AURA Clinical Trial Concurrence Request Guidelines

Table of Contents

This document outlines the Clinical Trial (CT) concurrence request process. Below are acronyms, abbreviations, and key codes used throughout the CT concurrence request.

Note: Prior to creating a concurrence request, if you would like to be the Principal Investigator Delegate (PI-D) email the URA-M a request. PI-D may complete the PI Concurrence AURA activity, but must upload written concurrence from the PI in the PI Concurrence AURA activity.

Guidelines Acronym/ Abbreviations/ Key Codes

Acronym/Abbreviation	Title
URA	University Research Administration
OCR	Office of Clinical Research
FP	Funding Proposal
URA-M	University Research Administration Manager
PC-O	Proposal Creator Owner
PI	Principal Investigator
CR	Change Request/ Concurrence request

Key Code (Roles)	
Blue	PC-O
Green	OCR
Orange	URA-M
Purple	PI

Step 1: *(PC-O)* create change request

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Locate proposal by "Filter by" "ID" and entering "%" and the FP number in the search field, and click "Go" button
"My Home" page	Select the project by clicking on the Name
FP summary page	Click on "Create Concurrence" button in left green navigation bar
Create Concurrence Request 1.0	Check box
Create Concurrence Request 3.0	Select "No" radio button.
Create Concurrence Request	Click "Continue" button in top blue navigation bar
CR 1.02	Select "Changes to Clinical Trial" from dropdown menu
CR 1.03	Enter due date or, if none, enter 2/2/2222
CR 1.04	Select "Mail Date" radio button
CR 1.05	Select "E-mail" radio button
CR 1.07	Select your Department Post-Award Administration or, if none, yourself
CR 1.08	Select your SAA Manager
CR 1.0	Click "Continue" button in bottom blue navigation bar
CR 2.01	Upload relevant documents.
CR 2.0	Click "Continue" button in bottom blue navigation bar
CR 4.0	Click "Save" button, then "Exit" button in top blue navigation bar
CR summary page	*Complete this activity only if PI is unavailable to access AURA, if PI has provided concurrence in writing, and if PC-O is PID* Click on "PI Concurrence" button in left green navigation bar
PI Concurrence 1.0	Check box
PI Concurrence 2.0	Upload PI's written concurrence as a PDF file
PI Concurrence	Click "OK" button
CR summary page	*Complete this activity if PI is available to access AURA* Click "Notify PI or Delegate" button in left green navigation bar
Notify PI or Delegate 1.0	Check box for "Principal Investigator (PI) or Fellow (FW)"
Notify PI or Delegate 2.0	Enter information and request for PI to log in to AURA to review and provide PI Concurrence
Notify PI or Delegate	Click "OK" button
system email "Notified PI or Delegate" to PI	

Step 2: *(PI)* complete concurrence

AURA View/Field	Instructions
aura.uchicago.edu	Log in with CNET ID
My Home page	Click on "PI Inbox" tab
My Home page	Locate and select change request
CR summary page	Click on "Printer Version" button in left green navigation bar
Printer Version	Review information and document in CR 2.01
Printer Version	Click "Close" button in top gray navigation bar
CR summary page	Click "PI Concurrence" button in left green navigation bar
PI Concurrence 1.0	Check box
PI Concurrence	Click "OK" button
system email "PI Concurrence Completed" to PC	

Step 3: *(PC-O)* forward CR to OCR for review

AURA View/Field	Instructions
CR summary page	Click "Forward CR for Review" button in left green navigation bar
Forward CR for Review 1.0	Check box
Forward CR For Review	Click "OK" button
system email "CR in OCR Review" to OCR	

Step 4: *(OCR)* change request review

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "OCR" tab
"My Home" page	Locate and select change request
CR summary page	Click on "Printer Version" button on left green navigation bar
CR Printer Version	Review amendment document in CR 2.01
CR Printer Version	When done reviewing, click "Close" button in top right hand corner
CR summary page	Click "CR OCR Approval" button in left green navigation bar
CR OCR Approval 1.0	Check box
CR OCR Approval 2.0	*Only complete this section if OCR requires changes before approving* Enter "OCR DOES NOT YET APPROVE" and describe the changes required
CR OCR Approval	Click "OK" button
system email "CR in URA Review" to URA-M	

Step 5: *(URA-M)* change request review

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "URA Inbox" tab
"My Home" page	Locate and select the project
FP summary page	*Only complete this activity if the "CR OCR Approved" line in the "History" tab indicates "OCR DOES NOT YET APPROVE"* Click on the "CR Request Changes" button in the left green navigation bar
CR Request Changes 1.0	Check box
CR Request Changes 2.0	Select "No" radio button
CR Request Changes 3.0	Enter "See OCR comment"
CR Request Changes	Click "OK" button
system email "CR Changes Requested" to PC-O	

Note: **If changes are _not_ required, skip to Step 8 and URA-M completes process**

Step 6: *(PC-O)* **IF** changes requested proceed with the following

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "PC Inbox" tab
"My Home" page	Locate and select project
CR summary page	Click "Edit Change Request" button in left green navigation bar, make changes
CR summary page	When changes are completed, click "Forward CR for Review" button in the left green navigation bar
Forward CR For Review 1.0	Check box
Forward CR for Review	Click "OK" button
system email "CR OCR Review" to OCR	

Step 7: *(OCR)* change review

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "OCR" tab
"My Home" page	Locate and select change request
CR summary page	Click on "Printer Version" button on left green navigation bar
CR Printer Version	Review amendment document in CR 2.01
CR Printer Version	When done reviewing, click "Close" button in top right hand corner
CR summary page	Click "CR OCR Approval" button in left green navigation bar
CR OCR Approval 1.0	Check box
CR OCR Approval 2.0	*Only complete this section if OCR requires changes before approving* Enter "OCR DOES NOT YET APPROVE" and describe the changes required
CR OCR Approval	Click "OK" button
system email "CR in URA Review" to URA-M	

Step 8: *(URA-M)* change request review continued

AURA View/Field	Instructions
CR summary page	Click on "Printer Version" button on left green navigation bar
CR Printer Version	Review amendment document in CR 2.01
CR Printer Version	When finished reviewing, click "Close" in top gray navigation bar
CR summary page	*Complete this task only if the History tab indicates that PI Concurrence was completed by PID* Click on "PI Concurrence Completed" link
Activity Details (PI Concurrence Completed)	Click on "Documents/Tasks/Notifications" tab
Activity Details (PI Concurrence Completed)	Confirm that written concurrence from the PI has been uploaded
Activity Details (PI Concurrence Completed)	Click on breadcrumb for CR in to gray navigation bar
FP summary page	*Only complete this activity change are required before URA can endorse the CR* Click on the "CR Request Changes" button in the left green navigation bar
CR Request Changes 1.0	Check box
CR Request Changes 2.0	Select "No" radio button
CR Request Changes 3.0	Describe required changes
CR Request Changes	Click "OK" button
system email "CR Changes Requested" to PC-O	

Note: **If additional changes are _not_ required, skip to Step 11 and URA-M completes process**

Step 9: *(PC-O)* **_IF_** changes requested proceed with the following

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "PC Inbox" tab
"My Home" page	Locate and select project
CR summary page	Click "Edit Change Request" button in left green navigation bar, make changes
CR summary page	When changes are completed, click "Forward CR for Review" button in the left green navigation bar
Forward CR For Review 1.0	Check box
Forward CR for Review	Click "OK" button
system email "CR OCR Review" to OCR	

Step 10: *(OCR)* review and approval

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "OCR" tab
"My Home" page	Locate and select change request
CR summary page	Click on "Printer Version" button on left green navigation bar
CR Printer Version	Review amendment document in CR 2.01
CR Printer Version	When done reviewing, click "Close" button in top right hand corner
CR summary page	Click "CR OCR Approval" button in left green navigation bar
CR OCR Approval 1.0	Check box
CR OCR Approval 2.0	*Only complete this section if OCR requires changes before approving* Enter "OCR DOES NOT YET APPROVE" and describe the changes required
CR OCR Approval	Click "OK" button
system email "CR in URA Review" to URA-M	

Step 11: *(URA-M)* change request approval and completion

AURA View/Field	Instructions
FP summary page	When the amendment is institutionally endorsed, click the "CR URA Approval" button in the left green navigation bar
CR URA Approval 1.0	Check box
CR URA Approval 2.0	If amendment is fully-executed, select "No" radio button. If amendment is partially-executed, select "Yes" radio button
CR URA Approval	Click "OK" button
CR summary page	*Completed this task only if amendment if the answer to CR URA Approval 2.0 is "No" When fully-executed amendment is received, click "CR Approved by Sponsor" button in left green navigation bar
CR Approved by Sponsor 1.0	Check box
CR Approved by Sponsor	Click "OK" button
CR summary page	Click "Edit Change Request" button in left green navigation bar.
CR 1.0 Concurrence Request General Information	Select "CR 2.0 Concurrence Request Proposal Attachments" from the "Jump to" dropdown menu
CR 2.0 Concurrence Request Proposal Attachments CR 2.02	Upload a copy of the fully-executed amendment
CR 2.0 Concurrence Request Proposal Attachments	Click "Save" button, the "Exit" button in top blue navigation bar
CR summary page	Click on "CR Complete" button in left green navigation bar
CR Complete 1.0	Check box
CR Complete 3.0	Select "No" radio button
CR Complete	Click "OK" button
system email "CR Complete" to PI, PC, OCR	
CR summary page	*Complete this task only if URA needs to make changes to the original FP record (ex. PI change or end date extension)* Click on breadcrumb for project in top gray navigation bar
FP summary page	Click on "Edit Funding Proposal" button and make necessary changes

Change Request Complete