IRES PD (Proposal Development) for Clinical Trials

Contents

Objective ........................................................................................................................................... 1
IRES PD Access ................................................................................................................................. 1
Additional Information .................................................................................................................... 1
Initiating a Proposal: Non-S2S (non-system to system) .............................................................. 2
  Log into IRES ................................................................................................................................ 2
  New Proposal Questionnaire ........................................................................................................ 2
  Setup Questions ............................................................................................................................ 4
  Personnel Tab ................................................................................................................................ 5
  Budget Tab .................................................................................................................................... 6
  Internal Documents ....................................................................................................................... 6
  Finalize Tab .................................................................................................................................... 10
Using IRES PD ................................................................................................................................ 11
PD Resources .................................................................................................................................... 11

Objective

This document provides step-by-step instructions for creating a clinical trial record in PD, and is designed to be used as a reference guide as you create your clinical trial record.

IRES PD Access

Access to IRES PD for Clinical Trials, with the ability to create new PD records for clinical trials, is granted after completing the following steps:

- Your department Lead Administrator needs to submit the IRES Department User Access Request form
- Once the IRES Department User Access Request form has been processed the user will receive an email with an IRES PD for Clinical Trials attestation statement and a training guide.
- Complete and submit the attestation statement (per instructions on the form).
- You will receive an email notification when your access has been setup.

For questions regarding IRES PD access contact: ires@yale.edu

Additional Information

Chrome is the preferred browser for the IRES PD application. IE (Internet Explorer) is not recommended.

For questions regarding creating a PD clinical trial record, contact your OSP Clinical Trials Manager

For technical issues with the IRES system, (error messages, login...), contact: ires@yale.edu

For questions regarding IRES PD training contact: osp.training@yale.edu
Initiating a Proposal: Non-S2S (non-system to system)

To create a non-S2S proposal in IRES Proposal Development (PD):

- Log into IRES (https://ires.yale.edu/) and select: My Proposals
- Select: Create New Proposal
- The New Proposal Questionnaire window opens. Complete the questionnaire per the following instructions.

New Proposal Questionnaire

Step 0. Select: Change PI and start typing the PI’s name: last name, first

💡 This is a progressive search box, as you type possible matches appear below.

Select the correct PI from the list and click the Select button (top right).
Your name will be replaced by the PI’s name.

Step 1.  In the scroll box list select: **Create a New Proposal**  
Select: **Continue to Next Step**

Step 1.  **Continued...**  
Use the drop-down menu to select: **Setup Proposal Manually**  
Select: **Continue to Next Step**

Step 2. **Please Select a Proposal Type:** use the drop-down menu to select the type of proposal you want to create.  Select: **New.**  
Select: **Continue to Next Step**

⚠️ Press the **Back button** (the window back button ![Back](top right), not the browser back button) at any time to change prior entries.

Step 3. Enter the **Sponsor’s name** in the **progressive search field**.  
Select the sponsor’s name in the resulting search list.  
Select: **Continue to Next Step**

💡 If needed, you can add a sponsor to the list by completing the **New Sponsor Request form**.

Step 4.  Take no action for step 4, the IRES system will create a Proposal Number for the PD record which will be displayed when the form is completed.

Step 5. Enter the **Proposal’s Title**  
Select: **Continue to Next Step**

Step 6. Use the **Calendar** icons to select the project **Start** and **End dates**.  
*(Or type dates using the following formats: DD-MMM-YYYY or MMDDYY)*  
Select: **Continue to Next Step**

Step 7. Verify that the number of years and/or budget periods is correct or edit if necessary.  
Select: **Continue to Next Step**

- Verify that the information entered in Steps 1 thru 7 is correct.
  - Select: **No, Go back and make changes** to edit a specific section. Use the window’s Back button (top right) (not the browser Back button) to move backwards step-by-step.
  - Select: **Yes, Create Proposal** to create a new proposal record with the properties you’ve entered.  
    When the **Yes, Create Proposal** button is selected the **Setup Questions** screen opens and the PD record number displays (top right).
IRES PD (Proposal Development) for Clinical Trials

Make note of the proposal number, it will make future searches easier.

Setup Questions

Submission Mechanism/Form Information
1. Confirm the Sponsor is correct. If incorrect, use the Click here link to change.
2. Please select a submission Mechanism/Screen Template.
   Select: Corporate Clinical Trial.
   - A dialog box will open (top of screen). Click OK to confirm the template change. The screen will refresh to show the fields needed for corporate clinical trials.

General Proposal Properties
   - PI Departments: the PI department, (that was selected previously in Step 0), will display and cannot be removed. (Note: in some cases the PI Departments will not be visible on this screen.)
   - Associated Departments: additional Associated Departments can be added.

   To add departments:
   1. Click the Add button to include additional departments. (Note: It’s possible that the PI dept will not even display on this screen.)

   ![General Proposal Properties]

   2. If a department has been added by mistake, click the Remove icon to remove it from the list. (Note: You must reassign the Prime indicator before you’re able to remove a department marked as Prime.)

   ![General Proposal Properties]

   3. A pop-up window will open at the top of the screen to confirm the removal, click OK.

Budget Setup Information
1. For Program Type select (will default to): Corporate Clinical Trial.
2. Designate if the majority of research will be conducted **On** or **Off campus**.

3. Click the **Save** button (bottom left)

4. Click the **Completed** check box (top right corner) to finalize and lock-down the setup questions.

5. A dialog box will open (top of screen). You will be prompted to save. Click **OK**.

6. A red check mark will appear next to the Setup Question tab (left panel) indicating completion. We’ll need to complete the questions in each of the following tabs (sections).

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**Personnel Tab**

- Select the **Personnel** tab from the menu list (left panel).

1. The first name in the Personnel list will always default to the PI. If necessary, to add additional personnel, follow these steps:
   - **For Yale personnel** (or those with a NetID), click in the **Name** field and begin typing **last name, first name** to activate the progressive search feature. *(Yale affiliates and YNHH personnel are likely to be included in this search.)*
   - **For Non-Yale personnel**, if the person cannot be found using the progressive search box follow these steps, *(it’s unlikely you would need to add non-Yale personnel)*:
     a) Click the **Create Profile** button and complete the **New Profile** form
IRES PD (Proposal Development) for Clinical Trials

b) Click Save (top right) to close the Create Profile window and the information will appear in the name field.

2. Select the appropriate entries for the following drop-down fields:
   - **Personnel Type**
   - **Role**

3. Click the **SAVE** button to add the person to the personnel list.

4. When done, click the **Completed** check box (top right corner) to finalize and lock-down the personnel list.

5. A check mark will appear next to the Personnel tab (left panel) indicating completion.

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**Budget Tab**

- Select the **Budget** tab from the menu list (left panel). A new budget window opens.

1. No information is required in the budget window. Click the **Complete Budget** button (top right) to finalize the budget.

2. Click **Done** (top left) to close the budget window.

3. A check mark will appear next to the Budget tab (left panel) indicating completion.

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**Internal Documents Tab**

- Select the **Internal Documents** tab from the menu list (left panel).
- The **Regulatory** form must be completed. Follow these steps to complete the form:
1. Click the **Edit** icon to open the form.

![Form/Document Name](image)

**Regulatory Form**

<table>
<thead>
<tr>
<th>Field</th>
<th>Status</th>
<th>Upload</th>
<th>Remove</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal Regulatory Information</td>
<td>Incomplete</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Use the Print button (left panel) if you need to review questions with your PI.*

2. **Proposal Short Title:** enter an identifying title (30 character limit), this title will appear in reports.

3. **Instrument type:** click the **Edit** icon and select **Contract** from the drop-down menu. Contract must be selected.

   *IMPORTANT: **Contract must be selected** in the Instrument Type field or the routing will not work correctly.*

4. **Administrative contact:** click the **Edit** icon and type the business office contact name (last name, first name) into the search box.

5. **Primary Location of Research:** click the **Edit** icon and use the search box to find the building name. Enter the **Room Number** and **Floor**.

6. Complete the **Laboratory Animal** and **Human Subjects** check boxes.
   
   If you answer **YES**, then you must provide additional information in the next section. *(Clinical trial forms will always default to No for animals, and Yes for humans.)*

   - **Will the project involve...:** enter **Human Subjects**
   - **Is the... being conducted by:** enter **Yale**
IRES PD (Proposal Development) for Clinical Trials

- **If...conducted by subrecipient:** enter subrecipient’s name
- **What country:** enter country (most likely U.S.A.)
- **Protocol #:** enter protocol number, or if not yet approved enter **Pending**
- **Protocol Approval Date:** enter date if it’s been approved
- If additional lines are needed, click the plus icon + to add another line.

> **Animals and Human Subjects:** Enter one line for each combination of Animal/Human Subjects work being conducted by Yale and one line for each combination being conducted by a subrecipient.

> ![Click the trash can icon to remove unwanted lines.](image)

7. **Guidance on Export Controls and Electronic Devices in International Travel**
   Answer questions in this section per discussions with your PI.
   - **Will this project involve any foreign travel...:** If you enter YES, then you will be required to enter the country. Click the **Edit** icon and search for the country name.

   ![You can come back to this form and edit entries at another time if necessary. Be sure to use the Save button (top left) before exiting.](image)

8. **EHS (Environmental Health and Safety) materials:**
   Check No if none apply.
   Use the check list to identify which type of EHS materials will be used.

9. **Personnel:** check whether or not any personnel have a joint VA appointment.

10. **Subrecipient Conflict of Interest:** skip this section, it does not have to be completed for clinical trials.

11. When done, scroll up to the top and click the **Completed** check box (top right corner) to finalize and lock-down the information in the Regulatory form.

12. The form closes and the status of the regulatory tab changes to: Completed.

   ![Add Institution Forms/Supporting Documents: To attach supporting documentation to the PD record, click Add Institution Forms/Supporting Documents and the upload window](image)
1. **Name:** Enter the document name using the following naming conventions.

<table>
<thead>
<tr>
<th>Document Description</th>
<th>Document Naming Convention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Clinical Trial Agreement</td>
<td>Draft_CTA</td>
</tr>
<tr>
<td>Sponsor Correspondence</td>
<td>Corres_Sponsor</td>
</tr>
<tr>
<td>Draft Budget</td>
<td>Draft_Budget</td>
</tr>
<tr>
<td>Payment Schedule</td>
<td>Draft_Payment_Schedule</td>
</tr>
</tbody>
</table>

*These are the most frequently uploaded documents.*

2. **Location:** click the **Choose file** button and navigate to the file on your computer, and select the file to be uploaded.

3. **Category:** select **Proposal**.

4. **Folder:** select **General**.

5. Click the **Upload** button (top right) and wait for the file to upload.

6. Click **Close** when you see the following message at the top of the window: *Please click ‘Close’ to complete the upload of your documents.*

7. Repeat this process for each document that needs to be uploaded. Successfully uploaded documents will be displayed in the list.
8. When done uploading, click the Completed check box (top right corner). A check mark will appear next to the Internal Documents tab (left panel) indicating completion.

Finalize Tab

- Select the **Finalize** tab from the menu list (left panel).
- In this step the documentation is submitted and routed for approvals.
  1. Click the **Thumbs-up** icon next to **Submit Final Review** (middle-right of window)
  2. A new window opens showing the route path.
    By default, the route includes the PI and the GCA Review (now called the OSP TA, Team Assistant) who supports the department associated with the record.
    **Note:** the OSP TA was formerly called the GCA Reviewer, which still appears on the form.
  3. If additional approvers are needed, add their names, do not add anyone from OSP. To insert additional people:
    - **Every route needs to have Approval from the appropriate department business administrator.**
    - a) Click the box next to the PI’s name to insert a new name under the row you select
      **NOTE:** **GCA Review (the OSP TA) must always be the last name in the list.**
    - b) A window opens. Start typing the name: **last name, first** into the progressive search box and select the person’s name from the list.
    - c) Select the appropriate routing type: **Informational Only** or **Approval Required.**
    - d) Click the **Add** button (top right).
      You will see the name appear under the row you selected.
      A **remove** icon appears next to any names you’ve added manually. Remove any names that appear under GCA Review and add above if necessary.
4. Click **Submit** to begin routing.

5. The Routing information appears and shows the date and time stamp when the email notification was sent to the PI, the first person on the route.  
   
   *You can come back to the Finalize tab at any time to check the route progress.*

6. Click the **Done** icon (top left) to exit and close the record.

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### Using IRES PD

- **Save**  
  Click **Save** after entering information in any PT record.

- **Done**  
  Be sure to click **Done** to exit a PT record and go back to the previous screen.  
  *If you click Done and you haven’t saved first – you’ve lost your work!*

- **Exit**  
  Click to **Exit** the IRES application.

- **In Use**  
  Shows someone else is using the record. When you open a record, it locks the record for others and you need to click **Done** to exit in order to unlock the record. Records unlock automatically after a period of inactivity (approximately 2 hours).  
  *(Note: if you need to get into a locked record, contact ires@yale.edu)*

- **Show**  
  Displays help information for individual fields.

- **Info**  
  Hover over to view additional information.

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### PD Resources

**OSP Clinical Agreements website**  
https://your.yale.edu/research-support/office-sponsored-projects/clinical-agreements

**PD FAQs** – including Routing and Approvals  

**PD Quick Guides**  
https://your.yale.edu/policies-procedures-guides/pd-quick-guides

**PD Training**  
https://bmsweb.med.yale.edu/tms/tms_enrollments.courses?owner=GCFA2&category=DEPTS&std_id=&key word=&category_id=689