Penn Medicine

Central Research Services – Pre-award Procedures

INTERNAL BUDGET BUILD (3 weeks)

- Upon completing the "CRS New Study Submission Form," the study coordinator/project manager will provide <u>all</u> sponsor documents below:
    o Draft CTA
    o Draft ICF
    o Draft Budget
    o Most-recent Protocol
- The study team will submit requests for all Internal Cost Estimates (IDS, CHPS, CACTIS/CAMRIS, etc.)
- An <u>internal</u> budget will be provided to the study team for review and discussion within 3 weeks.
- During this time, a PennERA record will be created, notifying ORS Legal that there is a new study to be reviewed.

EXTERNAL NEGOTIATION (<90 days)

- Once the internal budget has been compiled, CRS will initiate budget/payment terms with the sponsor or CRO
- Estimated timeline for conclusion is 90 days
- During this period, the study team may be contacted for further budgetary input, based off of sponsor/CRO's counteroffers
- During this period, the study team should have submitted the project for IRB review and received a, IRB Number
    o At this time, please send a completed PRA form to CRS
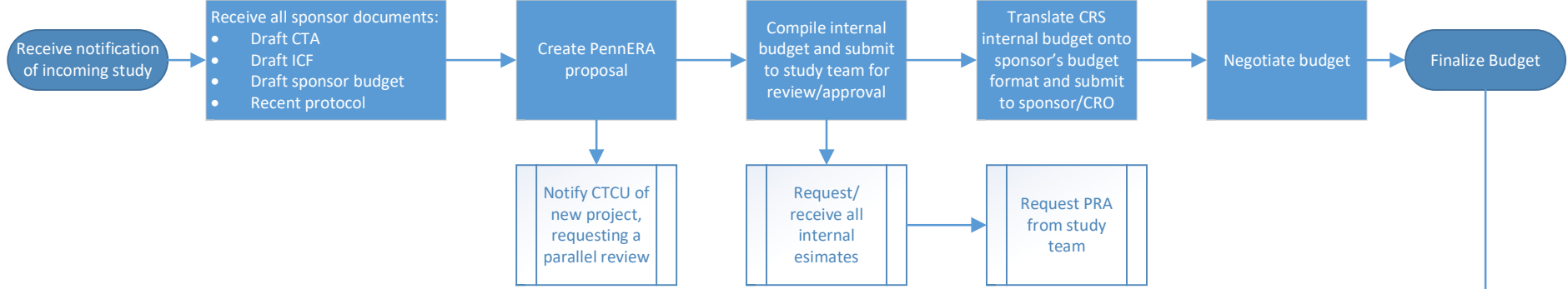
INTERNAL ROUTING (1 Week)

- Once the budget/payment terms have been successfully negotiated, CRS will input the final budget into PennERA for internal approvals
    o Note: The PI is the first person required to 'certify' the project before it can be routing for further internal approvals (directions will be provided for convenience)
- CRS will collaborate with OCR Finance to ensure review approval and resolve any issues
- CRS will collaborate with OCR Legal to ensure legal negotiations are ongoing or finalized
- CRS will continue monitoring the project until notification is received that the CTA has been fully-executed
- CRS will monitor the project for fund number assignment

POST-AWARD PREPARATION (4 Weeks)

- CRS will send notification/reminder to the study team that a fund number has been issued and an RBN should be requested
    o CRS will approve the RBN request at a 'BA' level; an RBN should be issued within the next few days
- Please ensure that this protocol is marked as "Approved" within the IRB system, or we will not be able to approve the request
- CRS will build the internal workbook and upload the 'Subject Tracking' into PennBox

Pre-Award Flowchart (CRS)

Budget Build & Negotiation

Receive notification of incoming study → Receive all sponsor documents:
- Draft CTA
- Draft ICF
- Draft sponsor budget
- Recent protocol

→ Create PennERA proposal → Compile internal budget and submit to study team for review/approval → Translate CRS internal budget onto sponsor's budget format and submit to sponsor/CRO → Negotiate budget → Finalize Budget

Create PennERA proposal → Notify CTCU of new project, requesting a parallel review

Compile internal budget and submit to study team for review/approval → Request/ receive all internal esimates → Request PRA from study team

Internal Routing

Enter final budget into PennERA → Route Proposal → Collaborate with OCR & CTCU offices to address any review issues → Receive email announcing the awarding of the new project → Receive fund number

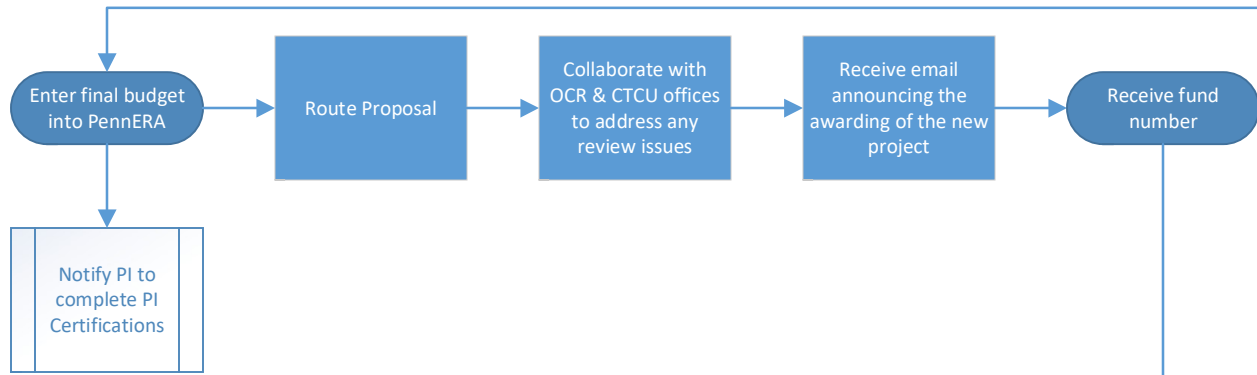Enter final budget into PennERA → Notify PI to complete PI Certifications

Post-award Preparation

Send notification/ reminder email to the study team that a fund number has been issued and an RBN should be requested. → Approve/submit any service center approval forms → Build the project's internal spreadsheet → 'Publish' the new spreadsheet within the division's "Z" folder → Send notification email to the responsible post-award accountant to add to respective tracking log

Send notification/ reminder email... → Approve RBN request on the BA level → CAMS:
1. Add PI as spender within RBA
2. Link protocol to fund/study

Build the project's internal spreadsheet → Send the 1st invoice. If fund incurred IRB startup charges, send 2nd invoice (IRB)