Clinical Trials Proposal Preparation Quick Guide for Department Users
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Getting Started

Before You Begin

1. Make sure you have a current browser.

2. Have your Business Systems login username and password ready.

3. Turn off pop-up blockers on your browser.

4. **Never** use the browser back and forward arrow buttons to toggle between screens doing so may cause an error.

5. The ePD System will timeout remember to ‘Save’ your work frequently.

6. You are required to answer any question with a red asterisk (*). You may save your proposal at any time, but you will be unable to submit your proposal unless all required fields have been answered.

7. Use the ‘Validation Checks’ function to check for errors as you go and before you submit for approval.

8. Use an asterisk (*) during searches to conduct wildcard searches that will return better results (Example: *neuro* or *science or Stan*)

9. Once you click ‘Save’ wait for the system to respond. Clicking ‘Save’ multiple times may cause an error.

10. ‘Print’ is a function that can be used to view and download various questionnaires, general proposal and budget documents.

**NOTE:** Additional Help on particular screens and specific fields can be found by clicking the symbol or visiting the ePD Help site, which will open a new browser window. Use the Help site left navigation to locate help specific to that screen and fields.
Log In
1. To access the ePD System go to epd.ucsd.edu/coeus

2. Once you are directed to the login screen, use your Single Sign On (SSO) business systems username and password to ‘Login’ into the system.

Log Out
To log out of the system click ‘Log Out.’ Be sure to ‘Log Out’ after each use and before closing the browser.

NOTE: If you do not click ‘Log Out’ before closing the browser you may lock yourself out of the proposal, however, it can be unlocked – see ‘Current Locks’ for more information.
Current Locks

Proposals can be locked for two reasons:

1. Someone else is currently working on the proposal at the same time you have tried to access it.

2. You forgot to click ‘Log Out’ before closing your browser and have therefore ‘Locked’ yourself out of the proposal.

To unlock the proposal click ‘Current Locks’ and then click ‘Unlock’ – you may have more than one line to unlock – be sure to ‘Unlock’ each line in order to fully unlock your proposal.

NOTE: You can use this feature while working on a proposal – you do not need to exit the proposal in order to ‘Unlock’ it.
ePD Basics

ePD Home Welcome Screen
After logging on to ePD Lite you will be directed to the ‘ePD Home Welcome Screen.’ Click on ‘My Proposals’ to access the Proposal Development module.

![ePD Home Welcome Screen](image)

**ePD Home**
Returns you the ‘ePD Home Welcome Screen.’ On this screen the ‘Finding Opportunities Resources’ link will open the Blink Funding Opportunities website in a new window. ‘Launch ePD Premium’ will open the premium module.

![ePD Home](image)

**NOTE:** ePD Premium is only accessible if installed with java and is Primarily for Central Office use.
**Inbox**
Takes you into the message ‘Inbox’ where you can manage your actions.

- **Unresolved Messages**
- **Resolved Messages**
- **Proposal Search**

NOTE: ‘From’ refers to the last person that took action on the proposal, not the person who sent the message.
My Proposals

Once you have selected ‘My Proposals’ you will be directed to the main Proposal Development screen used for managing and creating proposals. You will be automatically directed to the ‘Proposals In Progress’ view.

This view displays proposals currently ‘In Progress,’ ‘Approval in Progress,’ and ‘Rejected.’ Each list of proposal views displays the Proposal Number, Status, Title, Lead Unit, PI and a direct link to the Budget.

Each column within the various views is hyperlinked for quick access to the proposal record.

‘Proposal Number’ is the number automatically assigned by the ePD Lite System once a proposal record is created.
‘Status’ is the state of the proposal and includes *(In Progress, Approval In Progress, Recalled, Rejected, Submitted)*.

‘Title’ is the name of the proposal.

‘Lead Unit’ is the code of the primary unit or department that is submitting the proposal.
‘PI’ is the name of the Lead Unit’s Principal Investigator.

‘Budget’ is a link that takes you directly to the budget module within that particular proposal.

To open a proposal record you have the option to click anywhere on the line to access the proposal of your choice or you can click on ‘Budget’ and it will take you directly to that proposal’s budget.

Additional functionality is available using the links below.
‘All Proposals’ shows all the proposals in your dashboard regardless of status. This view includes proposal of every ‘Status’ including:

- **In Progress** - proposal has been started but has not been routed for approval yet and the record is still open for editing at this time
- **Approval in Progress** – proposal is in approval routing, is waiting for approval and the record is closed for editing at this time
- **Recalled** - proposal has been recalled by the person who created the proposal (Aggregator) and is open for editing
- **Rejected** – proposal has been rejected by an approver because there required changes and the record for is open for editing
- **Submitted** – proposal has been submitted to the sponsor, an Institute Proposal record has been created and the ePD record is now permanently closed for editing

‘Create New Proposal’: click to start a new proposal (see [Create New Proposal](#) for more information).

‘Proposal Search’: click to search all proposals and retrieve proposals by entering in specific search criteria.
‘Grants.gov Opportunity Search’ is used to search for a Grants.gov opportunity by entering the ‘CFDA Number’ OR the ‘Opportunity ID’ to perform the search and retrieve results.

Note: Not applicable for Sponsor initiated clinical trials or PI initiated clinical trials solely with Industry funding.
Create New Proposal

After logging into the system and clicking ‘My Proposals’ to begin a new proposal click ‘Create New Proposal.’

If you are authorized to create proposals in more than one Lead Unit, you will first be directed to a list of those units. Select the ‘Lead Unit’ under which the proposal will be created and submitted as you will be able to add additional participating units later. This is the department that will submit the proposal and manage the award if funded.

NOTE: Always use this ‘Wild Card Search’ technique of (*) when using the ePD System to conduct and return better search results.

NOTE: If you do not create proposals for multiple departments you will be directed straight into the ‘General Info’ screen to begin creating the proposal and will skip this step.
General Info Screen

Complete various appropriate fields on the ‘General Info’ Screen and click ‘Save’ in order to create the record and generate the Proposal Number. (*) indicates a mandatory field.

Remember, all clinical trials should have a proposal type of ‘New.’

NOTE: You can manually enter dates or use the calendar tool.
Use the ‘Search’ function to look up information for that field.

Click on the ‘Sponsor Name’ or any blue hyperlink of the entity you want to select to populate the field.

NOTE: If looking for the NIH – Miscellaneous sponsor use the SPONSOR NAME search box and enter *misc* into the SPONSOR NAME search field

NOTE: Remember to use the (*) Wild Card Search – however entries must match exactly
Notice that the field has auto populated with the search selection.

Use the radio button ‘Receipt’ or ‘Postmarked’ in correspondence with the ‘Proposal Deadline Date’ to indicate whether the proposal needs to be received or postmarked by that date. This will appear on the UCSD Internal Routing Form. For Clinical Trials that are urgent use the date two weeks from the date of proposal or the anticipated date of site visit with the sponsor.

NOTE: If you cannot find the sponsor you are looking for and have exhausted your searches, use the sponsor code *9850* (sponsor code pending) until the new sponsor is added to the database.
Continue filling out the appropriate fields for the record. Click ‘Save’ and move to the next screen.

Once you click ‘Save’ the proposal record has now been created within the ePD System. A ‘Proposal Number’ has been generated for your reference. You may now either continue working on the proposal or exit and return later. A checkmark ‘√’ will appear next to the title of completed screens. Some screens may have pre-populated data and will therefore show a ‘√’ even if no action was taken.

NOTE: For additional help click the ‘I’ icon in the upper right hand corner. The ePD Help Site will open in a different window.
**Organization**

This screen auto populates the ‘Proposal Organization’ and the ‘Performing Organization’ and will default to University of California, San Diego or Scripps Institute of Oceanography depending on which area of campus is submitting the proposal. Simply double check the correct information is showing.

**Investigators/Key Persons**

Add any and all persons named on the proposal using the ‘Employee Search’ or ‘Non Employee Search.’

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**NOTE:** Only persons named on the proposal - such as PI’s, Co-PI’s, Co-I’s and Key Study Persons should be listed on this screen. To learn more about Key Persons contact the COI department.
Click on the ‘Name’ or any blue hyperlink of the contact you want to select to populate the field.

Notice that once the person is selected their information will auto populate. Here you can add additional information like the ‘Agency Credentials,’ change the ‘Proposal Role,’ ‘% Effort,’ and designate multiple PI’s (by ticking the box) next to ‘Multi PI’ on each of the PI’s details screen.
Add additional details and/or click ‘Save.’

Once the personnel information has been saved a new line will populate.

From here you can also ‘Remove’ a person.

NOTE: To edit an Investigator/Key Personnel that is already listed click on the name.
Or view/edit ‘Details’ and also ‘Add Degree’ if necessary.

Click ‘Return to Investigator’ to go back to the previous screen.

**NOTE:** Only Proposal Creators with adequate permissions will be able to edit the ‘Details’
If you are required to enter percentage of effort, go to the ‘% Effort’ field and enter the percentage as a decimal (ex: enter 0.10 for 10%). For more information see the SPO Procedure for Proposal Creator’s Entry of Project Personnel’s Effort into ePD standard operating procedure.
Employee/Non Employee Search
If the person(s) to be added was not found using the ‘Employee Search’ or ‘Non Employee Search’:

1. Double check the name of the person and try the search again using various search terms and methods (i.e. full name, last name, first name and/or user name)
2. If the person(s) is still not showing - Use the Add New Rolodex Entry function to enter the person – (see Add New Rolodex Entry)
3. For UCSD employees not found in the system contact epdhelp@ucsd.edu
4. For Non-UCSD Employees see the Adding non-UCSD Employees to Coeus ePD standard operating procedure.

Multi-PI
In some instances multiple PI’s are named on the proposal.

To designate a multiple PI’s on a proposal once the PI’s have been added click the tick box next to ‘Multi PI’ on each PI’s details screen.

NOTE: After each record has been ‘Saved’ the MPI box will be ticked beside each PI designating each person as a PI even if the role is showing as ‘Co-Investigator’
**Unit**

The primary PI’s ‘Unit’ will default to the ‘Lead Unit’ of the proposal creator. All other persons added will display the home unit of that person.

**NOTE:** Only participating Units can be overridden. To change the ‘Lead Unit’ you will need to start a new proposal with an account associated with the new unit.
To override the unit for the purpose of the proposal click on the name of the person whose unit will be changed. Next, click ‘Search’ beside the ‘Unit’ field to find and select the appropriate unit.

Click on the ‘Name’ or any blue hyperlink of the contact you want to select to populate the field.
Click ‘Save’ to complete the change.

NOTE: Just a reminder that ‘Lead Units’ cannot be overridden. Trying to do so will add an additional department.
If mistakenly added you can remove the additional department by clicking ‘Details.’ You can also use the ‘Details’ function to add an additional unit.

To remove click ‘Remove’ next to the incorrect unit. Then click ‘Save.’
To add, click ‘Add Unit’ and use the search function to find the unit to add.

Certify
Every PI and Co-PI named on the proposal will need to ‘Certify’ participation and compliance on the proposal. PI’s and CO-PI’s MUST certify themselves. This can be done at any point in the proposal process once the record has been created and saved and MUST be completed before ‘Submit for Approval’. Co-Investigators and Key Study Personnel do not need to certify. Certification is indicated on the ‘Investigator/Key Persons’ screen.

For more information on ‘Certify’ see the PI Certification Quick Guide and/or the PI Certification 3 Step Guide).

NOTE: A red ‘X’ indicates the person needs to certify, but has not done so; a green ‘√’ signals a complete certification; if the space is blank it indicates that no certification is needed.
Send Notification
To notify the person(s) named on the proposal needing to 'Certify' click on 'Send Notification.'

Select tick box next to the person(s) to be notified and click 'Send.' This will trigger an instant Email notification to be sent to the selected person(s) with a message and link to certify the proposal.

This will send an email notification with a link to the proposal asking that individual to answer the certification question. For more information see the Notifications Matrix.

NOTE: If you do not use the ‘Send Notification’ feature the PI(s) and CO-PI(s) will not receive a notification to certify.

NOTE: Remember only PI’s and CO-PI’s need to certify. Therefore, ONLY send notifications to the PIs and CO-PIs. Notifications can be sent more than once.
Special Review

This screen is utilized by adding items that need Special Review by additional compliance offices, such as Conflict of Interest, Environmental Health & Safety, Human Subjects, etc. Here you can ‘Add Special Review’ type along with the ‘Status,’ ‘Protocol Number’ and ‘Comments.’ For more information on Special Review procedures see the Special Review standard operating procedure.

Use the drop down menus to select the appropriate ‘Special Review’ and ‘Approval’ status. The ‘Comments’ box can also be used to add additional information.

Because the level of regulatory and policy complexity varies across different research areas, each special review type is handled differently. For information about specific compliance requirements related to a specific review type, please contact the appropriate special review office.
Once the information has been entered click ‘Save’ and a new line will appear for each added review.

NOTE: For COI lines the person’s name MUST be added in the Protocol Number field (Last Name, First Name, Middle Initial) and the Approval Status MUST be listed as ‘Pending.’ If a COI line is not required do not add a line. For COI forms add the ePD Number using the following format: ePD ### (you do not need to add 0s).

NOTE: eCOI is still in progress. For current COI procedures, in ePD Lite, use the Special Review screen to add a COI line for each applicable person following the procedures mentioned above.
Use ‘View’ to see comments and ‘Remove’ to delete the line.

NOTE: Items entered in this field will validate against the answers provided in the various ‘Questionnaires.’
Abstract

Abstracts
Select the type of ‘Abstract,’ copy and paste the corresponding text/content and click ‘Save.’ This information will appear on the UCSD Routing Form. To delete, simply click on the ‘Abstract’ highlight, delete the text and click ‘Save.’

Once the information has been saved a ‘✓’ will appear next to the ‘Abstract’ title and a ‘Last Updated by’ name, time and date stamp will appear to indicate when field was last updated.

Internal Comments

‘Internal Comments’ can be used to add additional comments regarding the proposal.

NOTE: Use plain text only - special characters and formatting will not copy correctly. Also, more than one ‘Abstract’ can be added.
Others

The ‘Others’ tab is where you can complete UCSD specific information regarding the proposal such as the ‘Copy Index Number,’ ‘Department Proposal Contact,’ ‘Dpt. Contact Email,’ ‘Dpt. Contact Phone #,’ ‘UCSD Org Code’ and select the ‘UCSD Proposal Type.’ Type information directly in the free form fields or where available use the ‘Search’ function to look up and/or select the content for the field or to simply select the entry from the ‘Search’ menu. ‘Department Proposal Contact,’ ‘UCSD ORG Code’ and ‘UCSD Proposal Type’ are mandatory in order to complete this screen and in order to submit the proposal for approval.

Click ‘Save’ and move to the next screen.

Proposal Roles

On a proposal by proposal basis additional users can be added with the following permissions:

- **Aggregator** – Person creating the proposal record/managing the proposal, can make changes to any part of the proposal, answer questionnaires, perform offline approvals, add additional users to the proposal using proposal roles, submit for approval and recall the proposal at any time
- **Approver** – Primary and alternate approvers in the department and central office that must approval the proposal prior to submission, **Note: additional approvers must be added using the ‘Approval Routing’ functionality**
- **Narrative Writer** - Create and edit the attachments
- **Budget Creator** - Create and edit the budget
- **Viewer** - View any part of the proposal, but cannot edit the proposal
- **Access Proposal Person Institutional Salaries – DO NOT USE** – This role is not currently in use
- **Modify Proposal Rates – DO NOT USE** - This role is not currently in use
- **UCSD Department Proposal Assistant** – also known as the Proposal Routing Coordinator, this person serves as a triage/back up and facilitates offline approvals and proposal reassignments
To add users find the ‘Proposal Role’ then click the ‘Add User’ associated with the role. Once the search box appears enter search criteria in order to find the person to be added.
Click on the ‘Name’ or any blue hyperlink of the contact you want to select to populate the field.

The user will populate under the ‘Proposal Role.’ To remove users click ‘Remove.’
Questionnaires
This section of the proposal provides the opportunity to gather additional information regarding the details of the proposed research. At a minimum user’s will be asked to complete the ‘Space,’ ‘Administrative – Clinical Trial,’ and ‘Research – Clinical Trials’ questionnaires. Depending on the type of proposal additional questionnaires such as, ‘Proposal Revisions’ and ‘PI Exception’ may appear and will need to be answered before the proposal can be submitted for approval routing/re-routing.

Administrative – Clinical Trial
This questionnaire is intended for proposal creator/managers and asks questions regarding administrative components of the clinical trial.
Space
The space questionnaire asks questions regarding where the research will be conducted and if any special reviews are needed.

Research – Clinical Trials
This questionnaire is intended for those familiar with the research being conducted and ask questions regarding the research activities that will take place in the event the proposal is funded and if any special reviews are needed.
NOTE: If you do not know the answers to these questions and would prefer to send them to the PI you can either give the PI additional access to the proposal using the ‘Proposal Roles’ function. Or you can go to ‘Proposal Summary’ and click on ‘Proposal Print,’ then ‘UCSD Internal Routing Form’ and click ‘Print Selected.’ This will give you a PDF of the proposal summary details and the research questionnaire that you can both attach to an email or copy and paste from.

Proposal Revisions
Only appears if the proposal was ‘Rejected’ after having received approval from the department reviewers and reached the SPO office for approval. It uses questions to facilitate re-routing for all approvals or quick map depending on whether or not significant changes have been made to the proposal.
PI Exceptions
Only appears if the title code of the PI that was added under the ‘Investigator/Key Persons’ screen does not have a title code that makes them automatically eligible to submit a proposal.

Answering a Questionnaire
Begin by clicking on the name of the questionnaire, which will prompt the first question. To answer click the radio button and then click ‘Save & Proceed’ to move to the next question. There is also the ability to return to a ‘Previous’ question, ‘Modify’ the questionnaire and to ‘Start Over.’
Once all of the questions have been answered a review screen will appear displaying all questions and answers for that questionnaire. To view, save or print a copy of the questionnaire, click ‘Print’ and the form will open in a new window.

Editing a Questionnaire
To edit the questionnaire click ‘Modify.’
Change the answers to the appropriate questions or leave the answer and click ‘Save & Proceed’ to move to the next question or ‘Save & Complete’ to save changes and exit the questionnaire.

To complete the next questionnaire, click on the name of the questionnaire, which will bring up the corresponding questions.

For additional information on questions, click ‘More’ and an information box will appear with additional content and links regarding that particular question.

NOTE: Clicking on the blue hyperlinks will open the page within the ‘More’ box.
Budget Module

Only the Budget Summary information needs to be completed in order to complete the budget portion of the ePD record. All detailed budget information should be uploaded to the record under ‘Upload Attachments.’ S2S functionality will not be used at this time.

To begin click the ‘Budget’ screen and click ‘OK’ to the prompt.

You will then be directed to the ‘Budget Summary’ screen.
Budget Summary

This screen is used to enter the Direct Costs, Indirect Costs and brief comments about the budget. All detailed budget information (including subawardee information) will be added as attachments under the ‘Upload Attachments’ screen, for more information (see Upload Attachments).

This is also where Budgets can be marked as ‘Complete’ and ‘Final,’ however remember to first enter in the dollar amounts, click ‘Save’ and then go back to mark the budget as complete/final.

To exit the budget module at any time and return to the main proposal details, ‘Save’ your work and click ‘Return To Proposal’ do not use the browser back button.

NOTE: Comments about subawardees can be entered in the budget comments. Budget details (including subawards) will be available in the attached budget.

Remember to save budget comments in the ‘Complete’ and ‘Final’ budget version.
Budget Set Up

‘Budget Set Up’ is a section that is used to adjust periods that are not standard 12 month periods before entering information in the ‘Budget.’

- **Adjust Periods** – lists proposal periods that will be used in the budget and is used to adjust period start/end dates, add periods and remove periods

All budget periods will default to 12 month time frames based off the start date and end date that were entered on the ‘General Info’ screen.

Adjust Periods

Click ‘Adjust Periods’ to double check that the periods listed for the budget are correct. To adjust periods that are not standard 12 month periods, the ‘Start Date’ and ‘End Date’ can be adjusted by entering values in manually or using the calendar function; users can ‘Add Period’ and/or ‘Remove’ periods in order to adjust budget periods accordingly.

**NOTE: Adjust Periods (if necessary) before completing the ‘Budget Summary’**
Budget Versions

‘Budget Versions’ and ‘Print’ provide high level budget functionality.

‘Budget Versions’ allows users to create multiple versions of the budget, which can be edited, copied or marked as the final version to be used in the proposal submission. Click ‘Budget Version’ to access the various budgets that have been created.

Click ‘Add New Version’ to start a new budget from scratch or ‘Open’ to enter that version of the budget or ‘Copy’ to create a new budget using that budget version’s information.
When ‘Add New Version’ is selected you will be directed to the ‘Budget Summary’ screen.

If opening a budget version from this screen, you should automatically be directed to the ‘Budget Summary’ screen - always double check to make sure you are on the correct version of the budget.

NOTE: Once a Version has been created it cannot be deleted, but unless it is marked as ‘Complete’ and ‘Final’ will not show in the final print package.
Click ‘Add New Version’ to start a new budget from scratch or ‘Open’ to enter that version of the budget or ‘Copy’ to create a new budget using that budget version’s information.

If copying a ‘Budget Version’ select whether one or all periods should be copied then click ‘OK’ to generate the new version of the budget. After clicking ‘OK’ the new version of the budget will be created and you will be directed to the ‘Budget Summary’ screen. Continue to work through the budget as normal.

Print (Budget) – NOT IN USE
This section is not currently in use. To review, view, print or save a copy of the budget view the attachments in the ‘Proposal Summary’ view or under ‘Upload Attachments.’
Upload Attachments
This screen is where all proposal attachments can be uploaded.

- **Institutional Attachments** – Upload **ALL** proposal related documents

First, select the ‘Attachment Type.’
Next, enter a ‘Description.’ This can be particularly helpful in calling out drafts and/or additional notes about the attachment.

Then, attach the document by using ‘Choose File.’

**NOTE:** ALL attachments can be updated even during routing; however, new attachments can only be added when the record is open for editing.
Use the ‘Complete’ flag to call out documents still in draft form by unselecting it or leave the flag selected and use the description as needed. Click ‘Save’ when done.

Repeat to add additional documents.

If you copied an existing proposal with attachments, make sure you update the attachments and mark them as “complete”.

NOTE: The system will automatically time/date stamp when the document was last updated and by whom. There is the option to override the file OR to create versions.
Copy Proposal

‘Copy Proposal’ can be used in several different ways.
1. To create a basic template of frequently used proposals
2. To copy a proposal listed in any status

To copy a proposal you are currently working on click ‘Copy Proposal.’ Use the tick boxes and radio buttons to indicate whether or not to ‘Copy Budget’ (All Budget Versions or Final Version Only), ‘Copy Attachments’ (all attachments will be copied), and/or ‘Copy Questionnaire’ (all questionnaires will be copied). Click ‘Copy Proposal’ and the new proposal will open automatically.

Any of your ‘My Proposals’ can be copied by first selecting the proposal to be copied and following the ‘Copy Proposal’ steps.
Delete Proposal

The ‘Delete Proposal’ feature is only available to those with eProposal Development – Department Manager and eProposal Development – Department Assistant roles (a.k.a Department Routing Coordinators). Proposals can only be deleted prior to being submitted for approval routing, while they are still ‘In Progress.’

To delete a proposal open the record and click ‘Delete Proposal’ and select ‘OK’ to the prompt.
Email
This feature allows you to send an Email via the ePD system. This feature can be used in a variety of ways, including but not limited to:

- Contacting an Alternate Approver or those named on the proposal
- Requesting Changes to a proposal
- Communicating/Notifying one, some or all people associated with the proposal on information or actions needed

To use this function, open the proposal record that you would like to send the email from. Click on the ‘Email’ Screen within the ePD Record.

Select the ‘Add Employee,’ ‘Add Non Employee,’ or ‘Add Role’ hyperlink in order to add the person(s) you would like to Email.

NOTE: The Email function can be used at any time. Both before and after the record has been submitted for approval routing.
If using the ‘Add Employee’ or ‘Add Non Employee’ search feature enter the appropriate search term(s) and be sure to use the (*) wild card searches for best results.

Click ‘Search’ and when the result appears click on the blue hyperlink to select the person.

**NOTE:** More than 1 person can be added to the Email.
To use ‘Add Role’ click on the hyperlink and use the drop down menus to select the proposal roles you would like to Email, then click ‘Select.’

Continue by adding desired content to the ‘Subject’ and the ‘Message.’ Click ‘Send’ to complete the action and send the Email.

NOTE: Remember to add your name in the Message of the Email so that the recipient(s) will know who the Email is from.
The Email will then be sent to the people specified in the Email Notification screen.

The body of the email will contain any comments written by the sender, some details about the proposal and a hyperlink to that proposal record.
Add New Rolodex Entry

Use ‘Add New Rolodex Entry’ to add a person(s) not found using the ‘Employee’ or ‘Non-Employee’ Search under the ‘Investigator/Key Persons’ screen. To do so, click on ‘Add New Rolodex Entry.’ Enter the person’s details and use the ‘Comments’ box for additional comments, then click ‘Save.’

Return to the ‘Investigator/Key Persons’ screen, use the ‘Employee/Non-Employee’ search to find and add the person.

This person will later be uploaded to the permanent database if applicable.

Next Steps

Congratulations on preparing your proposal!

Now that the proposal has been completed you can Request a Review or Submit for Approval Routing. For more information please see the:

- Request a Review User Guide
- Submit for Approval Routing User Guide
Appendix

The purpose of the manual is to instruct users on how to enter clinical trial information into ePD. For more information on Clinical Trials through OCTA and OCGA please visit these quick links.

Clinical Trial Definition
The controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol (reviewed by OCTA) or an investigator-developed (reviewed by OCGA) protocol. Financial support for the clinical trial must be provided by a for-profit entity to use the 26% indirect cost rate (total direct cost).

OCTA is responsible for sponsor-initiated clinical trials (with For-profit entities only)
- The company or non-UC San Diego investigator authored the protocol
- The company or non-UC San Diego investigator is the holder of the Investigational New Drug (IND) or Investigational Device Exempt (IDE).
- That the clinical investigation is conducted under a protocol that is a FDA Phase I, II, III, or IV drug study or a FDA regulated medical device study.
- That the sponsor provides its proprietary product and study protocol to the University for the purpose of conducting a clinical trial; and
- That the sponsor will fully fund the cost of the trial (i.e., no work will be supported in whole or in part with other fund, including Federal funds).

No federal funds are allowed for sponsor-initiated clinical trials. If there are federal funds, then please review “OCGA federal funding” below.

OCGA is responsible for PI-Initiated with For-Profit entities
It’s determined to be a PI-initiated clinical trial when the protocol is authored by UC San Diego Investigators within the course and scope of their University employment, or UC San Diego Investigators within the course and scope of their University employment jointly with an employee of another entity (e.g., an employee of another non-profit institution, an employee of the industry-sponsor, etc.).
UC San Diego is usually the holder of the Investigational New Drug (IND) or Investigational Device Exempt (IDE).

OCGA is responsible for Sponsor-Initiated Clinical trials (with all entities except those that are For-profit)
- The entity or non-UC San Diego investigator authored the protocol
- The entity or non-UC San Diego investigator is the holder of the Investigational New Drug (IND) or Investigational Device Exempt (IDE).
- That the clinical investigation is conducted under a protocol that is a FDA Phase I, II, III, or IV drug study or a FDA regulated medical device study.
• That the entity provides its proprietary product and study protocol to the University for the purpose of conducting a clinical trial; and
• That the entity will fully fund the cost of the trial with its own funds or with other funds, including Federal funds

Please note: *solely federal grants would be not be processed or marked CTO.