Industry Study Activation Workflow Guide for Study Teams

Study Team Action post Pre-Study Meeting:
1. WIRB payment – Confirm sponsor direct pay or pass thru.
2. Finalize Feasibility Assessment, obtain required signatures.
3. Initiate Budget Development:
   (a) Prepare ancillary service requests.
   (b) Based on protocol requirements, estimate PI, Coordinator, and other study staff time.

Study Team Action after receiving Pre-Study Meeting summary:
1. Review draft Coverage Analysis/Billing Plan, request changes as needed.
2. Finalize Coverage Analysis documentation: Obtain PI Signature.
3. Informed Consent – edit as necessary, including:
   a. Edit cost (to participant) section based on final coverage analysis (as needed)
   b. Send to CRS for injury language negotiation with sponsor.
4. IRB/Regulatory – Prepare RAMS and WIRB submission and other regulatory documents.
5. Continue budget development.

Documents Required for SOMCT Initial Review:
1. Draft Budgets – internal and sponsor
2. Supporting materials - ancillary agreements, time/effort grids, WIRB payment
4. Coverage Analysis documents – signed by PI
5. Feasibility Assessment – signed by PI and Department Chair
6. Clinical Trial Agreement (in Word) with any red-line study team edits

Documents Required for SOMCT Final Review:
1. Final budgets – internal and sponsor
2. Signed ancillary service agreements
3. Approved Informed Consent (injury language, cost to participant)
4. CTA - OSP negotiated CTA with final budget & payment updates added by study team per final negotiated budget.

Study Team Actions for Administrative Finalization:
1. Review and finalize RAMS-SPOT submission
2. PI – Initiate RAMS-SPOT approval routing
3. PI- Sign CTA in acknowledgment

Study Team Action to receive Open to Accrual approval in OnCore:
1. Study Team completes all required items on Study Team Task List in OnCore.
2. After the task list is complete, Coordinator Sign-off is completed in OnCore.
For more details see: SOM OnCore Roles & Responsibilities, Item E

Have Questions?
Contact: SOMCT@vcuhealth.org
At any time during this process.

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