AURA Clinical Trial FP Guidelines

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<u>Overview:</u> This document outlines the Clinical Trial (CT) *non-system-to-system (i.e. non grants.gov)* funding submission process to assist users in pre-award proposal development. Use bookmarks to your left to navigate; view the entire CT process or jump to requirements by role. Below are acronyms/ key codes used throughout the CT process guidelines.

Note: When submitting system-to-system CT's, Question 1.3 will be marked as "research" and does not follow this workflow.

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What is a Clinical Trial?

A clinical trial is as a prospective study involving human subjects designed to answer specific questions about the effects of biomedical or behavioral interventions. Such studies may include drugs, treatments, devices, or behavioral or nutritional strategies. Behavioral clinical trials include studies of interventions to increase behaviors (e.g. cancer screening, physical activity, fruits and vegetable intake), eliminate/ reduce behaviors (e.g. smoking, sun exposure) or improve coping, quality of life, and decrease negative side effects of treatment. Observational studies and those that do not test interventions are not considered clinical trials.

In the area of molecular or imaging diagnostics, a study is a clinical trial if it uses the information from the diagnostic test in a manner that somehow affects medical decision-making for the study subject. In this way the information from the diagnostic test may have an impact on some aspect of outcome, and assessment of this outcome may be a key goal of the trial. By contrast, studies that do not use information from the diagnostic test in any manner that can affect the outcome of study subjects, but whose objective is only gathering data on the characteristics of a new diagnostic approach, are not clinical trials and are not covered by this DSM policy, unless performing the diagnostic test itself imposes some risk on study subjects.

Guidelines Acronym/ Abbreviations/ Key Codes

Acronym/Abbreviation	Title
URA	University Research Administration
OCR	Office of Clinical Research
FP	Funding Proposal
PC-O	Proposal Creator Owner
URA-M	University Research Administration Manager
PI	Principal Investigator
UA	Unit Approver
BAFO	Best and Final Offer
COI	Conflict of Interest
CRO	Contract Research Organization
IB	Investigator's Brochure
ICF	Informed Consent Form

Key Code	
Blue	PC-O
Green	OCR
Orange	URA-M
Purple	PI
Maroon	UA

Step 1: (PC-O) Create CT and route to OCR/ URA-M for advance review

auragrants.uchicago.edu Log in with CNET ID "My Home" page Click "New Funding Submission" button in the green navigation bar on the left side of the screen 1.1 Enter full protocol title or your preferred abbreviation 1.2 Enter full protocol title 1 1.3 Select "Clinical Trial" from dropdown menu 1.4 Click "Add" button Edit UC ReportingCreditUnit 1.4.1 Select PC's department 1.4.2 Edit UC ReportingCreditUnit 1.4.3 Select "Ves" radio button Edit UC_ReportingCreditUnit 1.4.3 Select "Ves" radio button 1.5 Select funding source (not the CRO, not the institution giving us a subaward) 1.8 Select "Grant," "Contract," or "Subaward" radio button, as appropriate is giving a subaward to the University) 1.0 Enter full protocol title or your preferred language for use on Current & Pending Support forms. 1.0 Click "Continue" button 2.1a Select "No" radio button 3.1 Select "No" radio button 3.2 Select "No" radio button 3.3 Enter "Ina" 3.1 Select "No" radio button 3.2 Select "No" radio button 3.3 Enter "Ina" 3.1 Select "No" radio button 5. Select "No" radio button 6. Enter "Ira" 6. Select "No" radio button 7. Select "No" radio button 7. Select "No" radio button 7. Select "Po" radio button 8. Select "No" radio button 7. Select "No" radio button 7. Select "Po" radio button 7. Select "Po" radio button 7. Select "Po" radio button 7. Select "No" add radio button 7. Select "No" radio button 7. Select	AURA View/Field	Instructions
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Step 1 Cont'd:

11.1	*View 11.0 will only appear if 9.5 was "Yes"* Click "Add" button
Edit UCFP_Subawardee 11.1.1	Select outgoing subaward organization. If unknown, select "PLACEHOLDER" and email <u>AURA-Help@uchicago.edu</u> for assistance.
Edit UCFP_Subawardee 11.1	Select "OK" button if done, select "OK and Add Another to add more outgoing suabwardees."
11.0	Click "Continue" button
13.1	Select phase, if evident from the protocol title. Otherwise select "Other" radio button.
13.2	*Only complete if 13.1 is "Other"* Enter relevant information. Ex. registry, chart review, n/a, unknown
13.3	Select "Yes" or "No" radio button, as appropriate
13.4	*Only complete if 13.3 is "Yes"* Enter IND number
13.5	Select "Yes" or "No" radio button, as appropriate
13.6	*Only complete if 13.5 is "Yes"* Enter IDE number
13.7	Select "Yes" or "No" radio button, as appropriate
13.8	Select "Yes" or "No" radio button, as appropriate
13.10	Select "Yes" or "No" radio button, as appropriate
13.11	*Only complete if 13.10 is "Yes"* Enter CRO name
13.13	Enter CRO (or, if no CRO, Sponsor) contact name for contract negotiations
13.16	Enter CRO (or, if no CRO, Sponsor) contact email for contract negotiation
13.17	Upload all documents required for advance review, clearly labeled, using upload date in file name for version control
13.0	Click "Continue" button
15.1	Skipping the radio buttons, insert date of IRB meeting intended for review in "Date Project Starts."
15.1	Return to radio buttons and select the "Yes" radio button
15.1	Enter date of IRB meeting intended for review in the "Start" date field of the first budget period row
15.0	Select "18.0 Internal Documents" from "Jump To" dropdown menu in the top blue navigation bar
18.1	Select "Yes" or "No" radio button, as appropriate
18.0	Click "Save" button, then "Exit" button in top blue navigation bar
Funding Proposal summary page	When ready to route for OCR and URA advance review, click "CT - Route Concurrence" button under "My Activities" in the left green navigation bar
CT - Route Concurrence 1.0	Check box
CT - Route Concurrence 3.0	enter comments, if any
CT - Route Concurrence	Click "OK" button
syste	m email "In CT Advance Review" to OCR and URA

PC-O routes CT concurrence to OCR & URA-M

OCR/ URA-M receive system notification

Step 2: (OCR, URA-M, PC-O) Advance review & PC-O uploads final budget

OCR, URA-M, and PC-O complete review accordingly by role.

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on My Funding Proposals tab
"My Home" page	Locate the project by "Filter by" "ID" and entering "%" and the FP number (found in the "In CT Advanced Review" email) and clicking the "Go" button. Select the project by clicking on the Name
FP summary page	Click on "Printer Version" button on left green navigation bar
FP Printer Version	Complete advance review, including documents in 13.17, and provide comments to PC and URA via non-AURA email
FP Printer Version	When done reviewing, click "Close" button in top right hand corner

OCR

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	Click on "Printer Version" button on left green navigation bar	
FP Printer Version	Complete advance review, including documents in 13.17, and provide	
	comments and contract markup to PC and OCR via email	
FP summary page	When ready to negotiate, click "CT - Ready to Negotiate" button in left green navigation bar	
CT - Ready to Negotiate 1.0	Check box	
CT - Ready to Negotiate 2.0/3.0	Upload markup in 2.0. If negotiation is not necessary, enter "n/a" in 3.0	
CT - Ready to Negotiate	Click "OK" button	
FP Summary page	If negotiations are not required, or when negotiations are complete, click "Email PC-O" button on left green navigation bar	
Email PC-O 1.0	Enter "contract is final"	
Email PC-O	Click "OK" button	
system email "Emailed PC-O"		

URA-M

AURA View/Field	Instructions
auragrants.uchicago.edu	*Complete this activity only when budget negotiations have been completed outside of AURA* 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 "Edit Funding Proposal" button in left green navigation bar
1.0	Select "13.0 Clinical Trials" on the "Jump to" dropdown menu
13.17	Upload final internal and external budgets, using "BAFO" and the upload
	date in the file name for version control
13.0	Click "Save" button, then "Exit" button in the top blue navigation bar
FP summary page	Click on Email "URA-M" button in left green navigation bar
Email URA-M 1.0	Enter "budget is final"
Email URA-M	Click "OK" button
system email "Emailed URA-M" stating "budget is final" to URA-M	

URA-M e-mail PC-O informing contract is final

PC-O

PC-O e-mail URA-M informing budget is final

Step 3: (URA-M) Route BAFO for unit review

AURA View/Field	Instructions
auragrants.uchicago.edu	*Complete this step only once PC has "Emailed URA-M" that the budget is final and URA-M has "Emailed PC-O" that the contract is final* Log in with CNET ID
"My Home" page	Click on URA Inbox tab
"My Home" page	Locate and select the project
FP summary page	Click "Route BAFO for Unit Review" button in left green navigation bar
CT- Forward BAFO for Unit Review 1.0	Check box
CT - Forward BAFO for Unit Review 2.0	Upload final contract
CT - Forward BAFO for Unit Review 3.0	Enter instructions, if any, for routing (ex. hard copies, PI signature required, email okay)
CT - Forward BAFO for Unit Review	Click "OK" button
	system email "CT in PC-PI Approval"

PI & PC-O receive system notification to complete concurrence and COI

Step 4: (PI) Concurrence and COI

Note: PC-O is not permitted to complete COI on PI's behalf.

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "PI Inbox" tab
"My Home" page	Locate and select the project
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	Click "CT - PI Concurrence and COI" button in left green navigation bar
CT - PI Concurrence and COI 1.0-5.0	Answer all required questions
CT - PI Concurrence and COI	Click "OK" button

Note: Currently no system e-mail in place to notify PC-O that Step 5 is complete. PC-O should periodically check CT to confirm PI concurrence/ COI

Step 5: (PC-O) Complete AURA budget grid, Update IRB, Route BAFO for unit approval

AURA View/Field	Instructions
auragrants.uchicago.edu	*Complete this step after PI Concurrence is completed* Log in with CNET ID
"My Home" page	Click on "PC Inbox" tab
"My Home" page	Locate and select the project
FP summary page	Select "Budget Workspaces" tab
FP Summary page	Select project budget
Budget	Select "Grid: Inflation and F&A Rates" link on left green navigation bar
Grid: Inflation and F&A Rates	Change rate percentage from 40% to 25%
Grid: Inflation and F&A Rates	Click "Apply" button, then "OK" button in top blue navigation bar
Budget	Click "Edit Budget" button in left green navigation bar
General Budget Information 4.0	Select appropriate answer
General Budget Information	Click "Continue" button in top blue navigation bar
Personnel Costs	Add 1 row to the grid
Personnel Costs	Select PI from "Person" dropdown menu, enter "0%" in Effort and SalReq fields
Personnel Costs	Select "3.7 General Costs - Grid" from "Jump to" dropdown menu
General Costs	Add 2 rows to the grid
General Costs	In one row, select "Clin Trial - Start-Up Fees" from the "Cost Type" dropdown menu, enter the start-up costs (direct costs only) in the "Unit Cost" field, enter "1" in "# of Units" field
General Costs	In the second row, select "Clin Trial - Per-Patient Fees" from the "Cost Type" dropdown menu, enter the per-patient amount (direct costs only) in the "Unit Cost" field, enter anticipated number of subjects in the "# Units" field
General Costs	Click "Save" button, then "Exit" button in top blue navigation bar
Budget	Click the project breadcrumb in the top gray navigation bar
FP summary page	Click "Edit Funding Proposal" button in left green navigation bar
1.0	Select "10 - Compliance" from the "Jump to" dropdown menu
10.3-10.4	Update protocol number and status (if approved, include approval date and upload a copy of the IRB approval letter)
10.0	Click "Save" button, then "Exit" button in top blue navigation bar
FP summary page	Click "CT - Forward BAFO for Unit Approval" button in left green
CT Forward DATO for Unit	navigation bar Check box
CT - Forward BAFO for Unit Approval 1.0	CHECK DOX
CT - Forward BAFO for Unit	Select your Unit Approver
Approval 2.0	
CT - Forward BAFO for Unit Approval	Click "OK" button
Si	ystem email "In CT Unit Approval State" to UA

PC-O route to Unit Approver (UA)

UA receives system notification

Step 6: (UA) Review and approval

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
My Home page	Click on "UA Inbox" tab
My Home page	Locate and select the project
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	Click "Unit Approval" button in left green navigation bar
Unit Approval 1.0	Select "I approve without additional comments" radio button
Unit Approval	Click "OK" button
S	ystem email "In CT OCR Review State" to OCR

OCR receives system notification

Step 7: (OCR) BAFO review

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
My Home page	Click on "OCR Inbox" tab
My Home page	Locate and select the project
FP summary page	Under "History" tab, select the link to "PI Concurrence Completed"
Activity Details (CT - PI	Review PI's answers
Concurrence Completed) 1.0,	
2.0a, and 2.0b	
Activity Details (CT - PI	Click breadcrumb for project in top gray navigation bar
Concurrence Completed)	
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	*Complete this activity only if changes are required* Click "CT - Request
	Changes" button in the left green navigation bar
CT - Request Changes 1.0	Check box
CT - Request Changes 2.0	Select "No" If PI needs to redo COI and concurrence, note that in section
	3.0 of the activity and check the History tab for re-"PI Concurrence and
	COI" activity
CT - Request Changes 3.0	Describe required changes
CT - Request Changes	Click "OK" button
syster	n email "In CT OCR Requested Changes State" to PC

Note: If changes are <u>not</u> required, skip to Step 9

PC-O receives system notification

Step 8: (PC-O) Make changes for OCR

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
FP summary page	Click "Edit Funding Proposal" button in left green navigation bar, make changes
FP summary page	When changes are completed, click "CT - Changes Made" button in the left green navigation bar
CT - Changes Made 1.0	Check box
CT- Changes Made	Click "OK" button
	system email "CT - OCR Review" to OCR

OCR receives system notification for approval

Step 9: (OCR) BAFO approval

AURA View/Field	Instructions
FP summary page	Click "OCR Approval" button in left green navigation bar
Unit Approval 1.0	Check box
Unit Approval	Click "OK" button
system email "In CT Pending Institutional Endorsement State" to URA-M and PC	

PC & URA-M receive system notification for approval

Step 10: (URA-M) BAFO 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	Under "History" tab, select the link to "PI Concurrence Completed"
Activity Details (CT - PI	Confirm that a COI Assurance is on file for the current year, and check
Concurrence Completed) 1.0,	answers
3.0-5.0	
Activity Details (CT - PI	Click breadcrumb for project in top gray navigation bar
Concurrence Completed)	
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	*Complete this activity only if changes are required* Click "Email PC-O"
	button in left green navigation screen
Email PC-O 1.0	Describe required changes
Email PC-O	Click "OK" button
	system email "Email PC-O" to PC

Note: If changes are not required, skip to Step 12 and URA-M completes process

URA-M e-mail PC-O
requesting changes

Step 11: (PC-O) Make changes for URA-M

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Locate the project by "Filter by" "ID" and entering "%" and the FP number (found in the "In CT Advanced Review" email) and clicking the "Go" button. Select the project by clicking on the Name
"My Home" page	Select project by clicking on the Name
FP summary page	Click on "Edit Funding Proposal" in left green navigation bar and make requested changes
FP summary page	When changes are completed, click "Email URA-M" in left green navigation bar
Email URA-M 1.0	Enter "changes made"
Email URA-M	Click "OK" button
	system email "Emailed URA-M"

PC-O e-mail URA-M for final review

Step 12: (URA-M) Endorsement, notice of award, budget period update

AURA View/Field	Instructions
FP summary page	When contract has been signed, click "CT - Institutional Endorsement"
	button in left green navigation bar
CT - Institutional	Check box
Endorsement 1.0	
CT - Institutional	*Only complete this step if the contract is partially executed (i.e. not yet
Endorsement 2.0	fully-executed)* Upload a copy of the partially-executed contract
CT - Institutional	Click "OK" button
Endorsement	
	In CT Waiting for Fully Executed Endorsement State" to PC
FP summary page	When contract is fully-executed, click "CT - Notice of Award" button in
	left green navigation bar
CT - Notice of Award 1.0	Check box
CT - Notice of Award 2.0	Upload a copy of the fully-executed contract
CT - Notice of Award 3.0	*Only complete this step if IRB approval is not yet shown in View 10 of
	the FP* Enter "This project does not have an approved protocol from
	the Institutional Review Board (IRB). Any work with Human Subjects may
	not begin on this project until the protocol has been approved by the
	appropriate Institutional Review Board."
	appropriate institutional neview board.
CT - Notice of Award	Click "OK" button
system em	nail "Clinical Trial Notice of Award Sent" to PC, PI, OCR
FP summary page	Click "Edit Funding Proposal" button in left green navigation bar
1.0	Select "15.0 - Budget Periods" in the "Jump to" dropdown menu
15.0	Update Start and End date fields, based on the term of the contract. If
	there is no date-specific End date, leave End date field blank
15.0	Click "Save" button, then "Exit" button in top blue navigation bar

PC-O receives system notification

Guidelines by Role

PC-O

Create CT and route to OCR/ URA-M for advance review

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click "New Funding Submission" button in the green navigation bar on
, , , ,	the left side of the screen
1.1	Enter full protocol title or your preferred abbreviation
1.2	Enter full protocol title
1.3	Select "Clinical Trial" from dropdown menu
1.4	Click "Add" button
Edit UC ReportingCreditUnit	Select PC's department
1.4.1	
Edit UC_ReportingCreditUnit	Enter "100"
1.4.2	
Edit UC_ReportingCreditUnit	Select "Yes" radio button
1.4.3	
Edit UC_ReportingCreditUnit	Click "OK" button
1.4	
1.5	Select funding source (not the CRO, not the institution giving us a
	subaward)
1.8	Select "Grant," "Contract," or "Subaward" radio button, as appropriate
1.9	*Only complete if 1.8 is "Subaward"* Select Prime Grantee (agency that
	is giving a subaward to the University)
1.10	Enter full protocol title or your preferred language for use on Current &
	Pending Support forms.
1.0	Click "Continue" button
2.1a	Select PI
2.2a	Select "No" radio button
2.0a	Select "3.0 Agency/Sponsor Details" on the "Jump To" dropdown menu
	in the top blue navigation bar
3.1	Select "No" radio button
3.3	Enter "n/a"
3.12	Select "Yes" or "No" radio button, as appropriate
3.0	Click "Continue" button
7.1	Select "No" radio button
7.2	Select PC (yourself)
7.3	*Only complete if you would like to assign Read or Edit access* click
7.5	"Add" button
Edit	Choose individual
UCFP SupportPerson7.3.1	
Edit	Choose type of access for both FP and Budget
UCFP_SupportPerson7.3.2	Shoose type of access for both in and badget
Edit UCFP Support Person	Click "OK" button if done, click "OK and Add Another" to add another
7.3	individual
7.4	Choose a PID
7.5	Select URA Manager to review from dropdown menu
7.6	Enter "2/2/2222"
7.8	Select "URA" radio button
7.0	Click "Continue" button
9.1	Select "Yes" radio button
9.5	Select "Yes" or "No" radio button, as appropriate
9.9	Select "Yes" or "No" radio button, as appropriate
9.0	Click "Continue" button
10.3	Select "Yes" radio button
10.0	Click "Continue" button
10.0	CHER CONTINUE DULLOIT

11.1	*View 11.0 will only appear if 9.5 was "Yes"* Click "Add" button
Edit UCFP_Subawardee 11.1.1	Select outgoing subaward organization. If unknown, select "PLACEHOLDER" and email <u>AURA-Help@uchicago.edu</u> for assistance.
Edit UCFP_Subawardee 11.1	Select "OK" button if done, select "OK and Add Another to add more outgoing suabwardees."
11.0	Click "Continue" button
13.1	Select phase, if evident from the protocol title. Otherwise select "Other" radio button.
13.2	*Only complete if 13.1 is "Other"* Enter relevant information. Ex. registry, chart review, n/a, unknown
13.3	Select "Yes" or "No" radio button, as appropriate
13.4	*Only complete if 13.3 is "Yes"* Enter IND number
13.5	Select "Yes" or "No" radio button, as appropriate
13.6	*Only complete if 13.5 is "Yes"* Enter IDE number
13.7	Select "Yes" or "No" radio button, as appropriate
13.8	Select "Yes" or "No" radio button, as appropriate
13.10	Select "Yes" or "No" radio button, as appropriate
13.11	*Only complete if 13.10 is "Yes"* Enter CRO name
13.13	Enter CRO (or, if no CRO, Sponsor) contact name for contract negotiations
13.16	Enter CRO (or, if no CRO, Sponsor) contact email for contract negotiation
13.17	Upload all documents required for advance review, clearly labeled, using upload date in file name for version control
13.0	Click "Continue" button
15.1	Skipping the radio buttons, insert date of IRB meeting intended for review in "Date Project Starts."
15.1	Return to radio buttons and select the "Yes" radio button
15.1	Enter date of IRB meeting intended for review in the "Start" date field of the first budget period row
15.0	Select "18.0 Internal Documents" from "Jump To" dropdown menu in the top blue navigation bar
18.1	Select "Yes" or "No" radio button, as appropriate
18.0	Click "Save" button, then "Exit" button in top blue navigation bar
Funding Proposal summary page	When ready to route for OCR and URA advance review, click "CT - Route Concurrence" button under "My Activities" in the left green navigation bar
CT - Route Concurrence 1.0	Check box
CT - Route Concurrence 3.0	enter comments, if any
CT - Route Concurrence	Click "OK" button
syste	m email "In CT Advance Review" to OCR and URA

Upon receipt of URA-M e-mail confirming contract is final, upload final budget

AURA View/Field	Instructions
auragrants.uchicago.edu	*Complete this activity only when budget negotiations have been completed outside of AURA* 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 "Edit Funding Proposal" button in left green navigation bar
1.0	Select "13.0 Clinical Trials" on the "Jump to" dropdown menu
13.17	Upload final internal and external budgets, using "BAFO" and the upload date in the file name for version control
13.0	Click "Save" button, then "Exit" button in the top blue navigation bar
FP summary page	Click on Email "URA-M" button in left green navigation bar
Email URA-M 1.0	Enter "budget is final"
Email URA-M	Click "OK" button
system ema	ail "Emailed URA-M" stating "budget is final" to URA-M

After URA-M routes BAFO for unit review, PI completes concurrence, THEN

AURA View/Field	Instructions
auragrants.uchicago.edu	*Complete this step after PI Concurrence is completed* Log in with CNET ID
"My Home" page	Click on "PC Inbox" tab
"My Home" page	Locate and select the project
FP summary page	Select "Budget Workspaces" tab
FP Summary page	Select project budget
Budget	Select "Grid: Inflation and F&A Rates" link on left green navigation bar
Grid: Inflation and F&A Rates	Change rate percentage from 40% to 25%
Grid: Inflation and F&A Rates	Click "Apply" button, then "OK" button in top blue navigation bar
Budget	Click "Edit Budget" button in left green navigation bar
General Budget Information 4.0	Select appropriate answer
General Budget Information	Click "Continue" button in top blue navigation bar
Personnel Costs	Add 1 row to the grid
Personnel Costs	Select PI from "Person" dropdown menu, enter "0%" in Effort and SalReq fields
Personnel Costs	Select "3.7 General Costs - Grid" from "Jump to" dropdown menu
General Costs	Add 2 rows to the grid
General Costs	In one row, select "Clin Trial - Start-Up Fees" from the "Cost Type" dropdown menu, enter the start-up costs (direct costs only) in the "Unit Cost" field, enter "1" in "# of Units" field
General Costs	In the second row, select "Clin Trial - Per-Patient Fees" from the "Cost Type" dropdown menu, enter the per-patient amount (direct costs only) in the "Unit Cost" field, enter anticipated number of subjects in the "# Units" field
General Costs	Click "Save" button, then "Exit" button in top blue navigation bar
Budget	Click the project breadcrumb in the top gray navigation bar

FP summary page	Click "Edit Funding Proposal" button in left green navigation bar
1.0	Select "10 - Compliance" from the "Jump to" dropdown menu
10.3-10.4	Update protocol number and status (if approved, include approval date and upload a copy of the IRB approval letter)
10.0	Click "Save" button, then "Exit" button in top blue navigation bar
FP summary page	Click "CT - Forward BAFO for Unit Approval" button in left green navigation bar
CT - Forward BAFO for Unit Approval 1.0	Check box
CT - Forward BAFO for Unit Approval 2.0	Select your Unit Approver
CT - Forward BAFO for Unit Approval	Click "OK" button
SV	stem email "In CT Unit Approval State" to UA

UA will review/ approve, OCR reviews/ approves BAFO

Upon receipt of system notification for OCR change request proceed with the following/ *IF no changes* skip this step & PC-O role is complete

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
FP summary page	Click "Edit Funding Proposal" button in left green navigation bar, make changes
FP summary page	When changes are completed, click "CT - Changes Made" button in the left green navigation bar
CT - Changes Made 1.0	Check box
CT- Changes Made	Click "OK" button
	system email "CT - OCR Review" to OCR

OCR & URA-M review/ approves changes

Upon receipt of e-mail from URA-M for change request proceed with the following/ *IF* no changes skip this step & PC-O role is complete

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Locate the project by "Filter by" "ID" and entering "%" and the FP number (found in the "In CT Advanced Review" email) and clicking the "Go" button. Select the project by clicking on the Name
"My Home" page	Select project by clicking on the Name
FP summary page	Click on "Edit Funding Proposal" in left green navigation bar and make requested changes
FP summary page	When changes are completed, click "Email URA-M" in left green navigation bar
Email URA-M 1.0	Enter "changes made"
Email URA-M	Click "OK" button
	system email "Emailed URA-M"

^{**}Note: To view complete workflow (all roles in the process) see pages 3-10**

OCR

Upon receipt of system notification that CT is ready for advance review, THEN

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on My Funding Proposals tab
"My Home" page	Locate the project by "Filter by" "ID" and entering "%" and the FP
	number (found in the "In CT Advanced Review" email) and clicking the
	"Go" button. Select the project by clicking on the Name
FP summary page	Click on "Printer Version" button on left green navigation bar
FP Printer Version	Complete advance review, including documents in 13.17, and provide comments to PC and URA via non-AURA email
FP Printer Version	When done reviewing, click "Close" button in top right hand corner

Upon receipt of system notification confirming UA approval, THEN

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
My Home page	Click on "OCR Inbox" tab
My Home page	Locate and select the project
FP summary page	Under "History" tab, select the link to "PI Concurrence Completed"
Activity Details (CT - PI Concurrence Completed) 1.0, 2.0a, and 2.0b	Review PI's answers
Activity Details (CT - PI Concurrence Completed)	Click breadcrumb for project in top gray navigation bar
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	*Complete this activity only if changes are required* Click "CT - Request Changes" button in the left green navigation bar
CT - Request Changes 1.0	Check box
CT - Request Changes 2.0	Select "No" If PI needs to redo COI and concurrence, note that in section 3.0 of the activity and check the History tab for re-"PI Concurrence and COI" activity
CT - Request Changes 3.0	Describe required changes
CT - Request Changes	Click "OK" button
system email "In CT OCR Requested Changes State" to PC	

IF changes are required, PC-O will make edits and forward back for review/ approval, THEN

AURA View/Field	Instructions
FP summary page	Click "OCR Approval" button in left green navigation bar
Unit Approval 1.0	Check box
Unit Approval	Click "OK" button
system email "In CT Pending Institutional Endorsement State" to LIRA-M and PC	

IF no changes skip this step and OCR role is complete

URA-M

Upon receipt of system notification that proposal is ready for advance review, THEN

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	Click on "Printer Version" button on left green navigation bar
FP Printer Version	Complete advance review, including documents in 13.17, and provide
	comments and contract markup to PC and OCR via email
FP summary page	When ready to negotiate, click "CT - Ready to Negotiate" button in left green navigation bar
CT - Ready to Negotiate 1.0	Check box
CT - Ready to Negotiate 2.0/3.0	Upload markup in 2.0. If negotiation is not necessary, enter "n/a" in 3.0
CT - Ready to Negotiate	Click "OK" button
FP Summary page	If negotiations are not required, or when negotiations are complete, click "Email PC-O" button on left green navigation bar
Email PC-O 1.0	Enter "contract is final"
Email PC-O	Click "OK" button
	system email "Emailed PC-O"

PC-O reviews/ updates budget

Upon receipt of e-mail from PC-O that budget has been finalized, THEN

AURA View/Field	Instructions
auragrants.uchicago.edu	*Complete this step only once PC has "Emailed URA-M" that the budget is final and URA-M has "Emailed PC-O" that the contract is final* Log in with CNET ID
"My Home" page	Click on URA Inbox tab
"My Home" page	Locate and select the project
FP summary page	Click "Route BAFO for Unit Review" button in left green navigation bar
CT- Forward BAFO for Unit Review 1.0	Check box
CT - Forward BAFO for Unit Review 2.0	Upload final contract
CT - Forward BAFO for Unit Review 3.0	Enter instructions, if any, for routing (ex. hard copies, PI signature required, email okay)
CT - Forward BAFO for Unit Review	Click "OK" button
	system email "CT_in PC-PI Approval"

PI completes concurrence, UA reviews/ approve, OCR review/ approve

IFOCR requires changes, URA-M receives notification for review and approval, THEN

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	Under "History" tab, select the link to "PI Concurrence Completed"
Activity Details (CT - PI	Confirm that a COI Assurance is on file for the current year, and check
Concurrence Completed) 1.0,	answers
3.0-5.0	
Activity Details (CT - PI	Click breadcrumb for project in top gray navigation bar
Concurrence Completed)	
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	*Complete this activity only if changes are required* Click "Email PC-O"
	button in left green navigation screen
Email PC-O 1.0	Describe required changes
Email PC-O	Click "OK" button
	system email "Email DC-O" to DC

system email "Email PC-O" to PC PC-O makes changes and e-mail URA-M for final review

URA-M Endorsement, notice of award, budget period update

AURA View/Field	Instructions	
FP summary page	When contract has been signed, click "CT - Institutional Endorsement"	
	button in left green navigation bar	
CT - Institutional	Check box	
Endorsement 1.0		
CT - Institutional	*Only complete this step if the contract is partially executed (i.e. not yet	
Endorsement 2.0	fully-executed)* Upload a copy of the partially-executed contract	
CT - Institutional	Click "OK" button	
Endorsement		
system email "	In CT Waiting for Fully Executed Endorsement State" to PC	
FP summary page	When contract is fully-executed, click "CT - Notice of Award" button in	
	left green navigation bar	
CT - Notice of Award 1.0	Check box	
CT - Notice of Award 2.0	Upload a copy of the fully-executed contract	
CT - Notice of Award 3.0	*Only complete this step if IRB approval is not yet shown in View 10 of	
	the FP* Enter "This project does not have an approved protocol from	
	the Institutional Review Board (IRB). Any work with Human Subjects may	
	not begin on this project until the proposal submitted to the agency has	
	been reviewed by the appropriate Institutional Review Board. It is	
	imperative that you provide URA with a copy of this approval or	
	amendment upon receipt."	
CT - Notice of Award	Click "OK" button	
	system email "Clinical Trial Notice of Award Sent" to PC, PI, OCR	
FP summary page	Click "Edit Funding Proposal" button in left green navigation bar	
1.0	Select "15.0 - Budget Periods" in the "Jump to" dropdown menu	
15.0	Update Start and End date fields, based on the term of the contract. If	
	there is no date-specific End date, leave End date field blank	
15.0	Click "Save" button, then "Exit" button in top blue navigation bar	

^{**}Note: To view complete workflow (all roles in the process) see pages 3-10**

<u>PI</u>

Upon receipt of system notification to complete PI concurrence & COI, THEN

Note: PC-O is not permitted to complete COI on PI's behalf.

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
"My Home" page	Click on "PI Inbox" tab
"My Home" page	Locate and select the project
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	Click "CT - PI Concurrence and COI" button in left green navigation bar
CT - PI Concurrence and COI 1.0-5.0	Answer all required questions
CT - PI Concurrence and COI	Click "OK" button

PI role complete

^{**}Note: To view complete workflow (all roles in the process) see pages 3-10**



Upon receipt of system notification that proposal is ready for approval, THEN

AURA View/Field	Instructions
auragrants.uchicago.edu	Log in with CNET ID
My Home page	Click on "UA Inbox" tab
My Home page	Locate and select the project
FP summary page	Click "Printer Version" button in left green navigation bar
Printer Version	Review clinical trial information and documents in 13.17 and 13.19
Printer Version	Click "Close" button in top right corner when done reviewing
FP summary page	Click "Unit Approval" button in left green navigation bar
Unit Approval 1.0	Select "I approve without additional comments" radio button
Unit Approval	Click "OK" button
system email "In CT OCR Review State" to OCR	

UA role complete

^{**}Note: To view complete workflow (all roles in the process) see pages 3-10**