

Business Process: Coeus Proposal Development Module

This Business Process describes routing of corporate-funded clinical trial agreements. The corporation may be the Sponsor or the Prime Sponsor.

1. Corporate-funded clinical trials should be routed when the study budget has been finalized.
2. Create a new proposal record in the Coeus Proposal Development Module by entering proposal title, start and end dates of the performance period, and proposal type. Enter "Clinical Trial Corporate" as the Activity Type. Enter the Financial Department that will oversee financial management of the award. Enter the Sponsor and, when applicable, the Prime Sponsor. If Sponsor does not exist in Coeus, PI/Administrator will need to fill out the "Request New Sponsor" form and submit to ORD via the UMB Coeus Website (<http://www.umaryland.edu/coeus/>). Until notification is received from ORD, leave the Sponsor field blank. Enter the Sponsor on the Proposal Detail tab when available but prior to submission for approval.
3. Complete the Organization tab. List all performance sites where study subjects will be seen by UMB investigators and estimate the "% Work Done" for each location. [NOTE: At this point and throughout the process, the record may be saved and the proposal continued later.]
4. Complete the Investigator, Key Person, and Special Review tabs.
5. In the budget module, select OH Rate Type "TDC". Enter budget information using general categories (salary, supplies, other). At minimum, in Period 1, choose cost element "Other Operating Expenses" and enter the anticipated direct cost amount, then calculate and save according to standard procedures. This budget will be carried forward for award budget entry in eUMB Financials.
6. Attach an electronic copy of the clinical study agreement to Narrative Type "Clin_Study_Agreement_Docs" (may be selected multiple times). Attach the Sponsor's protocol to Narrative Type "Clin_Study_Protocol". If the Center for Clinical Trials (CCT) performed a study budget coverage analysis for this study, scan and attach the resulting study budget to Narrative Type

"Clin_Study_Budget" (may be selected multiple times). Attach other relevant documents using Narrative Type "Other" and complete the Module Title field to identify the attachment.

7. If Sponsor payments will NOT cover all research study costs, complete and attach a Cost Sharing Approval Form to Narrative Type "Cost Share Form".
8. Answer Yes-No Questions
9. Validate the proposal using Action → Validation Checks.
10. **Principal Investigator** certifies (on Investigator tab) and submits for approval.
11. ORD reviews and approves.
12. ORD processes the agreement for a chartstring upon receipt of the fully executed clinical trial agreement.