CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

JOB AID FOR REOPENING HUMAN SUBJECTS RESEARCH

Study teams should consider the points below as they prepare to resume in-person human subjects research.

1. Activities that can be conducted remotely should continue to be conducted remotely.

Investigators are permitted to use remote procedures for enrolled subjects, such as phone or Zoom interviews, without obtaining prior approval from the IRB. These changes, however, must be submitted promptly as Reportable New Information, and they must be incorporated into the Investigator Study Plan at the next regularly scheduled Modification or Continuing Review.

2. Study teams must adhere to IRB approved recruitment procedures.

UMMS does not permit cold-calling patients to recruit them for participation in research. IRB approved recruitment generally involves patients being contacted first in writing by someone they recognize as having access to their protected health information and then by a member of the study team by phone. These recruitment letters and scripts continue to require prior IRB review and approval.

If a study is already approved for a provider to ask the patient if it is ok for a researcher to approach them, the approach can be replaced with phone contact or Zoom. Unless the patient is contacting the researcher or has signed an authorization to contact form, there must be an IRB approved HIPAA waiver in place to permit the release of the patient's contact information to researchers.

3. Use remote consent procedures if possible.

Plan to have informed consent discussions by phone, Zoom, FaceTime or similar means, and share unsigned consent materials by mail, fax, email, or other electronic means.

Consent forms that potentially disclose stigmatizing information, such as mental health or HIV diagnoses, may not be sent via regular email. Consent forms that relate to non-sensitive health information can be sent via regular email if you explain to subjects that the information is not secure, and they provide affirmative agreement to using this method anyway. The conversation should be documented appropriately.

4. Document consent in writing.

This requirement does not apply if the IRB has approved a waiver of written documentation of consent for your minimal risk study.

REDCap supports ways to obtain a "wet" signature from a subject electronically. Although not offered through UMMS IT, Docusign also supports e-consent. At this time, neither is necessarily Part 11 compliant, so if this is a requirement for your FDA regulated research, make sure you are using an appropriate version of the software or use alternative methods.[1]

Subjects can send back a signed form by mail or a signed signature page by fax.

Subjects can send back a snapshot of a signed signature page by regular email if you explain to subjects that the information is not secure, and they provide affirmative agreement to using this method anyway. The conversation should be documented appropriately. Secure email is preferred.

Otherwise, follow the steps in *HRP-803 Investigator Guidance - Documentation of Informed Consent- Temporary Exceptions for COVID19 Therapeutic Trials* for documenting consent with a witness https://www.umassmed.edu/globalassets/ccts/other/resources/hrp-803-temporary-covid19-guidance-31mar2020.pdf

5. Make sure the study team is knowledgeable of current institutional requirements, including those related to employee testing, social distancing, visitor and guest policies, and providing own PPE.

UMMS information is updated regularly here:

- https://umassmed.edu/coronavirus
- https://www.umassmed.edu/ccts/covid-19/

6. Make sure the study team has coordinated with clinical departments before resuming in-person contact.

Departments will differ as they ramp up patient care operations. Principal Investigators should help study teams navigate the resumption of research in a manner that is respectful of clinical needs.

7. Screen study subjects for SARS-CoV-2 exposures and symptoms by phone a day ahead of research visits and again at the start of a visit.

If this process is conducted as part of clinical care, the research team does not have to repeat it.

A telephone script for the return of study participants is attached. This is intended as a tool for research teams and may be adjusted as needed. Screening via the telephone script does not require prior IRB review and approval.

[1] If your FDA regulated study is utilizing e-consents on REDCap, Docusign, or another platform provided through an outside sponsor or CRO, you will need to confirm Part 11 compliance with them.