

AURA Clinical Trial FP Guidelines

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Overview: 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.*

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

| 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 1.4.1 | Select PC's department |
| Edit UC_ReportingCreditUnit 1.4.2 | Enter "100" |
| Edit UC_ReportingCreditUnit 1.4.3 | Select "Yes" radio button |
| Edit UC_ReportingCreditUnit 1.4 | Click "OK" 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 |
| 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 "Add" button |
| Edit UCFP_SupportPerson7.3.1 | Choose individual |
| Edit UCFP_SupportPerson7.3.2 | Choose type of access for both FP and Budget |
| Edit UCFP_Support Person 7.3 | Click "OK" button if done, click "OK and Add Another" to add another 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 |

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 AURA-Help@uchicago.edu for assistance. |
| Edit UCFP_Subawardee 11.1 | Select "OK" button if done, select "OK and Add Another to add more outgoing subawardees." |
| 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 |

system 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

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

| 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 | |

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 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 |

system 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 |
| system 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 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 | |

Note: If changes are not 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 Concurrence Completed) 1.0, 3.0-5.0 | Confirm that a COI Assurance is on file for the current year, and check 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 "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 Endorsement 1.0 | Check box |
| CT - Institutional Endorsement 2.0 | *Only complete this step if the contract is partially executed (i.e. not yet fully-executed)* Upload a copy of the partially-executed contract |
| CT - Institutional Endorsement | Click "OK" button |
| 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 protocol has been approved by the appropriate Institutional Review Board." |
| 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 |

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 "Add" button |
| Edit UCFP_SupportPerson7.3.1 | Choose individual |
| Edit UCFP_SupportPerson7.3.2 | Choose type of access for both FP and Budget |
| Edit UCFP_Support Person 7.3 | Click "OK" button if done, click "OK and Add Another" to add another 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 |

| | |
|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 AURA-Help@uchicago.edu for assistance. |
| Edit UCFP_Subawardee 11.1 | Select "OK" button if done, select "OK and Add Another to add more outgoing subawardees." |
| 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 |
| system 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 email "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 |
| system 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 URA-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

IF OCR 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 Concurrence Completed) 1.0, 3.0-5.0 | Confirm that a COI Assurance is on file for the current year, and check 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 "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 | |

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 Endorsement 1.0 | Check box |
| CT - Institutional Endorsement 2.0 | *Only complete this step if the contract is partially executed (i.e. not yet fully-executed)* Upload a copy of the partially-executed contract |
| CT - Institutional Endorsement | Click "OK" button |
| 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*****

PI

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

UA

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