CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

TO: University of Massachusetts Medical School Faculty and Staff

FROM: Katherine Luzuriaga, MD, Vice Provost for Clinical and Translational Research
Carol Bova, PhD, RN, ANP, IRB Chair

DATE: March 25, 2021

RE: **HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent – Temporary exceptions for research requiring written documentation of consent during the COVID-19 pandemic**

The memo is based on the following FDA guidance document, released March 2020 and updated January 27, 2021: *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards*. The memo replaces a similar version initially released and updated in March 2020 pertaining to temporary exceptions for COVID-19 therapeutic trials. This memo is consistent with the clinical system mandate to minimize the exchange of items to reduce the risk of infection.

GENERAL PRINCIPLES:

Unless the IRB has explicitly approved alternative procedures for a given research study, study teams must obtain the written informed consent of a subject prior to conducting any research procedures.

Study teams must have IRB approval to enroll a subject via their legally authorized representative (LAR).

Consent forms and signature blocks that contain sensitive information must be transferred securely, e.g., in person or through mail or secure email. Health information is sensitive information.

Links to consent forms in DocuSign or REDCap that do not divulge sensitive information can be sent via regular email – e.g., while speaking with a potential subject or their LAR, you can email them a link directly.

Study teams that implemented the original March 2020 memo and have not yet updated studies under direct UMMS IRB oversight must submit a Modification to bring their recruitment and consent procedures up to date **by April 30, 2021**.

Investigators conducting industry-sponsored research or research reviewed by an external IRB (not the UMMS IRB) should continue to obtain prior approval for all consent procedures that do not involve a subject signing a paper form and providing that signed form to the study team prior to the start of research procedures.

ALTERNATIVES TO SIGNED PAPER CONSENTS

REDCap

FDA guidance states: *When an electronic system that is Part 11 compliant is not available, regulated entities must have an alternate means of obtaining required signatures (e.g., handwritten wet ink signatures executed on documents, handwritten stylus or finger-drawn signatures executed on electronic documents that are then printed or appropriately witnessed).*

Although the standard UMMS REDCap instances are not 21 CFR Part 11 compliant, REDCap does support handwritten stylus or finger-drawn signatures that are executed on electronic documents and that can then be printed or appropriately witnessed.

Links to consent forms in REDCap that do not divulge sensitive information can be sent via regular email – e.g., while speaking with a potential subject or their LAR, you can email them a link directly and walk them through the consent.

Copies of consents that are personally signed and dated by subjects or their LARs should be sent to them via mail or secure email or individuals should be provided a means to download copies from REDCap.

Each subject's study file should include documentation of the consenting process such as a progress note that documents how informed consent was obtained, that the subject was given sufficient time to review the consent, that all of the subject's questions were answered, that informed consent was obtained prior to participation in the trial, and that a copy of the signed consent was given to the subject.

DocuSign

Links to consent forms in DocuSign that do not divulge sensitive information can be sent via regular email – e.g., while speaking with a potential subject or their LAR, you can email them a link directly and walk them through the consent.

Until there is a UMMS instance of DocuSign that is 21 CFR Part 11 compliant, DocuSign should not be used for FDA regulated research.

Subject or LAR signs consent and transmits a photo of the signature block per FDA guidance

- Study team shares an unsigned consent form with the subject or their LAR
- Study team conducts the consent process by call or video call following a standard process
    - Identify who is on the call
    - Review the informed consent document and answer any questions
    - The subject or LAR verbally confirms that their questions have been answered, that they would like to participate in the trial, and that they have signed and dated the informed consent document that is in their possession
- A photograph of the signed consent form is taken and is provided to the investigator
    - Signature blocks that include sensitive information should be transferred using secure means (e.g., secure email)

- Study team enters photograph into the study records along with an attestation that states how the photograph was obtained and that it is a photograph of the informed consent document signed by the subject or LAR

Subject or LAR signs consent with independent witness attestation instead of photo per FDA guidance

- Study team shares an unsigned consent form with the subject or their LAR
- Study team conducts the consent process by call or video call following a standard process
    - Identify who is on the call – including the required independent witness
    - Review the informed consent document and answer any questions
    - The subject or LAR verbally confirms that their questions have been answered, that they would like to participate in the trial, and that they have signed and dated the informed consent document that is in their possession
- When using a witness, documentation in the trial records includes: (1) a signed and dated attestation by the witness who participated on the call that the subject or LAR confirmed their agreement to participate in the trial and signed the informed consent document; and (2) a signed and dated attestation by the investigator/designee stating why the signed informed consent document was not retained (e.g., due to potential contamination of the document by infectious material)

Subject or LAR receives consent but is unable to print it out or sign it electronically with independent witness attestation per FDA guidance

- Study team shares an unsigned consent form with the subject or their LAR
- Study team conducts the consent process by call or video call following a standard process
    - Identify who is on the call – including the required independent witness
    - Review the informed consent document and answer any questions
    - The subject or LAR verbally confirms that their questions have been answered and that they would like to participate in the trial
- Subject or LAR signs and dates a blank piece of paper with a written statement that they voluntarily agree to participate in Protocol # and Brief Title, and then provides that document to the study team by mail, (secure) email, or in person at a later visit
    - Protocol titles that include sensitive information should be transferred using secure means (e.g., secure email)
- Independent witness signs and dates attestation that patient confirmed agreement and signed paper
- Consent documentation once received is appended to a copy of the consent document that was reviewed with the subject or their LAR
- If consent documentation will be received after research procedures are initiated, the case history for each trial participant must document that informed consent was obtained prior to participation in the trial

Please contact Allison Blodgett, Director of IRB Operations (Allison.Blodgett@umassmed.edu), with any questions or concerns.