Using PennERA—Proposal Development for Clinical Trials Submissions

- 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:
    - Select ‘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 the number of budget periods to one (1).
    - Continue to next step
    - Is all of the above information correct? Select appropriate response, when you are ready…
    - ‘create proposal’
- 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 <u>second</u> 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
  - Select ‘budget items’ subcategory
    - All Effort must be added for key personnel to do this, under the heading ‘Personnel costs’
      - Click on the ‘open’ (folder) icon for PI
      - Complete the effort worksheet for PI
      - Save
  - Once again, select ‘Budget Items’ subcategory
      - If you need to enter other Key Personnel and their subsequent effort you may do so by selecting ‘click to add’ under the heading ‘Personnel Costs’
      - Select appropriate staff from the alpha split list and/or by filling out the ‘new staff’ section then
      - Completing the effort worksheet
      - Save
  - Once again, select ‘Budget Items’ subcategory
    - Under the heading ‘Non-Personnel costs’ select ‘click to add’
    - Under the Budge Detail heading in the text box under ‘Description’: enter ‘total direct cost’
    - Under Budget/Charge Category: select ‘other costs’
    - Under Purchase/Usage Schedule subheading
      - Leave units as one (1)
      - Under Price/Charge Each: enter total direct cost
      - Change the ‘end date’ to match the end date of project
    - All remaining fields may be left blank
    - Save

- Select the ‘budget items’ subcategory again
  - Mark Budget Items subcategory completed
- Select ‘F&A’ subcategory
  - Under ‘facilities and administration costs’ heading select “manual (lump sum by period)” for the sponsor calculation method
  - In the totals section, enter the appropriate dollar amount for F&A Totals
  - All remaining fields may be left blank
  - Save
  - Mark F&A subcategory completed
- Select ‘Cost Sharing’ subcategory
  - If necessary, fill in section as appropriate then, or otherwise…
  - Mark section completed
- Select ‘Justifications’ subcategory (*this is where you will upload a copy of the Budget*)
  - Select ‘upload form’ radio button
  - Browse to select
  - ‘open’ document when found, this action will automatically return you to the application
  - upload a copy of project budget
  - Mark section completed

- 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 th: Protocol, Protocol Summary, and Informed Consent*)
  - Following the same procedure outlined above add:
    - Add protocol
    - Protocol summary
    - Informed consent
  - Save
  - Mark section completed
- Approvals
  - If the IRB protocol <u>has not yet been submitted</u> 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 <u>has been submitted</u> 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
- Finalize
        - Build—when build is complete you will automatically be brought to ‘Assemble Application’ subcategory
        - Under ‘Assemble Application’ you have the option of reorganizing the proposal sequence and/or page numbers
        - Build, regardless of whether or not you modified pagination or sequence—when build is complete you will automatically be brought to the ‘Submit for Internal Review’ subcategory
            - Open, “Certification by Principal Investigator” form (Note: only the PI can certify this form)
                - Answer all questions
                - Check form complete
            - Open, “Proposal Transmittal” form (Note: The BA and/or PI can certify this form)
                - Answer all questions
                - Check form complete
        - Submit
            - Only the PI can submit the proposal for internal review

- Click the “Done” icon to close the proposal record whenever you are finished using it