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 28, 2020
(*Reissued March 31, 2020, to reflect updated FDA guidance announced March 30, 2020*)

RE: **HRP-803 INVESTIGATOR GUIDANCE: Documentation of Informed Consent – Temporary exceptions for COVID19 therapeutic trials**

This memo affirms the need to document consent in writing when required.

For patients in isolation who are able to provide informed consent and for whom the COVID-19 infection control policy prevents removal of a signed consent document by the patient from the hospital room, the following FDA guidance applies:

FDA regulations generally require that the informed consent of a participant be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent (21 CFR 50.27(a)). In light of COVID-19 infection control measures, the following procedure would satisfy documentation of this requirement if the patient signing the informed consent is in COVID-19 isolation:

• If the technology is available, electronic methods of obtaining informed consent should be considered
• When it is not possible to obtain informed consent electronically, the sponsor should consider taking the following steps:

1. An unsigned consent form is provided to the patient by a heath care worker who has entered the room
2. If direct communication with the patient in isolation is not feasible or safe, the investigator (or their designee) obtains the patient's phone number and arranges a three-way call or video conference with the patient, an impartial witness, and if desired and feasible, additional participants requested by the patient, (e.g. next of kin)
3. To ensure that patients are approached in a consistent fashion, a standard process should be used that will accomplish the following:
    - o Identification of who is on the call
    - o Review of the informed consent with the patient by the investigator (or their designee) and response to any questions the patient may have
    - o Confirmation by the witness that the patient's questions have been answered
    - o Confirmation by the investigator that the patient is willing to participate in the trial and sign the informed consent document while the witness is listening on the phone

o Verbal confirmation by the patient 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.

If the signed informed consent document cannot be collected from the patient's location and included in the study records, FDA considers the following two options acceptable to provide documentation that the patient signed the informed consent document:

• Attestations by the witness who participated in the call and by the investigator that the patient confirmed that they agreed to participate in the study and signed the informed consent
OR
• A photograph of the informed consent document with attestation by the person entering the photograph into the study record that states how that photograph was obtained and that it is a photograph of the informed consent signed by the patient.

A copy of the informed consent document signed by the investigator and witness should be placed in the patient's trial source documents, with a notation by the investigator of how the consent was obtained, e.g. telephone. The trial record at the investigational site should document how it was confirmed that the patient signed the consent form (i.e., either using attestation by the witness and investigator or the photograph of the signed consent). The note should include a statement of why the informed consent document signed by the patient was not retained, e.g., due to contamination of the document by infectious material.

If the patient is unable to provide informed consent and there is a legally authorized representative, investigators must obtain consent from the participant's legally authorized representative in accordance with 21 CFR 50.27(a).

For patients in isolation <u>who are unable to provide informed consent</u> and for whom the COVID-19 infection control policy prevents visitors, **this memo permits enrollment into COVID19 therapeutic trials with documentation of verbal consent from the subject's legally authorized representative (LAR) when either the subject or the legally authorized representative (LAR) could not practicably document consent in writing.** The investigator (or their designee) obtains the LAR's phone number and arranges a call or video conference with the LAR and an impartial witness. To ensure that LARs are approached in a consistent fashion, a standard process should be used that will accomplish the following:

o Identification of who is on the call
o Review of the informed consent with the LAR by the investigator (or their designee) and response to any questions the LAR may have
o Confirmation by the witness that the LAR's questions have been answered
o Confirmation by the investigator that the LAR is willing to consent to the patient's participation in the trial while the witness is listening on the phone
o **The individual obtaining consent must document the informed consent process, including the name of the impartial witness in the source document. In addition, steps should continue to be taken to document consent in writing as soon as possible.**

Study teams must also obtain prior permission of the sponsor(s) and, if applicable, the external reviewing IRB.

Informed consent of the subject or the subject's LAR (when applicable) is still required prior to any research procedures being conducted. This memo modifies temporarily the requirement to document consent in writing in COVID19 trials only.

The memo is issued in accordance with *FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic Guidance for Industry, Investigators, and Institutional Review Boards (March 2020)* https://www.fda.gov/media/136238/download:

> *Sponsors, clinical investigators, and IRBs should consider establishing and implementing policy and procedures, or revise existing policy and procedures, to describe approaches to be used to protect trial participants and manage study conduct during possible disruption of the study as a result of COVID-19 control measures at study sites. Changes to policy and procedures could address, but not be limited to, impact on the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and changes in investigator(s), site staff, and/or monitor(s) secondary to travel restrictions, quarantine measures, or COVID-19 illness itself. Policy and procedures should be compliant with applicable (regional or national) policy for the management and control of COVID-19. Depending upon the nature of the changes described above, a protocol amendment may be required under the applicable regulations*.

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