| **Responsibility Assignment Matrix upon Award Notification (start-up activities)** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Tasks** | **PIs** | **Co-Is** | **Proj**  **Mgr** | **Clin**  **Supv** | **UNC**  **IT** | **Business Office** |
| 1. Notify UNC team of award; review all start-up requirements, activities, and deadlines; assign responsibilities using task list; monitor to ensure compliance | R, A | I | I | I | I | S |
| 1. Attend conference calls and face-to-face meetings with NICHD to collaboratively finalize protocol | R, A | R, A | I | S, C |  |  |
| 1. Ensure all security deliverables and deadlines are met as stated in contract (may include but not be limited to IT Security Plan, IT Risk Assessment, FIPS 100 Assessment, IT SC&A, Personal Identity Verification, Information Security Training, compliance review by external party, and ensuring access for inspection) | A |  | R, S |  | R |  |
| 1. Initiate IRB submission process as soon as possible; finalize IRB submission when protocol finalized (includes recruitment materials, consents, translations, etc.); manage   ongoing IRB process | A | S | R | S, C |  |  |
| 1. Review personnel needs; identify available personnel and additional personnel needed; write position descriptions and submit for approval; initiate and complete hiring process; orient new personnel and ensure they complete all appropriate training, including IT security, responsible conduct of research, training on protocol, and thorough understanding of team and role on it | A | S | R | R |  | R |
| 1. Ensure compliance with all personnel requirements as stated in the contract, including submitting a roster of personnel, ensuring background checks are carried out according to federal requirements, and ensuring that Project Officer is notified of any new personnel | A |  | R | R |  |  |
| 1. Review needs for materials and supplies; place orders in timely manner to ensure required materials and supplies are available at start of study recruitment | A | S | R | R |  | S |
| 1. Initiate contact with recruitment sites; provide education about protocol and recruitment approach; engage staff in study as much as possible; ensure appropriate clinic site management teams are informed of study | A | S | R | R |  |  |
| 1. Define/finalize chart abstraction process and conduct trial runs to ensure accuracy, quality, integrity, confidentiality, and availability | A |  | R | R |  |  |
| 1. Finalize local placenta and cord blood collection process; ensure team is educated on the process | A | S | S | R |  |  |
| 1. Compile a Manual of Procedures (MOP) and ensure it is kept updated as changes in protocol or practices occur | A | S | R | R |  |  |
| 1. Complete and deliver progress reports quarterly as specified in the contract | A |  | R | S |  | S |
| 1. With NICHD, seek and obtain OMB approval | A, R |  | S |  |  |  |
| 1. Collaborate with DCC on design of report of recruitment and retention; ensure all study staff receive education in appropriate and accurate reporting | A, R | S | R | R |  |  |
| **Legend**  R=Responsible for actually doing the work  A=Accountable overall  S=Supports person(s) responsible  C=Consults or provides input  I=Informed of outcomes or decisions |  |  |  |  |  |

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