

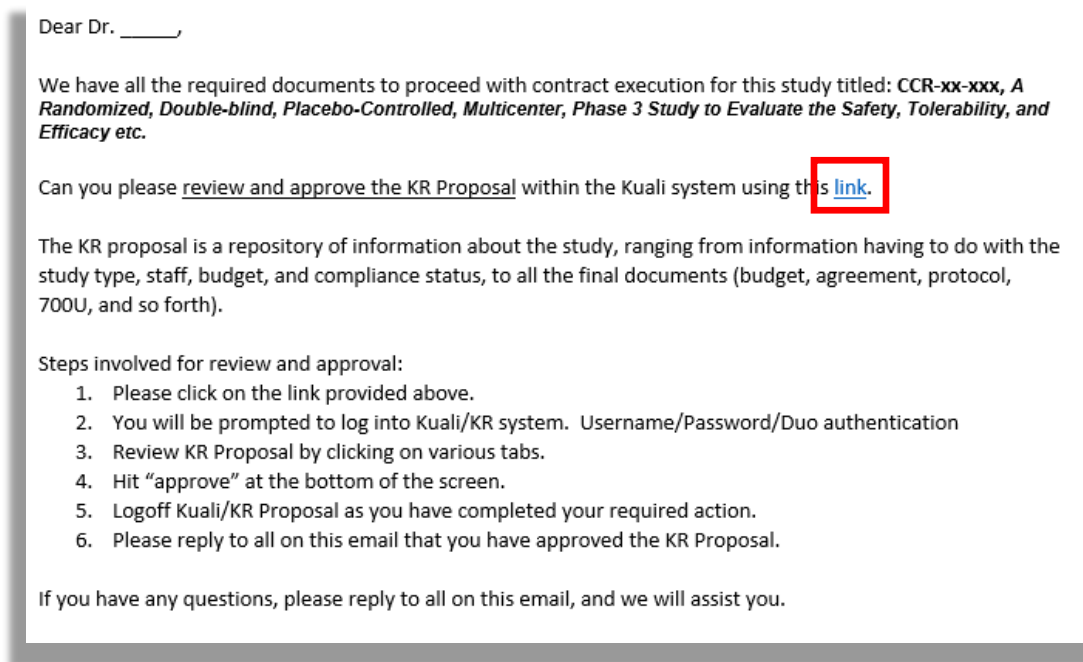
KR PROPOSAL REVIEW AND APPROVAL – the PI stage

The KR Proposal is a vehicle used by the Office of Research to circulate the study information and the study documents for final approval. Its approval is the last step before agreement (contract) execution. The CCR start-up team generates it and submits it for approval, after which the KR Proposal is transmitted automatically from one approver to the next as follows: the PI, dean's office, the contract officer.

It is important to note that the KR proposal approval is different from the contract execution (signing). Both are required and sometimes happen in quick succession. The contract execution is accomplished in most cases via a DocuSign envelope.

Here is a quick guide for your stage in the KR Proposal approval process:

1. You receive an email from one of the members of the start-up team (see below). The email contains information on how to review and approve the KR proposal. You will start by clicking on the link shown.



Dear Dr. _____,

We have all the required documents to proceed with contract execution for this study titled: **CCR-xx-xxx, A Randomized, Double-blind, Placebo-Controlled, Multicenter, Phase 3 Study to Evaluate the Safety, Tolerability, and Efficacy etc.**

Can you please review and approve the KR Proposal within the Kuali system using [this link](#).

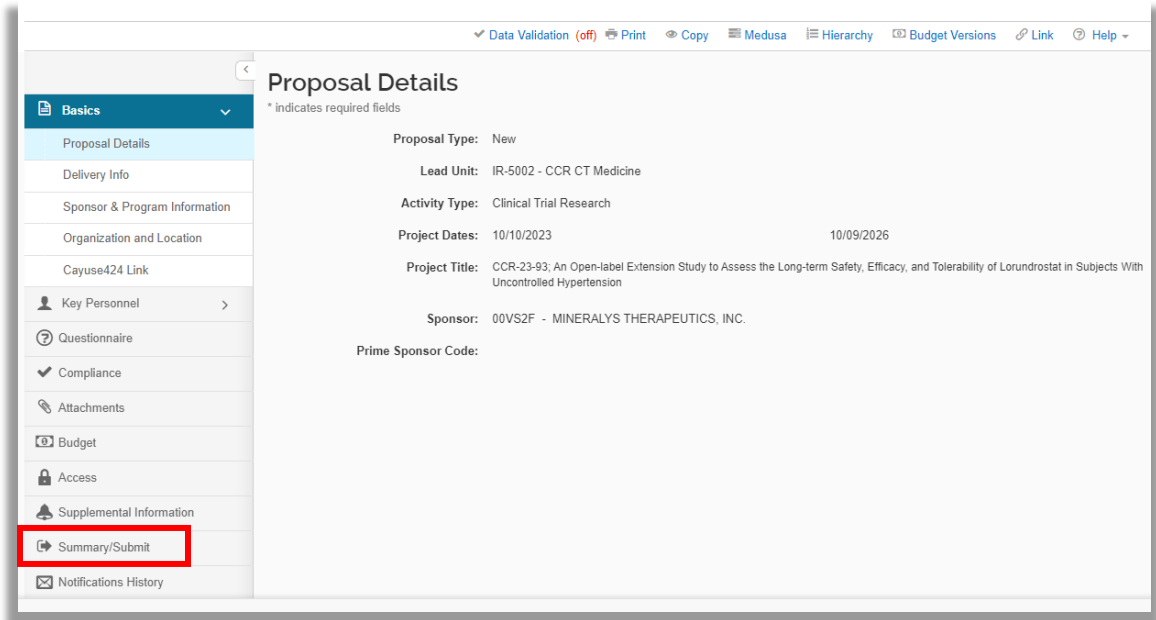
The KR proposal is a repository of information about the study, ranging from information having to do with the study type, staff, budget, and compliance status, to all the final documents (budget, agreement, protocol, 700U, and so forth).

Steps involved for review and approval:

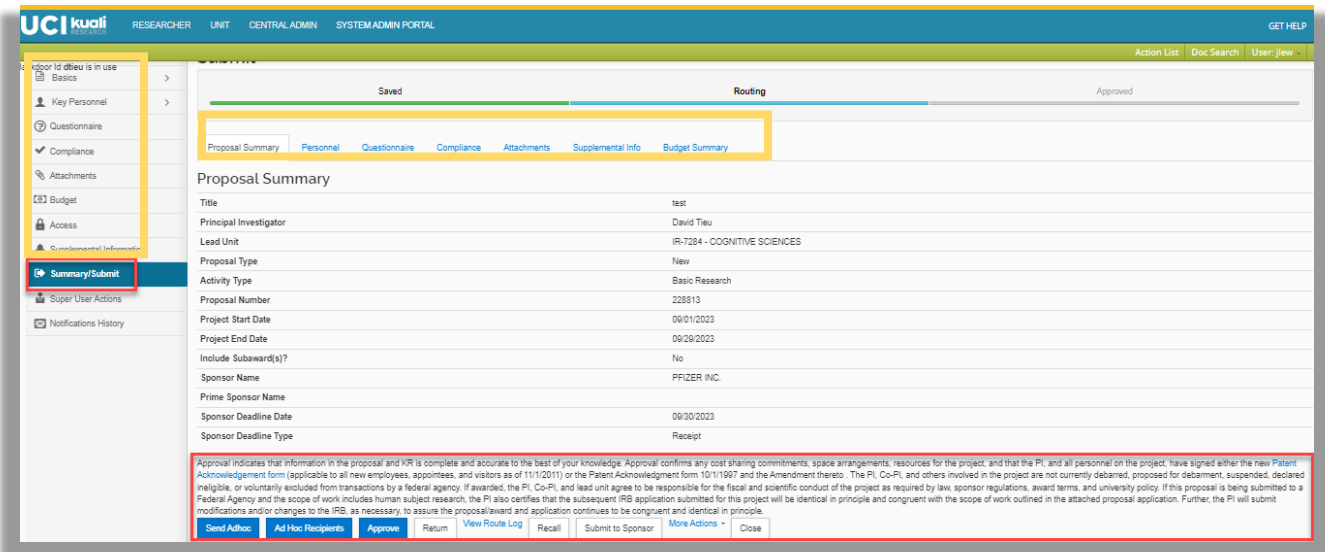
1. Please click on the link provided above.
2. You will be prompted to log into Kuali/KR system. Username/Password/Duo authentication
3. Review KR Proposal by clicking on various tabs.
4. Hit "approve" at the bottom of the screen.
5. Logoff Kuali/KR Proposal as you have completed your required action.
6. Please reply to all on this email that you have approved the KR Proposal.

If you have any questions, please reply to all on this email, and we will assist you.

2. The link will take you to the Kuali Research system. You may need to log in using your Username / Password / DUO authentication. After that you will see the screen on the next page. Click on the Summary/Submit menu option on the lower left side of the screen.



On this Summary/Submit screen, you have the option to review the proposal by clicking each tab – going across one by one. These are the same sections as if you were to navigate the menu along the left side.



Please note that your approval includes an acknowledgement/certification language. Here is the text:

Approval indicates that information in the proposal and KR is complete and accurate to the best of your knowledge. Approval confirms any cost sharing commitments, space arrangements,

resources for the project, and that the PI, and all personnel on the project, have signed either the new [Patent Acknowledgement form](#) (applicable to all new employees, appointees, and visitors as of 11/1/2011) or the Patent Acknowledgment form 10/1/1997 and the Amendment thereto . The PI, Co-PI, and others involved in the project are not currently debarred, proposed for debarment, suspended, declared ineligible, or voluntarily excluded from transactions by a federal agency. If awarded, the PI, Co-PI, and lead unit agree to be responsible for the fiscal and scientific conduct of the project as required by law, sponsor regulations, award terms, and university policy. If this proposal is being submitted to a Federal Agency and the scope of work includes human subject research, the PI also certifies that the subsequent IRB application submitted for this project will be identical in principle and congruent with the scope of work outlined in the attached proposal application. Further, the PI will submit modifications and/or changes to the IRB, as necessary, to assure the proposal/award and application continues to be congruent and identical in principle.

- The ultimate goal is for you to approve the KR Proposal. By clicking on the Approve button (circled below in red) you send the proposal to the next approver, which in most cases is dean's office.

IMPORTANT: If you have questions about the KR Proposal, please contact the original sender of the notification email, or email the startup team at GRP-CCRStartUp@hs.uci.edu.

They will be able to assist. If there are problems with the contents of the KR Proposal, they can recall it and fix it.

The screenshot shows a web application interface for proposal management. On the left, there is a sidebar with navigation options: 'Summary/Submit', 'Super User Actions', and 'Notifications History'. The main content area displays a form with the following fields:

Proposal type	new
Activity Type	Basic Research
Proposal Number	228920
Project Start Date	09/19/2023
Project End Date	09/30/2023
Include Subaward(s)?	No
Sponsor Name	PFIZER INC.
Prime Sponsor Name	
Sponsor Deadline Date	09/27/2023
Sponsor Deadline Type	Receipt

Below the form, there is a paragraph of text: "Approval indicates that information in the proposal and KR is complete and accurate to the best of your knowledge. Approval confirms any cost sharing commitments, space arrangements, resources for the project, and that the PI, and all personnel on the project, have signed either the new [Patent Acknowledgement form](#) (applicable to all new employees, appointees, and visitors as of 11/1/2011) or the Patent Acknowledgment form 10/1/1997 and the Amendment thereto . The PI, Co-PI, and others involved in the project are not currently debarred, proposed for debarment, suspended, declared ineligible, or voluntarily excluded from transactions by a federal agency. If awarded, the PI, Co-PI, and lead unit agree to be responsible for the fiscal and scientific conduct of the project as required by law, sponsor regulations, award terms, and university policy. If this proposal is being submitted to a Federal Agency and the scope of work includes human subject research, the PI also certifies that the subsequent IRB application submitted for this project will be identical in principle and congruent with the scope of work outlined in the attached proposal application. Further, the PI will submit modifications and/or changes to the IRB, as necessary, to assure the proposal/award and application continues to be congruent and identical in principle."

At the bottom of the form, there are several buttons: 'Send Adhoc', 'Ad Hoc Recipients', 'Approve', 'Return', 'View Route Log', 'Recall', 'Submit to Sponsor', 'More Actions', and 'Close'. The 'Approve' button is circled in red.