Conducting Research During the COVID-19 Pandemic

The information in this presentation comes from *FDA Guidance on the Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency* updated on April 16, 2020.

According to the FDA, the policies outlined in the guidance remain in effect only for the duration of the COVID-19 public health emergency.

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Obtaining Informed Consent & HIPAA Authorization Remotely

COVID-19

1) Submit a modification to the IRB adding a remote consent process to the protocol:
   - If research involves only minimal risk, request a waiver of documentation of consent (waiver of the requirement for a signature on the consent document.)
   - If a HIPAA Authorization (Form B) is needed, request a waiver of the signature requirement on the HIPAA Authorization.

2) Consider the technology you will use to conduct the consent process:

- UM IT recommends Zoom for Healthcare
  - To access this HIPAA-compliant form of ZOOM, contact the TeleHealth team at telehealth@miami.edu.
- If you cannot use Zoom, arrange a three-way call with the potential participant, an impartial witness, and if desired and feasible, additional people requested by the participant, (e.g. next of kin)

Remote Consent & Authorization

3) Arrange the time and communication method for the consent process for a new or existing participant, if the process is for reconsent.
   - Send a copy of the consent document via secure email or U.S. Mail.
   - Arrange for a witness to attend and witness the consent discussion.
   - Let the participant know that a witness will join the consent meeting.
   - Set up a Zoom meeting or 3-way call and send an invitation to the attendees.

Remote Consent & Authorization

4) During meeting:
   - Identify everyone on the call.
   - Review the informed consent with the participant, answer the participant's questions and ask questions of the participant to confirm comprehension.
   - Ask the participant if s/he consents to participate/continue participation.
   - If the participant agrees, ask him/her to sign and date the consent document.
   - If using 3-way call, ask the participant to confirm s/he signed & dated the document.

Remote Consent & Authorization

5) Follow the steps above4 to obtain a HIPAA authorization from the participant.
6) Ask the participant to scan or take a picture of each page of the documents and email the signed/dated documents to the study team. As an alternative, the research could establish a “UM Box” location for uploading the consent document.
7) If the participant is unable to take a picture, document the circumstances.
8) The person conducting the consent process should sign and date a copy of the consent document.

Remote Consent & Authorization

9) The witness should sign & date on the witness line of a copy of the consent document.

10) The person conducting the consent process should document the purpose for the remote consent (COVID-19), and each step of the process. The note should explain why the research team doesn't have the signed and dated document.

Documenting the Remote Consent Process

1) The originals of the informed consent document signed by the investigator and witness should be placed in the participant's research record.
2) The person obtaining consent should document how s/he confirmed that the patient consented and signed the consent form. The note should include a statement indicating why the informed consent document signed by the participant was not retained, (e.g., due to contamination of the document by infectious material.)
3) If the participant cannot send a picture of the signed document, the person obtaining consent should document why a copy of the signed document is not available. See example on next slides.

Example of Documentation:

Informed consent was obtained on Date at Time. The participant could not come to the site for the consent process due to COVID-19 social distancing requirements. A copy of the consent document was provided to the prospective participant before the consent discussion.

The consent process was performed by phone/ZOOM. The individuals attending the discussion were: (list the names of the individuals). The person obtaining consent explained the research to the participant and answered the participant's questions. The person obtaining consent asked the participant questions to ascertain whether the s/he understood the study, and the participant was able to answer the questions.

Example (Cont.):

The participant voluntarily agreed to participate. The subject/LAR signed and dated the consent document. The research team was not able to obtain the original signed consent document because consent was obtained remotely, and the document may transmit the COVID-19 infection. After signing the consent document, the participant took a picture and sent it to the research team/ OR The participant was unable to send a picture of the document. A witness observed the entire process.

The person obtaining consent should then add similar documentation about the HIPAA authorization.

Administering Investigational Product (IP) at an Alternative Location

COVID-19

1) The FDA recommends that PIs contact the appropriate FDA review division to discuss IP administration at an alternative site
2) PIs must obtain prior IRB approval for this revised procedure.
3) PIs must consider whether shipping the IP to the alternative location is safe & feasible.
4) Trained personnel must administer the IP under supervision of an MD with experience in the class of products involved and assure subject safety that is equal to administration at a trial site.
5) Local health care providers (HCPs) who are administering drugs in a manner that does not differ from their normal clinical practices are not sub-investigators.

6) These HCPs should be listed in research site records, such as a log of activities delegated by the PI.
7) HCPs performing study-specific research procedures or assessments that represent a direct and significant contribution to the clinical data are considered sub-investigators and must be listed on the 1572.
8) The PI must supervise shipping of the IP to assure accountability and quality.
9) The PI should ask participants to authorize access to medical records from the HCP to collect trial-related data pertaining to the IP administration.

Replacing IP With a Commercial Product When the Participant Cannot Obtain the Drug from the Site

COVID-19

1) A PI can prescribe the drug instead of shipping the product directly to the patient when:
   a) The participant cannot come to the trial site to obtain the investigational product.
   b) The clinical trial is investigating an FDA-approved drug, and
   c) The clinical trial does not require blinding.
2) The FDA recognizes that the commercial product will not have the following statement on the packaging: “Caution: New Drug--Limited by Federal (or United States) law to investigational use.”

3) During the COVID-19 Emergency, the FDA intends to exercise flexibility without sponsors needing to seek a waiver of the investigational labeling requirements.

4) The FDA will not object if the sponsor reimburses the participant for the cost of the drug obtained from a commercial venue.

Question?

Contact the HSRO **Help Desk**

For regulatory questions, please contact us at 305-243-3195

or e-mail us at hsro@miami.edu