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UCLA Clinical Research External Monitoring & Auditing Policy HS 9207 (NEW)

UCLA Policy XXX:	**UCLA Clinical Research External Monitoring & Auditing Policy**
Issuing Officer:	TBD
Responsible Dept:	UCLA Office of Clinical Research
Effective Date:	TBD
Supersedes:	New

I. PURPOSE & SCOPE

This Policy is intended to set forth the requirements for clinical research monitoring and auditing of UCLA clinical research studies by external entities. This policy applies to all clinical research studies, regardless of funding and/or support including, but not limited to, all NIH, other federal, industry, foundation, departmental sponsored, and/or unfunded clinical research studies subject to external monitoring and/or audit.

II. DEFINITIONS

"On-Site Monitoring" is the review of research related records conducted by an auditor/monitor at the site in which study conduct and/or management may take place. The FDA describes on-site monitoring as "an in-person evaluation carried out by sponsor personnel or representatives at the sites at which the clinical investigation is being conducted."

"**Remote Monitoring or Centralized Monitoring**" as described by the FDA, is, "a remote evaluation carried out by sponsor personnel or representatives (e.g., clinical monitors, data management personnel, or statisticians) at a location other than the sites at which the clinical investigation is being conducted."

"**UCLA Health System Space**" is any location owned or operated by UCLA hospitals and/or UCLA outpatient clinics, managed by either the UCLA Hospital or UCLA Faculty Practice Group utilized to provide clinical care to UCLA patients. This includes, but is not limited to, Ronald Reagan UCLA Medical Center, Santa Monica Medical Center, UCLA Orthopaedic Surgery, Resnick Neuropsychiatric Hospital, ambulatory sites, and the UCLA Faculty Practice Group.

III. POLICY STATEMENT

UCLA is committed to supporting clinical research monitoring and auditing while maintaining the privacy and confidentiality of research participants and in compliance with HIPAA rules and regulations. UCLA supports the use of remote monitoring/auditing for the majority of clinical research reviews with the allowance of on-site reviews for essential visits only, which is consistent with FDA guidance encouraging greater use of centralized monitoring practices, where appropriate, and less emphasis on on-site monitoring. To this end, and to the extent feasible, remote monitoring terms and conditions will be prospectively negotiated in clinical trial and clinical research agreements.

IV. PROCEDURE

A. Remote Monitoring / Auditing

1. HealthLink Access
   HealthLink Access for electronic medical record (CareConnect) review is managed through the Clinical and Translational Science Institute (CTSI) Office of Regulatory Affairs. Remote monitoring of clinical research through HealthLink requires execution of the UCLA HealthLink Electronic Health Record Access Participation Agreement. Execution of the agreement is managed by Clinical Trials Contracts & Strategic Relations (CTCSR). Once the terms, applicable fees and conditions of the remote monitoring agreement have been executed, the study monitor/auditor completes the necessary confidentiality and user forms and training. Provisioning of the monitor/auditor may be completed once these prerequisites have occurred. Only records for research participants selected for monitoring are provided in the access. Any printing or downloading of records will result in access termination (a one-time path to restore access includes recompletion of the UCLA HealthLink Electronic Health Record Access Participation Agreement, recompletion of the HealthLink remote monitor training, and a reprovisioning fee).
   Sponsors and CROs must execute the remote monitoring agreement at the time of initial study contract execution. For legacy studies, remote monitoring agreements should be executed as soon as possible to avoid delays in monitoring/auditing.
   For research studies where a study sponsor is NOT obligated by the FDA to monitor/audit the study source records, sponsors are generally not allowed to conduct monitoring of study records. Sponsors may request a special exception with the Office of Compliance. If approved, sponsors may only conduct monitoring through the remote access process.
   Provisioning timelines, fees and key considerations related to remote monitoring will be made available on the ResearchGo website www.researchgo.ucla.edu and are subject to change and updates.

2. Review of documents not stored in CareConnect

The current methods approved for remote monitoring/auditing of records not stored in CareConnect are:

a. Upload of redacted documents to UCLA Health Box

b. "Over the Shoulder" Zoom access

c. Other methods may be utilized with approval by the UCLA Office of Compliance Services

A. On-Site Monitoring / Auditing

1. On-site visits should only be scheduled when it is essential to participant safety and/or study integrity for FDA regulated studies only. (e.g., critical data locks, oral drug or device accountability, FDA inspections, legacy studies initiated prior to 2020, etc.) where reasonable efforts to facilitate remote monitoring are unsuccessful and/or not feasible.

2. For research studies where a study sponsor is NOT obligated by the FDA to monitor/audit the study source records, sponsors may not conduct on-site reviews.

3. Sponsors / CROs must provide reasonable, written rationale explaining why the objectives of the visit cannot otherwise be accomplished virtually.

4. For visits in non-Health System space, the study Principal Investigator must obtain Department Chair or Division Chief (or designee) written approval permitting the request for an on-site visit.
5. For visits in Health System Space, the study Principal Investigator must obtain Department Chair or Division Chief (or designee) written approval permitting the request for an on-site visit. In addition, approval must be obtained from the UCLA Office of Compliance Services as outlined on the ResearchGo website.
6. Where possible, the monitor/auditor should request the visit at least 4 weeks in advance to allow for the study team to arrange for the appropriate physical space to support the visit.
7. UCLA requirements for visitors must be followed for each monitor/auditor. Current guidance, which is subject to change, is available on the UCLA website.
8. Sponsor/CRO monitors whose visits do **NOT** entail patient interaction, patient care, sales solicitation, and other vendor related activities are subject to UCLA Campus and UCLA Health policies for visitors:

- **UCLA Campus visitor guidelines:** https://covid-19.ucla.edu/information-for-visitors/
- **UCLA Health visitor COVID guidelines:** https://www.uclahealth.org/conditions-we-treat/coronavirus/visitor-guidelines
- **UCLA Health preparing for a visit:**

https://www.uclahealth.org/patients-families/prepare-your-visit

A. **Activities That Are Not Considered Monitoring / Auditing**

As it relates to this policy, the following activities are not considering clinical research monitoring and/or auditing visits subject to this policy.

These visits should be conducted in compliance with all UCLA visitor policies at the time of the visit:

1. Site initiation visits.
2. Site selection visits.
3. Clinical procedure observations.

These activities should follow UCLA guidance and policies available at: https://medschool.ucla.edu/coronavirus-information/ramp-up-faqs

A. **Guidance Documents and Frequently Asked Questions**

Guidance documents and frequently asked questions are available on www.researchgo.ucla.edu.

I. **REFERENCES**

FDA Guidance for Industry "Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring" (https://www.fda.gov/media/116754/download)