Overview of IRB Review Requirements

Remote Consent, E-Consent & Other Considerations for Remote Procedures

A Few Notes:

- BU Medical Campus/Boston Medical Center IRB Only
  - apply to those research studies where BUMC/BMC is engaged in human subjects research; AND
  - the BUMC/BMC IRB is providing regulatory oversight for research activities.
- Existing requirements for IRB approval remain
  - For approval, all requirements under 46.111 must be met for non-exempt studies, and all requirements for exempt determinations must be satisfied
- This can be complicated stuff
  - Virtually no two research studies are identical. This means that how remote procedures are incorporated into a protocol is highly variable.
- These are substantive changes
  - If amending a protocol to include remote procedures, nearly all aspects of the study are impacted and must be carefully reviewed.
- We are all learning
  - From researcher to IRB analyst to institutional official, all of us have had to adapt overnight to this new (almost entirely) virtual landscape. As a result, institutional policies (and how they are applied) are constantly evolving to keep up with new information.
  - Evolution on federal level (FDA guidance on remote consent)

Consent: Definitions & Characteristics

Consent Process Type	Key Characteristics	Method of ICF Distribution & Receipt	Method of Obtaining Signature
REMOTE	• **Researcher and participant are NOT in the same physical room/location** • Consent discussion is conducted via video teleconference (Zoom) or telephone call • Signature may or may not be obtained electronically	• Electronic Platform (REDCap, DocuSign) • Email as attachment • Fax • Mail	• Electronic signature (typed or mouse/stylus): REDCap, DocuSign, Editable PDF • Wet Signature: Mail Email with signed, scanned PDF attachment Fax with signed, scanned PDF

Consent: Definitions & Characteristics

Consent Process Type	Key Characteristics	Method of ICF Distribution & Receipt	Method of Obtaining Signature
IN-PERSON	• **Researcher and participant ARE in the same physical room/location** • Consent discussion occurs in person • Can involve a wet or electronic signature	Provide hard copy in-person Provide electronic copy via REDCap or DocuSign	Electronic signature: REDCap, DocuSign Wet Signature on hard copy form

Consent: Definitions & Characteristics

Consent Process Type	Key Characteristics	Method of ICF Distribution & Receipt	Method of Obtaining Signature
MIXED METHODS **(In-person & Remote)**	• Decreases amount of in-person time • Distribute ICF ahead of in-person visit • Conduct initial phone call or teleconference to explain research study • Formal consent conducted in-person on day of visit	• Electronic Platform (REDCap, DocuSign) • Email as attachment • Fax • Mail	• Electronic signature (typed or mouse/stylus): REDCap, DocuSign • Wet Signature on hard copy form

Example 1a (Expedited Study – Remote & E-Consent)

Signature Is Required

- A BMC study with patients with diabetes seeks to determine if a 12-week online training program increases physical activity.
- Participants get a Fitbit to collect activity data.
- As a control, subjects will wear the Fitbit for 12-weeks with no training program.
- The study team will abstract data from EPIC at baseline, 6, 12, 18, 24 and 36 weeks.

Consent Process Type	Consent Discussion Details	Method of ICF Distribution & Receipt	Method of Obtaining Signature
REMOTE	Interested participants are provided ICF via securely emailed REDCap link. Consent discussion takes place either over the phone or using BMC Zoom account. Participant will have access to a copy of the consent form during the discussion.	Electronic Platform REDCap	Electronic signature Typed signature on REDCap

Example 1b (Expedited Study – Remote & E-Consent)

Q: What if obtaining participant signatures is especially difficult?

A: Potential waiver of the signature requirement

HIPAA Regulations Applicable?	Regulatory Requirements
YES	#1 Criteria for waiver of documentation of consent must be met (45 CFR 46.117); **AND** #2 Criteria for waiver of HIPAA Authorization for signature only must be met (45 CFR 164.512(i)(2)(ii)) • Must still include the HIPAA language in the consent form • High standard for impracticability • Prefer research teams demonstrate impracticability by attempting to collect a signature
NO	#1 Criteria for waiver of documentation of consent must be met (45 CFR 46.117)

Example 2 (Expedited Study – Mixed Methods Consent)

A BMC research study with HIV+ patients collects blood samples at two time points and administers a comprehensive questionnaire. Additional blood is collected for research purposes during a clinical blood draw at an SOC appointment.

Consent Process Type	Consent Discussion Details	Method of ICF Distribution & Receipt	Method of Obtaining Signature
MIXED METHODS (Remote & In-Person)	• Those individuals who do not opt out of recruitment call will receive a phone call. • If interested, the study team will send them the consent form (mail, email or REDCap) to discuss participation in-depth. • Formal consent and signature will be obtained during in-person SOC visit.	• REDCap • Email with attachment • Mail	Electronic Consent via REDCap OR Wet signature on hard copy ICF

Reminder

Mixed Methods: Both remote and in-person elements (e.g, research visit tacked onto existing SOC visit)

Example 3 (Expedited Study – Remote & E-Consent with Special Populations)

Consider if your research involves Special Populations:

- Limited- and non-readers
  - Witness required only if study is greater than minimal risk, and NOT utilizing the teach-back consent method
- Non-English speakers
  - Potential short form process involved
- Decisionally-Impaired Individuals
  - Assent process required
  - Legally Authorized Representatives (LARs) required
- Children
  - Assent process required
  - Parental permission
- Combination of Several Populations
  - Non-English speakers who are also limited- and non-readers
  - LARs who are also limited- and non-readers

(Not an exhaustive list)

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.	------

http://www.bumc.bu.edu/crro/tools/e-consent-tools-and-guidance/

Example 4a (Exempt Study – Remote Abbreviated Consent)

No Signature Required

A BU-SPH researcher is conducting anonymous FGDs via Zoom with MPH students to explore whether remote learning has impacted perceived academic performance, including what novel coping strategies students may have developed as a result.

Consent Process Type	Consent Discussion Details	Method of ICF Distribution & Receipt	Method of Obtaining Signature
REMOTE	• The researcher emails the exempt information sheet to participants ahead of the focus groups. • She also reads the exempt information sheet at the start of the FGD.	Email with attachment	No signature required (exempt study where HIPAA does not apply)

Reminder
Abbreviated consent is required if interacting with participants.
This process alone
does not require a signature.

Example 4b (Exempt Study – Remote Abbreviated Consent)

Signature Required (HIPAA)

A BMC study is surveying mothers who gave birth in March – June 2020 to determine how COVID impacted prenatal care. Researchers will then access medical records to record birth outcomes for mother and baby.

Consent Process Type	Consent Discussion Details	Method of ICF Distribution & Receipt	Method of Obtaining Signature
REMOTE	• Mothers are provided with a combined exempt information sheet and HIPAA Authorization via REDCap. Once they electronically sign the combined form, they can complete the survey. • Note that the HIPAA Authorization would apply to both mother and baby.	REDCap	Electronic signature via REDCap (Required due to medical record access)

Reminder:
A waiver of HIPAA Authorization for signature only can be considered with appropriate justifications.

Consent Procedures – IRB Application Requirements

Expedited Studies

- All studies must include information requested in the directions for the consent procedures directions.
- Ultimately, the description is study-specific. No one-size-fits-all approach.

Remote & Mixed-Methods

- How are subjects contacted?
- How will you provide the consent form?
- Will the subject have access to the consent form during the consent discussion?
- How are you conducting the consent discussion?
- How will subjects sign the consent form?

Reminder

Remote: Researcher and participant are NOT in the same room/location

In-Person: Researcher and participant ARE in the same room/location

Mixed Methods: Both remote and in-person elements (e.g, research visit tacked onto existing SOC visit)

For e-consent using REDCap, a jpeg of the approved, stamped consent form must be imbedded into REDCap (as opposed to typing the approved ICF into REDCap).

Consent Procedures – IRB Application Requirements

Exempt Studies

- Abbreviated consent is required if interacting with subjects.
- All studies must include information requested in the directions for the abbreviated consent section.
- Ultimately, the description is study-specific. No one-size-fits-all approach.

Reminder
A signature is generally only required in exempt research is HIPAA applies to the research.

Remote

- Will you providing the exempt information sheet? If so, how?
- How will you provide researcher contact information to subjects?
- How are you communicating with subjects?
- How will subjects sign the exempt information sheet/HIPAA Authorization, if applicable?

Other Procedural Changes due to COVID

Recruitment Procedures

- Cold-calls are generally NOT approved by BUMC/BMC IRB except in very specific circumstances
- EMR Pre-Screening
- Request that providers ask patients (during an SOC in-person/telemedicine visit) if a research team may contact them (via phone/email/BMC MyChart) about a possible study
- Send a recruitment opt-out letter via mail/email/BMC MyChart message (ideally signed by provider)
  - At least, obtain permission from provider to contact the patient & explicitly state this in the recruitment opt-out text

Other Procedural Changes due to COVID

Privacy & Confidentiality Protections

Secure communication methods

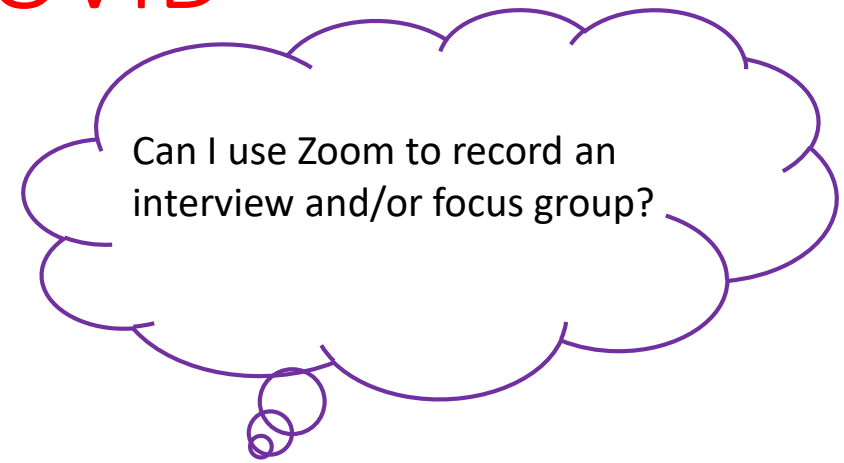
- Phone, BMC Zoom, BU Zoom Meetings for HIPAA, BU Teams, BMC MyChart
- BMC Email:
  - Type secure in the subject line for secure messaging system
  - If not sending PHI, you can use non-secure email with participants (documented) permission*
- BU Research:
  - Use BU SecureMail
  - Can use non-secure communications via email or text with participants (documented) permission*

Third Party Apps/Software

- Application should include information on confidentiality of third party applications used in the study (e.g. Twilio). BU Info Security website lists approved applications. Contact IRB for BMC studies.
- Information about third party applications/software must be in the consent form.

Use of non-secure communications can be included in the consent form

Other Procedural Changes due to COVID



Privacy & Confidentiality Protections

Audio- and Video- Recording

- BMC Studies:
  - Should NOT record using Zoom, seek other methods (recorder, cell phone). The recording should immediately be transferred to secure BMC storage (BMC network or Box.com)
- BU Studies:
  - BU Zoom for HIPAA disables recording/transferring data
  - BU studies not involving PHI can audio and video record using Zoom BUT participants must be told about the recording
  - If approved for audio-recording only, participants must be told that Zoom automatically records video but that this video will be deleted immediately upon download
  - If using Zoom to record, please download to local computer and then transfer to secure storage (Do not download to BU Zoom cloud)
  - See here for BU secure storage options

Keep in mind…

- Additional procedures might be required if the study involves special populations:
  - Limited- and/or Non-Readers
  - Non-English speaking participants
  - Minors
  - Decisionally-Impaired Individuals (LARs required)
- Recommend having multiple approved consent options to allow for flexibility
- Whether study is FDA regulated
  - BUMC/BMC REDCap system is not yet Part 11 compliant (requirement in FDA regulated studies)

Investigator Resources

E-Consent Tools & Guidance:

- http://www.bumc.bu.edu/crro/tools/e-consent-tools-and-guidance/

IRB Templates:

- http://www.bumc.bu.edu/irb/inspir-ii/irb-templates/

INSPIR II Instructions for Investigators:

- http://www.bumc.bu.edu/irb/inspir-ii/inspir-ii-instructions-for-investigators/

IRB COVID-19 FAQs:

- http://www.bumc.bu.edu/irb/faqs-impact-of-covid-19-on-human-subjects-research/

BU Secure Storage Options:

- https://www.bu.edu/tech/support/storage-options/

BU IS&T Approved Applications:

- https://www.bumc.bu.edu/it/infosec/researchcompliance/

BU SecureMail:

- http://www.bu.edu/tech/services/cccs/email/datamotion/using/

References

Using E-consent at BMC and BU Medical Campus:

- http://www.bumc.bu.edu/crro/files/2020/10/E-CONSENT-at-BUMC-BMC.pdf

Use of Electronic Informed Consent Questions and Answers: Guidance for IRBs, Investigators, and Sponsors, joint FDA/OHRP, Dec. 2016:

- https://www.fda.gov/media/116850/download

Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11, Questions and Answers, Guidance for Industry (Draft), FDA, June 2017:

- https://www.fda.gov/media/105557/download

Guidance for Industry: Part 11, electronic Records; Electronic Signatures – Scope and Application, FDA, August 2003:

- https://www.fda.gov/media/75414/download

Conduct of Clinical Trials of Medical Products During the COVID-19 Publich Health Emergency: Guidance for Industry, Investigators, and IRBs, FDA, March/Dec 2020:

- https://www.fda.gov/media/136238/download

How to Contact Us!

CRRO Contact Information

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Go online to find more information about BUMC/BMC CRRO and IRB.