SOM Process for Industry Clinical Trial Study Activation

**Purpose:** To outline the SOM process for industry study activation with a focus on increasing efficiency in study activation by overlapping budget and contact negotiation.

**Timing:** At the completion of SOM initial review, SOMCT will initiate contract negotiation by providing OSP with relevant documentation to begin contract negotiation with a sponsor. This will be done concurrently with SOMCT providing study teams initial budget feedback and approval to begin budget negotiation.

For more details see: [Industry Study Activation Workflow Guide](go.vcu.edu/SOMClinRes PDF]

**Process Outline:**

I. Study Team/SOMCT – Pre-study Meeting held

II. SOMCT: Distribute action items in pre-study meeting summary. Study Team begin work on action items.

III. Study Team - submit documents to SOMCT for Initial Review: congruency and budget (SOMCT@vcuhealth.org):
   a. Draft budgets (internal & sponsor) & supporting materials (ancillary pricing/time grids/WIRB payment verification)
   b. Draft informed consent – include injury language and cost sections (responsible payer language) negotiated
   c. Clinical Trial Agreement (CTA) in Word format
   d. Coverage Analysis form(s) signed by the Investigator
   e. Feasibility Assessment form signed by Investigator and Department Chair

IV. SOMCT conducts initial congruency and budget review for financial adequacy.
   a. SOMCT will note required edits on any/all necessary documents and requests follow up with the study team as needed for all action items identified.

V. SOMCT reviews sponsor CTA and makes initial red-line mark-ups and comments in addition to any made at department/study team level.

VI. SOMCT initiates budget & contract negotiation:
   a. Budget – SOMCT provides study team with SOM Budget Review Feedback form, provides approval to begin budget negotiation after any critical adjustments/corrections are made. SOMCT provides study team with current red-line version of CTA.
   b. Contract – SOMCT sends Red-line editable version of CTA and other relevant docs to OSP.
      i. SOMCT transmits CTA to OSP via RAMS-SPOT as “Document for Review”, linked to Funding Proposal (FP).
      ii. SOMCT uploads Protocol, Draft informed consent, executed Coverage Analysis form(s) and Feasibility Assessment under the FP in RAMS-SPOT [ancillary agreements as well if signed at this time point].

VII. Negotiation
   a. Study Team negotiates the budget with sponsor.
   b. OSP negotiates contract (OSP to upload negotiated CTA in RAMS-SPOT for incorporation of final budget terms.)

VIII. Budget / Contract Finalization (order depends on timing)
   a. OSP notifies study team and SOMCT that the CTA negotiation is complete, pending final budget terms.
   b. Study Team submits to SOMCT for final review: internal/sponsor budget, updated final OSP CTA with final budget/payment terms, signed ancillary agreements, approved informed consent.
   c. SOMCT conducts final review; congruency check, approves budget finalization with sponsor.
   d. SOMCT uploads final school-approved budgets & CTA in RAMS-SPOT.
IX. Final Approvals

a. PI/Study team – finalizes RAMS-SPOT proposal and budget smart forms – final budget figures, attachments not already uploaded: Compliance checklist, VCUHS Billing Set-up form, etc.
b. PI reviews/approves submission, initiates FP for approval routing in RAMS-SPOT.
c. SOMPROPOSALS receives FP from PI via RAMS-SPOT: School review/approval.
d. OSP final institutional review/approval in RAMS-SPOT; OSP initiates CTA execution.
e. OnCore Open to Accrual: OnCore Office opens a study after 1) Study team task list is complete, and 2) SOMCT administrative sign-off is complete

Visit the School of Medicine Clinical Research Administration website for additional information: go.vcu.edu/SOMClinRes
For SOM Guidance for Clinical Research Budget Development click here
For SOM Guidance on study team roles and responsibilities in OnCore click here
Note: CRS may be hired to fill the role of “study team” as noted above. Contact: CRSBUDGETS@vcu.edu