

PennERA—Proposal Development, Clinical Trials, Early Review

The institution number here generated will remain the unique identifier of the study both actively and historically. Therefore, before an electronic record is created for the clinical trial it is important to insure that none currently exist.

- Log on to PennERA
- Select ‘proposals’
- Select ‘create proposal’
- Change PI, if necessary
 - Continue to next step
- Step 1 continued...
 - Select: ‘neither of above’
 - Continue to next step
- Step 2:
 - New competing
 - Continue to next step
- Step 3:
 - Select a sponsor
 - Select mechanism: leave blank
 - Continue to next step
- Step 4:
 - do nothing, default entry
- Step 5:
 - enter proposal title
 - Continue to next step
- Step 6:
 - enter project start & end dates
 - Continue to next step
- Step 7:
 - How many years or budget periods would you like? For most CTAs adjust budget period to one (1).
 - Continue to next step
 - Is all of the above information correct? Select appropriate response, when you are ready...
 - ‘create proposal’

Make a note of the institution number created; you will need this number for the Request for Early Review Form as well as to easily access the record for final school and institutional routing and approval

- Step 8: Set up questions
 - Submission Mechanism/Form Information
 - Select UPenn generic template
 - Has your sponsor given a specific reference for this proposal? Answer: No
 - Select mechanism: leave blank
 - Mechanism Opt In/Out: Is this a US federal sponsored project? Answer: yes/no as appropriate
 - Deadline
 - Answer yes/no as appropriate
 - General proposal properties
 - Answer the second question, “Will you be working with other internal departments or divisions as Subprojects?” No.
 - Answer all other questions in this section as appropriate.
 - Budget set up information
 - What kind of budgeting model would you like to use? Select ‘budget by total project’
 - Is this a flow through project: Answer as appropriate
 - Select the program type: Select either ‘UPenn-CTA multiple sites’ or ‘UPenn-CTA single site’ as appropriate
 - The majority of research will be conducted: Answer as appropriate
 - Cost sharing information
 - Answer all questions under this heading as appropriate
 - Save & Continue
 - Section is automatically marked ‘completed’
- Abstract
 - Select the ‘manual entry’ radio button
 - In the free text box that appears type: N/A
 - Mark section ‘completed’
- Personnel
 - Under the heading ‘Internal Administrative Contact’ fill in responsible BA information
 - Save
 - Mark section ‘completed’
- Budget
 - Budget information is not required at the Early Review phase, but will need to be added before the submission is later routed for internal Review and Approval
- Supporting Documents (*this is where you will upload a copy of the Contract*)
 - Select ‘add new document’
 - Browse to find contract document
 - ‘open’ document when found, this action will automatically return you to the application
 - Name your document in the free text box provided (located under the ‘browse’ button)
 - Upload
 - Save
 - Mark section complete

- Research Plan (*this is where you will upload a copy of the: Protocol, Protocol Summary, or Informed Consent*)
 - Following the same procedure outlined above add:
 - Add protocol
 - Protocol summary
 - Informed consent
 - Save
 - Mark section completed
- Approvals
 - If the IRB protocol has not yet been submitted to Regulatory Affairs
 - Click add
 - Under Add/Edit Approvals section, type: human subjects
 - Select 'not attached' radio button
 - Continue
 - Status: pending
 - Save
 - Mark section completed
 - If the IRB protocol has been submitted to Regulatory Affairs
 - Click add
 - Under Add/Edit Approvals section, type: human subjects
 - Select 'attached' radio button
 - Continue
 - Either select by number or browse to find the appropriate protocol using search filters
 - If using browse function, after search results are returned, scroll down to the bottom of section and select the appropriate protocol by marking the 'select' box
 - Click 'select'
 - Save
 - Mark section completed

At this point the process for Clinical Trials, Early Review in PennERA is complete.

- **The next step is to complete the Request for Early Review Form, including the institution number you just generated, and send it to: ORSCTA@lists.upenn.edu**

This process does not replace the requirement for Department and School approvals. The budget must be uploaded and the proposal must be electronically routed and approved before any contract can be finalized.