COVID-19: CLINICAL RESEARCH MONITORING GUIDANCE

Temporary Policy: University of Utah Guidance for Site Monitoring of Clinical Investigations During COVID-19
August 10, 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. All on-site monitoring visits are currently restricted until further notice.

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.

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/

For distribution on Monday August 10, 2020