COVID-19: CLINICAL RESEARCH MONITORING GUIDANCE

Temporary Policy: University of Utah Guidance for Site Monitoring of Clinical Investigations During COVID-19
Revised: September 1, 2020

The Office of the Vice President for Research (VPR) is providing guidance related to on-site monitoring (including study initiation visits) and remote monitoring by external sponsors. Due to the COVID-19 pandemic, University of Utah leaders are taking precautions to protect our research participants, research personnel, and the broader University community. Remote monitoring is preferred, but this policy revision permits on-campus site monitoring.

Because this policy has the potential to impact monitoring plans, it is recommended that research teams maintain a copy of this dated guidance as a Note to File in their study regulatory binder and provide to Sponsor/CRO as needed.

Access to the EMR

Direct access to the electronic medical records at the University of Utah is limited. Faculty and staff are unable to provide direct EMR access to external entities at this time. Remote monitoring outside of the EMR may be requested with appropriate lead time and must be approved and conducted by Investigators and their relevant department on a case-by-case basis.

Approaches

Investigators or designees may provide EMR documents for a particular subject during a specified period, in the format of a PDF document via EpicCare link. Investigators or designees may also provide time-limited document access via EpicCare Link, UBox, and Zoom (HIPAA-compliant version only). If requested, other source documents can be scanned and submitted for the support of remote monitoring (e.g., regulatory documents, source forms, study questionnaires, etc.).

Investigational Drug Service monitoring may occur remotely when requested and scheduled appropriately.

It may be necessary to update clinical research agreements or contracts to accommodate the time and effort necessary for setup and conduct of remote monitoring visits.

On-Campus Site Monitoring Visits

The University of Utah acknowledges that restrictions on in-coming business travel impact the operational business needs of some research sponsors and designee organizations. External requests

Version dates: v1 for distribution 08/10/20; v2 08/27/20
Scheduling the Visit

1. Inform the monitor or sponsor representative that they will be contacted 24-48 hours prior to their visit to confirm that they are disease-free and ask about any COVID19 symptoms.
2. Inform the monitor or sponsor representative that they are required to complete the Visiting Traveler Self-Reporting Form 24 hours prior to arrival on campus.
3. Inform the monitor or sponsor representative that they will be required to wear a mask at all times while they are on campus unless they are in a room/office by themselves.

Pre-screening 24-48 hours in advance of on-site visit:

Study teams must call all visitors 24-48 hours prior to a scheduled visit to check for COVID19 symptoms, to remind them of the visitor restrictions and what to expect when they arrive for their visit.

All visitors will be required to complete the Visiting Traveler Self-Reporting Form here, 24 hours prior to visit: https://redcap01.brisc.utah.edu/ccts/redcap/surveys/?s=yL6LiqxcjD

Visits will not be approved for anyone answering “Yes” to COVID-19 symptom and exposure pre-screening questions. Visitors will not be re-screened for an on-site visit until they are at least 21 days out from a confirmed diagnosis of COVID-19 or symptom onset or from the time they were in close contact with an individual with confirmed diagnosis of COVID-19.

All visitors must be healthy--free from fever, cough or colds, body aches, or stomach virus symptoms and living with persons who are also healthy.

Do not come on-site if you have ANY of the following symptoms (even if you think they are symptoms of seasonal allergies):

- Fever
- Cough
- Sore throat
- Shortness of breath
- Wheezing
- Loss of smell or taste
- New onset of diarrhea
- Congestion (stuffy nose)
- Runny nose
- Muscle aches and pains
- Repeated shaking with chills
- Headache

Monitoring Procedures

Visitors will have to meet the current Utah State and Health authorities’ requirements, including but not limited to maintaining at least 6 ft distance between individuals, wearing a face covering at all times (even when alone), and use of frequent hand hygiene.

Monitors must utilize dedicated monitoring rooms that have been adapted to meet the 6 feet physical distancing restrictions. Monitors are not allowed to be seated elsewhere during their time on-site. Study teams are to notify facilities of specific rooms that will be utilized and are to ensure that appropriate cleaning measures are in place. When research staff are hosting an on-site visitor, such as a sponsor or monitor, they must remain on-site at all times until the visitor has departed campus.

NOTE: Monitors are not allowed to enter the hospital or any clinical space during the visit.

- Research staff are encouraged to minimize contact with the visitor and use phone, email, or teleconference to communicate as much as possible during the visit.
- Monitors are not allowed in IDS Pharmacies as they are located within HCI clinics. Investigational Pharmacy records will be provided/obtained as follows:
IDS staff will provide study teams with copies of drug accountability forms and temperature logs if IDS is provided sufficient notice of visit (at least 10 business days).

- All other IDS research records, including IDS protocol training records, must be obtained by study staff.
  - Study Staff: Please contact IDS to make an appointment to make copies of these records for your monitor.

**Relevant Policies Statement**

This temporary policy, “*University of Utah Guidance for Site Monitoring of Clinical Investigations During COVID-19*”, is separate from the *Utah Health Revised Visiting Policy* and from CDC guidance on *Travel during the COVID-19 Pandemic*.

Visit the Office of the Vice President for Research for complete University Guidance:
https://research.utah.edu/