment is not necessary unless the change will move the study out of an exemption category or alter the HIPAA determination. It is best practice to reach out to the IRB at medirb@bu.edu if you are unsure whether an amendment is needed.

As with a hardcopy in-person consent process, the IRB will want to know details such as who will lead the consent discussion, how long the subject has to decide to enroll, in what setting will the consent take place, and how the consent discussion will be handled for limited and non-readers, non-English speakers, and/or subjects without the capacity to consent for themselves. The IRB will also want to know specifics in regards to the e-consent process itself. This includes:

- How and by what method will you contact subjects?
- Are you using REDCap or DocuSign?
- How will the e-consent discussion take place? Will it be in-person or remote? And if remote, will the discussion take place via telephone, Zoom or other videoconferencing technology?
- How will the subject have access to the e-consent form *before* the consent discussion.
- How will the e-consent form be provided to the subject? Will it be via tablet such as for in-person e-consent, or via email, text, or some other method?
- What methods will you use to verify the identity of the subject? (FDA regulated research would require [two distinct identification components](#), such as identification code and password.)
- Will a password for accessing the e-consent be provided to the subject? If so, how?
- Provide details if your study [enrolls limited/non-readers, non-English speakers](#) (use of full translation and/or [short form process](#)), or requires [legally authorized representatives \(LARs\)](#), and how signing the e-consent will work for all involved parties. Refer to Table 1, below: Witnesses and Interpreters in the Consent Process, and to specific [HRPP policies](#) regarding these subject populations.
- Speak to confidentiality issues related to your e-consent process. Refer to the [IRB FAQs](#) on Impact of COVID-19 on Human Subjects Research (FAQ # 19), on confidentiality of electronic communications and provide relevant details to the IRB. For example, you may describe that your process will involve sending the e-consent link via email and that you will verbally inform the subject that sending messages by email is not necessarily secure.
- If you plan to make an audio-visual recording of the consent process (or any research activities), this should be described in your IRB application, including plans for disclosure to subjects and plans for transferring recordings to secure storage and deletion from the device.

What is remote consent, and how can I use e-consent for remote consent?

Remote consent is when the subject and the investigator are not in the same physical location, making it difficult or impossible to be able to sign the same hardcopy consent form, or to sign the same e-consent form using the same device. Note that not all instances of remote consent will require signatures.

E-consent can be in-person or remote. For e-consent where both the subject and investigator will sign the e-consent form in the same physical location (such as having the discussion in the same room, and signing the same e-consent using the same tablet) there is no need to email the consent to the subject prior to the discussion and there is no need to validate the identity of the subject by another method. For a

remote e-consent process, where the investigator is in a different location than the subject, the e-consent must be sent to the potential subject via e-mail or text message. In this case, to assure confidentiality, the e-consent process should include a password so that only the subject will be able to open the e-consent form. The password should be provided to the subject in a different manner than the e-consent (i.e. verbally, by e-mail or by text). This password also serves to verify the identity of the subject. If the study is FDA-regulated there should be [two methods to validate the identity](#) of the subject. FDA regulations do not specify any particular method for verifying the identity of an individual. A form of official identification such as driver's license or use of security questions are both examples of identification confirmation that can be used.

E-consent technology can facilitate the remote consent process by enabling the subject and the investigator to sign the form electronically, negating the need for a witness to sign on the subject's behalf, as would be needed (in most cases) for the remote hardcopy process. (But keep in mind that you may still need a witness for other reasons such as inclusion of limited/non-readers or the consent of non-English speakers using a [short form consent process](#).)

It is helpful to review [the 2016 joint FDA/ORHP guidance on e-consent](#).

There are many examples of scenarios using remote consent; here are a few:

- An exempt study involving an electronic survey in REDCap is determined to be exempt. A link to the electronic survey is sent by the researcher to the subjects. Before the survey there is "Exempt Information Sheet" language that the subject must review prior to answering the survey questions.
- A study involving a blood draw for research with IRB approval for a waiver of documentation of consent (no signatures needed on the consent form). The investigator sends the consent form to the potential subject via email or postal mail and conducts the consent discussion over the phone prior to the subject's next clinic visit, at which the subject will have extra blood drawn for research purposes.
- A study that is designed so that most or all procedures can be done remotely, such as ongoing monitoring of subjects using BP, ECG, # steps per day, etc. via personal monitoring devices. The consent process can be done remotely and the document signed remotely. The study team has chosen to use an e-consent process via REDCap, where the e-consent will be e-mailed to the subject. A password will be provided during a phone call or via text. The consent discussion will take place by phone. The subject will sign/date the e-consent form and then the investigator will sign/date the e-consent form. The subject will be e-mailed the signed copy of the consent.
- A COVID-19 inpatient study where the researcher cannot enter the hospital room due to possible COVID-19 transmission. The investigator must present the consent form remotely and the document must be signed remotely. The IRB has approved two methods for consent: 1) The subject and investigator each have a hardcopy of the consent form. The consent discussion takes place by phone, Zoom, or other method. When it is time to sign the form, the investigator utilizes the "Remote Consent Signature page" provided by the IRB. The subject directs a witness to sign/date the consent form on their behalf. The subject signs their own copy of the consent form. The investigator then signs the same form that that witness signed. This copy is kept for research records. 2) This method involves an e-consent form that will be signed remotely by the subject and the investigator. The subject is sent a link to the e-consent and a separate password to be able to access the e-consent. The investigator and patient conduct the consent discussion. The subject then signs the e-consent form by typing in his name (and the date auto-populates). The investigator then signs the e-consent form. The signed copy is e-mailed to the subject.

- A patient who is a candidate for a study is not able to consent for himself, and his Legally Authorized Representative (LAR) is not able to come to the hospital. The IRB has approved a [LAR process](#) for this study as well as consent using hardcopy forms or e-consent. The investigator calls the LAR and conducts a remote consent process that involves any of the following: 1) A hardcopy consent process with a witness who will sign the form on behalf of the LAR (similar to #1 in the previous example). 2) A hardcopy consent form that is signed by the LAR after the consent discussion and mailed back or scanned and emailed back to the investigator who will then sign the form. 3) An e-consent that will be signed by the LAR and the investigator (similar to #2 in the previous example).

If you use e-consent for a remote consent process that does require a signature, you will not need a witness to sign on behalf of and as directed by the subject as you would when using a process that involves a hardcopy form, where the subject and investigator cannot sign the same form. But you may still need a witness for other reasons. See Table 1 below for more information about witnesses needed in the consent process.

If you are enrolling COVID-19 patients within BMC clinical units, the BMC guidance *“Remote Consent for COVID-19 Patients at BMC”* will be helpful to you in describing your remote consent, whether or not you are using e-consent. It is available by contacting the [BMC Clinical Trials Office \(CTO\): clinicaltrialoffice@bmc.org](#). They can provide you with access to this guidance via Box. This guidance details the specific steps to conduct the consent discussion for COVID-19 patients within BMC clinical units.

What is an acceptable signature for e-consent?

[Both OHRP and FDA regulations permit the use of electronic signatures when written informed consent is required.](#) OHRP permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted.¹

A legally valid signature can be one of the following:

1. Wet signature (signed with pen on paper)
2. Electronic signature (typed name and date or signed name and date using mouse or finger or stylus)
3. Digital signature (typed name and date with authentication code (KEY))
4. Biometrix signature (biological signature i.e. DNA, fingerprint, face recognition)

21 CFR part 11 provides the criteria needed for FDA to consider electronic signatures to be “trustworthy, reliable and generally equivalent to handwritten signature on paper.” To be equivalent, electronic signatures must comply with all applicable requirements under [21 CFR part 11](#).¹

How do we handle signatures for witnesses and interpreters?

The researcher should determine in advance who needs to be involved in the consent process for a particular potential subject. Depending on the circumstances of the potential subject, it is possible that the following individuals may be involved: family member(s), interpreter, an impartial witness for limited/non-readers, a witness to the short form process. Please see Table 1 below for more information. Make sure you have IRB approval for the method(s) you plan to utilize in your research!

BMC interpreters are willing to be the witness for consent involving non-English speakers who are also limited/non-readers. The IRB allows investigators to write in the interpreter’s number on the witness signature line as appropriate documentation.

Witnesses should not receive a copy of the signed consent form.

How do I store e-consent files after the study ends?

Make sure to keep in mind what you have proposed in your IRB application in regards to specific storage requirements (location and length of time to keep records). BMC/BU Medical Campus policy on [Maintaining Research Records](#) is that research data be stored for a minimum of 7 years after the end of the study.

In REDCap, the project can be moved to archived status by clicking the “Other Functionality” tab and click “Archive the project.” Your archived projects can be found at the bottom of your “My Projects” list by toggling the button “Show/Hide Archived Projects.” The project can be un-archived at any time by accessing the same tab and clicking “Move to production status,” if necessary.

In 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.

Where do I go for further information about e-consent?

OHRP and FDA Joint Guidance: Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers, Dec. 2016 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers>; also: <https://www.fda.gov/media/116850/download>

FDA Guidance: Part 11, Electronic Records; electronic Signatures – Scope and Application, Sept. 2003: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>

FDA Regulations on Electronic Documents and Signatures: 21 CFR part 11: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11>

REDCap: <https://projectredcap.org/about/>

Related BMC/Boston University Medical Campus institutional and HRPP Policies/Guidance:

- BMC guidance: *Remote Consent for COVID-19 Patients at BMC* ([Contact the BMC CTO](#))

HRPP P&Ps:

- [Consent and Authorization](#)
- [Additional Requirements for Decisionally-Impaired Persons](#)
- [Non-English speakers full translated consent](#)
- [Non-English speakers short form](#)
- [Limited/non-readers](#)

BMC/BUMC Clinical Research Seminar 12/16/20: Remote and e-consent (including REDCap) <https://www.bumc.bu.edu/crro/training-education/past-seminars/>

Table 1: Witnesses and Interpreters in the Consent Process

1. Select rows in **green** that apply to your research. These are the requirements no matter whether you are using hardcopy or e-consent.
2. Select from rows in **blue** if you will utilize remote consent and whether it is hardcopy or e-consent (or both).
3. Follow instructions for selected rows in regards to witnesses needed for your study's consent process.

| Subjects and Consent Type | Interpreter | Witness | Other info |
|---|---|--|--|
| Non-English speakers Fully translated consent form | Interpreter needed if person conducting the consent discussion is not fluent in the language of the subject | No witness needed | ----- |
| Non-English speakers Short form | Interpreter needed if person conducting the consent discussion is not fluent in the language of the subject. | Witness present throughout the consent process; witness must speak English and the language of the patient. BMC Interpreter can be this witness. | -Short form must be signed by the subject, witness, and person conducting the consent discussion; -English form must be signed by the witness and the person conducting the consent discussion. |
| Limited/Non-readers | If the limited/non-reader is non-English speaking, the interpreter can also perform the role of impartial witness for limited/non-reader. | For > minimal risk: impartial witness must be present for the entire discussion unless teach back method is used to assess/confirm understanding. | Teach back method may be used in lieu of the witness. |
| Remote consent Hardcopy form | See above re: non-English speakers and limited/non-readers | Witness is required to sign on behalf of the subject, as directed by the subject; BMC Interpreter Services can serve as this witness if subject is a non-English speaker. | Remote consent signature page needed with witness signature line needed (from IRB). |
| Remote consent E-consent | See above re: non-English speakers and limited/non-readers | Witness not required to sign on behalf of the subject as the subject is signing consent for themselves. | ----- |

References

1. OHRP and FDA joint guidance: Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers, Dec. 2016 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers>; also: <https://www.fda.gov/media/116850/download>
2. Elements of consent OHRP https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116
3. Elements of consent FDA; Sec. 50.25 Elements of informed consent; <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50&showFR=1&subpartNode=21:1.0.1.1.20.2>