Monitoring Visits

PURPOSE

The purpose of this SOP is to outline the requirements for monitoring performed on research studies conducted at UAHS.

RESPONSIBLE ROLES

All UAHS staff members are expected to adhere to these procedures.

EXPECTATIONS

1) The rights and well-being of human subjects are protected.
2) The monitor is responsible for routine monitoring activities for the clinical trials as a continuous review of the conduct of the trial, including adherence to study design and documentation of appropriate reporting of related toxicities and adverse events.
3) The reported trial data is accurate, complete and verifiable from source documents.
4) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), GCP and the applicable regulatory requirements.
5) Frequency and requirements of monitoring is determined by the clinical trial.

PROCEDURES

1) The monitor will notify the PI and the study team of the scheduled monitoring visit in writing at least two weeks in advance of the visit.
2) Monitor will communicate with study team to determine system access needs. Study team will submit access requests on the monitor's behalf according to UAHS and Banner Health procedures.
3) The study team will ensure that all data is entered completely and accurately in the CRFs and is available for review.
4) The monitor will conduct an exit interview, as applicable, with the PI and applicable research staff to discuss findings of the monitoring visit.
5) The monitor will provide a written report of findings to the PI and applicable research staff. UAHS will address any action items in a timely manner.

REMOTE MONITORING (if applicable)

1) Remote monitoring may take place prior to visit, or entire visit may be conducted remotely.
2) Requested documents maintained in paper format should be scanned as searchable PDF files and PHI should be redacted.
3) Remote monitoring may include:
    a) Video or phone call with UAHS study staff. HIPAA-compliant video conferencing is available if subject documents will be reviewed on the call.
    b) Review of source documents scanned into HIPAA-compliant and 21 CFR Part 11 compliant system.
    c) May require direct access to EMR to confirm source documentation.
    d) Off-site review of eCRFs done in electronic data capture system.

REFERENCES

DEFINITIONS AND/OR ACRONYMS

CRF: Case Report Form

eCRF: Electronic Case Report Form

EMR: Electronic Medical Record

21 CFR Part 11: Code of Federal Regulations regarding Electronic Records; Electronic Signatures for FDA-regulated research

GCP: Good Clinical Practice

HIPAA: Health Insurance Portability and Accountability Act

PDF: Portable Document Format

PHI: Protected Health Information

PI: Principal Investigator

UAHS: University of Arizona Health Sciences

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1.0	01/17/2023	Gustavo Cornejo	Draft update