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| COMIRB #: |  |
| Principle Investigator: |  |
| Study Title: |  |
| Version Date: |  |

1. **BACKGROUND/SCOPE:**

See COMIRB-approved protocol and application.

1. **DEFINITIONS**

University: University of Colorado Denver | Anschutz Medical Campus

COMIRB: Colorado Multiple Institutional Review Board

1. **RESPONSIBILITIES:**
2. **University PI:**
   1. Oversee the development, submission and COMIRB approval of the research protocol and associated study documents.
   2. Oversee the development, submission and COMIRB approval of any necessary Amendments, Continuing Reviews, Reportable Events, and Study Closure.
   3. Identify qualified co-investigators and study personnel with appropriate expertise to participate in the protocol. Ensure all personnel are qualified through training and experience.
   4. Ensure that appropriate training on the protocol and protocol amendments is provided to all members of the multi-center study teams prior to site initiation and for the duration of the study.
   5. Ensure all sites and research team members are familiar with responsibilities for monitoring the study and reporting serious adverse events, protocol deviations/violations, and serious or continuing noncompliance.
   6. Ensure all sites and research team members are familiar with relevant COMIRB and University policies.
   7. Ensure inter-institutional agreements/contracts are in place to address:
      1. How participant information is sent between Participating Institutions and the Lead Site; and
      2. Financial arrangements for the conduct of the study.
   8. Designate and delegate a qualified study team member to manage the administrative responsibilities related to this oversight plan such as:
      1. Develop organization aids and checklists as needed to manage regulatory requirements and research start up activities.
      2. Prepare and maintain protocol specific case report forms.
   9. Document the delegation of research specific authorities.
   10. Oversee the development of data collection forms/case report forms.
   11. Develop the monitoring plan and monitor research progress, overall protocol conduct and data at all research locations in accordance with regulatory, COMIRB and University requirements.
   12. Establish regular communications (*e.g.*, convened meetings, teleconferences, emails, *etc.*) with all Participating Institutions and research team members to discuss research progress and protocol/subject-related issues. The frequency should be consistent with the protocol risks and as outlined in the multi-center data and safety monitoring plan. Maintain documentation of all communications.
   13. Maintain active oversight of protocol conduct. During extended absences, ensure this role is temporarily delegated to another person according to University and COMIRB policies.
   14. Monitor study progress and subject accrual. Carry out the plan to monitor Participating Institutions either by on-site inspection of selected subject records or through the review of source documents and research records submitted to the Lead Site as outlined in the protocol.
   15. Distribute protocol updates and COMIRB approvals to the Participating Institutions as needed.
   16. Promptly submit all Reportable Events (*e.g.*, SAEs, serious or continuing noncompliance, protocol deviations/violations) to COMIRB and/or other regulatory authorities when they meet the appropriate reporting requirements.
   17. Ensure prompt responses to any inquiries from regulatory agencies, COMIRB, other University oversight offices or committees, and Participating Institutions.
   18. Distribute SAE safety reports to each Participating Institution as required.
   19. Maintain any necessary regulatory documentation from each Relying Institution to confirm that each Relying Institution is complying with University and COMIRB regulatory requirements.
3. **Relying PIs:**
   1. Submit approved protocol and any other required documents to their local IRB for reliance on COMIRB.
   2. Submit any other information to the relying IRB as required by the relying IRB.
   3. Document the delegation of research specific authorities.
   4. Identify a primary contact for their site for communications with the Lead Site.
   5. Submit data according to protocol.
   6. Promptly provide information to the Lead Site regarding:
      1. Changes in research team members.
      2. Follow-up and/or corrective action plans for monitoring queries and audit findings.
   7. Report all serious adverse events (SAEs) to the Lead Site per the protocol and COMIRB policies.
   8. Submit deviation requests and protocol violations to the Coordinating Center per the UCD IRB requirements and the local IRB, as appropriate, per local requirements.
   9. Ensure research team members have the current version of the protocol and any other study documents.
   10. Conduct the protocol as approved and according to ethical, regulatory, and protocol-specific requirements.
   11. Maintain regulatory and research files for the duration of research.
   12. Meet with the Lead PI and study team as appropriate to discuss research activities.
   13. Participate in quality assurance activities and meet with study monitors or auditors at the conclusion of their visits to review findings.
   14. Prospectively notify the Lead PI of all scheduled audits which involve the protocol. Provide the Lead PI with a copy of the final audit report and corrective action plans, as applicable.
4. **COMMUNICATION PLAN**

[Specify schedule/frequency of meetings with Relying Sites study teams (*e.g.*, convened meetings, teleconferences, emails, *etc.*).]

1. **APPLICABLE REGULATIONS, POLICIES AND GUIDELINES:**

* 45 CRF 46 – Protection of Human Subjects
* COMIRB Policies and Procedures