



UTHealth®

START

Departmental Guidance Document:

**Creating and submitting a Proposal Record for
Clinical Trial Agreements**

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Introduction

This document addresses how to submit a Clinical Trial Agreement for processing within the UTHealth START system.

A “Clinical Trial Agreement” is a contract outlining the terms to conduct an industry sponsored study that involves the collection of clinical data.

The Proposal Development (PD) module is used in conjunction with the Agreement (AGT) module to Submit Clinical Trial Agreements to SPA for processing

Each Clinical Trial Agreement must have a Proposal record and an Agreement record in START. (These records are linked in START.)

Please note that the screenshots in this document may not exactly match what you see on your screen. This may be due to software updates, differing browsers and/or window sizes, the user having more or less security than assumed here, etc.

Create the proposal record first, then create the agreement record by linking from the proposal record.

The Proposal module is used for:

Submitting Project information to SPA for project and budget review and approval, regulatory approvals, and financial account set up.

The Agreement module is used for:

Submitting the Agreement itself to SPA for review and negotiations of legal terms.

Proposal Type

Monetary Agreement

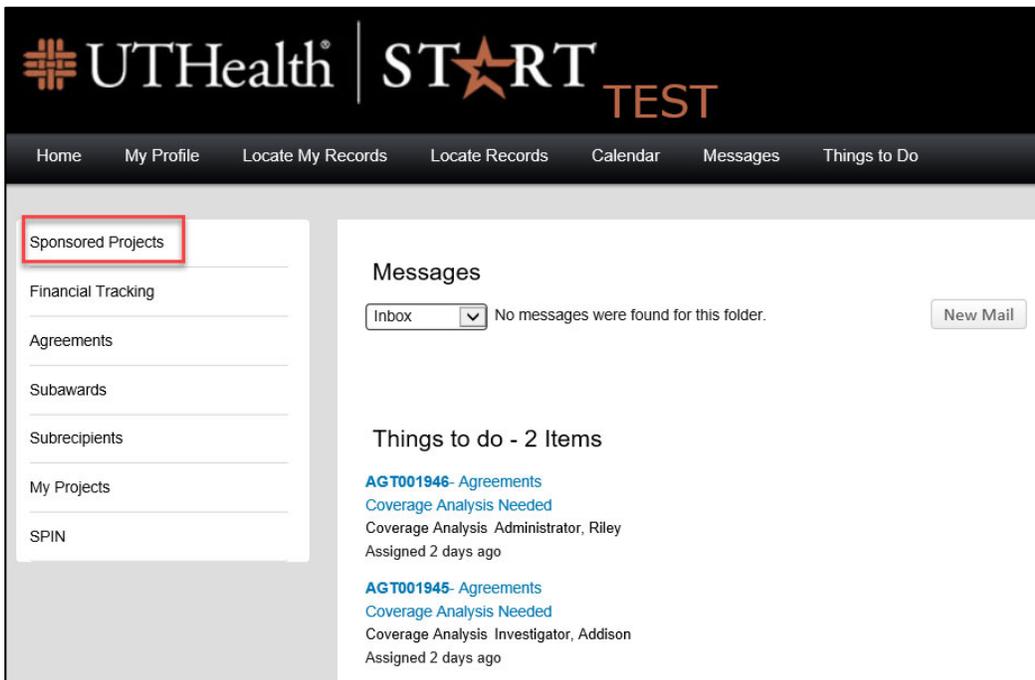
Section 1: Creating a Proposal Record

1. Login to UTHealth START utilizing the following link with your UTHealth credentials for the username and password.

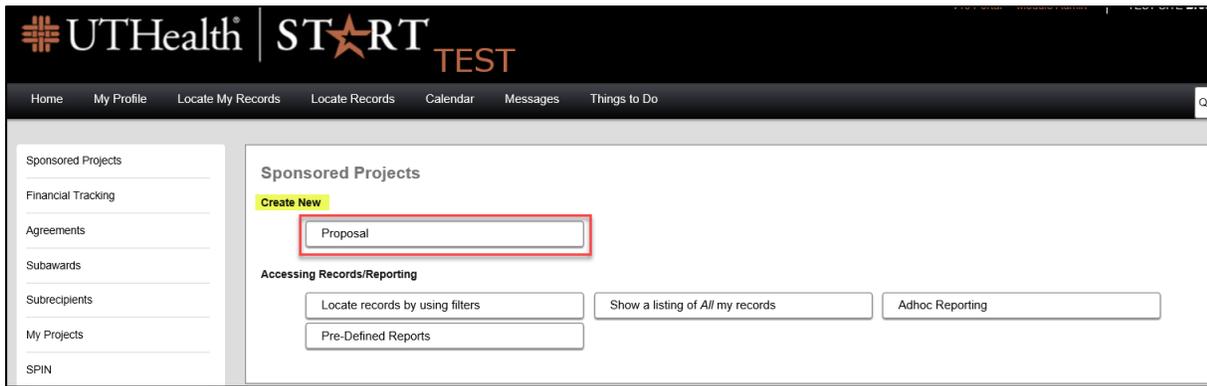
<https://uthealthstart.uth.edu>



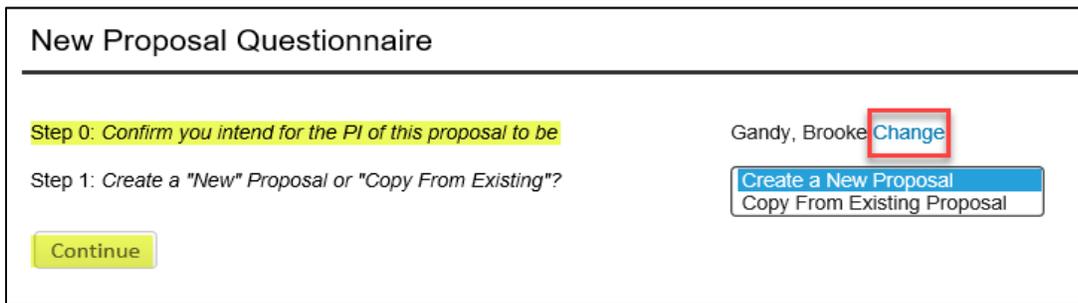
2. Once logged in using your SSO (Single Sign On), the site will directly take you to the Home Page. Click on **Sponsored Projects**.



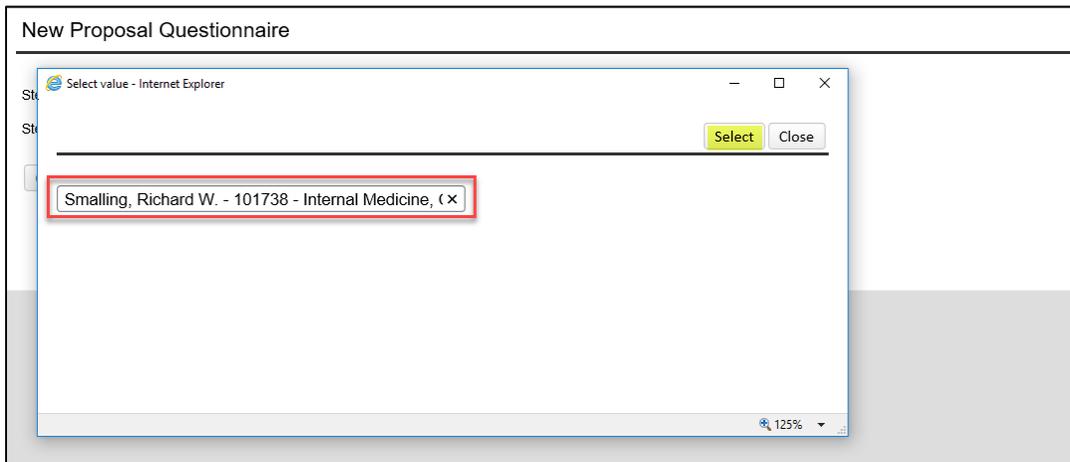
3. To create a new Proposal record, click on the **Proposal** tab.



4. A new pop-up screen will appear. Step 0 allows you to change the name of the PI. Click on **Change** to change the PI.



5. An additional pop-up screen will appear and requires you to **begin typing** in the box to fill in the PI's last name. Once located, additional information regarding the PI will also populate (dept, division, etc). Click **Select** when the PI has been chosen.



6. Once the PI name is changed, Step 1 requires you to select **Create a New Proposal** and click **Continue**.

New Proposal Questionnaire

Step 0: Confirm you intend for the PI of this proposal to be Smalling, Richard W. [Change](#)

Step 1: Create a "New" Proposal or "Copy From Existing"?

Create a New Proposal
 Copy From Existing Proposal

[Continue](#)

7. Step 1 also includes the option to select how this proposal will be setup. Click on **Setup Proposal Manually** from the drop-down menu, then click **Continue**.

New Proposal Questionnaire [Back](#)

Step 0: Confirm you intend for the PI of this proposal to be Smalling, Richard W. [Change](#)

Step 1: "New" or "Copy From Existing"? Create a New Proposal

Step 1: *Continued*

Setup Proposal Manually

▼



[Continue](#)

8. Step 2 indicates a selection for Proposal type. Select **Monetary Agreement** from the drop-down menu and click **Continue**. (Note: All Proposal records created for Internal budgets will always be a "Monetary Agreement" proposal type.)

New Proposal Questionnaire [Back](#)

Step 0: Confirm you intend for the PI of this proposal to be Smalling, Richard W. [Change](#)

Step 1: "New" or "Copy From Existing"? Create a New Proposal

Step 2: Please Select a Proposal Type

Monetary Agreement

▼



[Continue](#)

9. Step 3 requires your selection of a sponsor. Manually type the **sponsor name** and the system will automatically locate the sponsor within the institutional database. Select the sponsor and click **Continue**.

Note: If a sponsor does not appear in the text box, select Default sponsor then email Systems & Reporting: SystemsReporting@uth.tmc.edu with the sponsor information to be added by S&R.

New Proposal Questionnaire

Step 0: Confirm you intend for the PI of this proposal to be Smalling, Richard W. [Change](#)

Step 1: "New" or "Copy From Existing"? Create a New Proposal

Step 2: Proposal Type Monetary Agreement

Step 3: Select a Sponsor

Type sponsor name

[Continue](#)

10. Step 4 is automatically entered by the system; no task is needed for this step.

New Proposal Questionnaire

Step 0: <i>Confirm you intend for the PI of this proposal to be</i>	Smalling, Richard W. Change
Step 1: <i>"New" or "Copy From Existing"?</i>	Create a New Proposal
Step 2: <i>Proposal Type</i>	Monetary Agreement
Step 3: <i>Selected Sponsor</i>	Pfizer, Inc. (PFZ)
Step 4: <i>"Tracking" Number or "Proposal" Number</i>	This proposal will be automatically numbered.

11. Step 5 requires you to manually enter the Proposal's title (study title) into the text box. Click **Continue** to proceed. (Note: Be sure to add the entire, exact title. You may add the short title or Alias in quotations at the end of the full title but do not add any other information in the title field.)

New Proposal Questionnaire

Step 0: <i>Confirm you intend for the PI of this proposal to be</i>	Smalling, Richard W. Change
Step 1: <i>"New" or "Copy From Existing"?</i>	Create a New Proposal
Step 2: <i>Proposal Type</i>	Monetary Agreement
Step 3: <i>Selected Sponsor</i>	Pfizer, Inc. (PFZ)
Step 4: <i>"Tracking" Number or "Proposal" Number</i>	This proposal will be automatically numbered.

Step 5: Proposal's Title

Comparison of study drug ABCD vs. study drug XXXX

Continue

12. Step 6 allows you to enter the project start and end dates. The dates are estimated start and end dates and will be adjusted by SPA when the agreement is signed. Click on the calendar icon to select the appropriate dates, then click **Continue**.

New Proposal Questionnaire

Back

Step 0: <i>Confirm you intend for the PI of this proposal to be</i>	Smalling, Richard W. Change
Step 1: <i>"New" or "Copy From Existing"?</i>	Create a New Proposal
Step 2: <i>Proposal Type</i>	Monetary Agreement
Step 3: <i>Selected Sponsor</i>	Pfizer, Inc. (PFZ)
Step 4: <i>"Tracking" Number or "Proposal" Number</i>	This proposal will be automatically numbered.
Step 5: <i>Proposal's Title</i>	Comparison of study drug ABCD vs. study drug XXXX

Step 6: What are the project start and end dates?

From 01-Mar-2020 
To 01-Mar-2022 

Continue

13. For Step 7, using the drop-down menu, always select number 1 for the budget period for your study. Click **Continue** to proceed.

New Proposal Questionnaire

Step 0: <i>Confirm you intend for the PI of this proposal to be</i>	Gandy, Brooke Change
Step 1: <i>"New" or "Copy From Existing"?</i>	Create a New Proposal
Step 2: <i>Proposal Type</i>	Monetary Agreement
Step 3: <i>Selected Sponsor</i>	Pfizer, Inc. (PFZ)
Step 4: <i>"Tracking" Number or "Proposal" Number</i>	This proposal will be automatically numbered.
Step 5: <i>Proposal's Title</i>	ABCD
Step 6: <i>Project Start and End Dates</i>	01-Mar-2020 to 01-Mar-2021
Step 7: <i>How many years and/or budget periods would you like?</i>	<div style="border: 2px solid red; padding: 2px; display: inline-block;">1 ▼</div> *NOTE: If you need additional years/periods beyond 7, you may add them as needed inside the proposal.

[Continue](#)

14. Next, verify the information in Steps 0-6. If all of the items are correct, select **Create Proposal**. If edits need to be made, select **Step back through responses** until all of the items has been entered.

[Back](#)

New Proposal Questionnaire

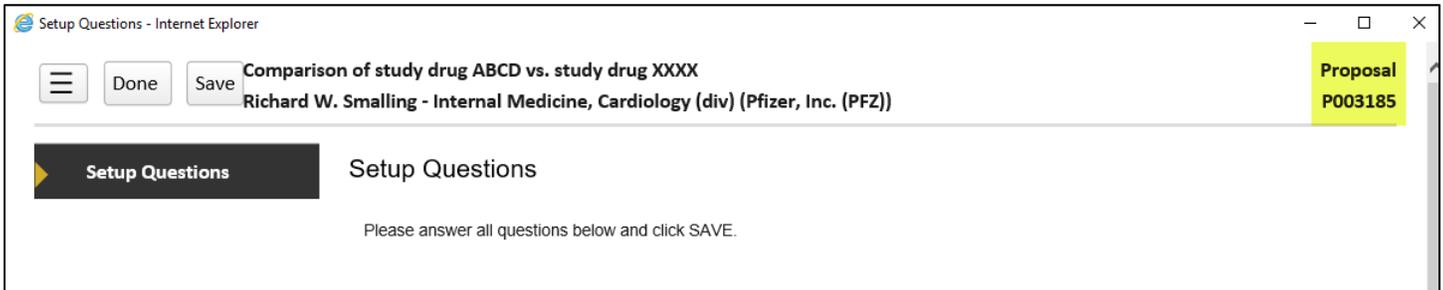
Step 0: <i>Confirm you intend for the PI of this proposal to be</i>	Smalling, Richard W. Change
Step 1: <i>"New" or "Copy From Existing"?</i>	Create a New Proposal
Step 2: <i>Proposal Type</i>	Monetary Agreement
Step 3: <i>Selected Sponsor</i>	Pfizer, Inc. (PFZ)
Step 4: <i>"Tracking" Number or "Proposal" Number</i>	This proposal will be automatically numbered.
Step 5: <i>Proposal's Title</i>	Comparison of study drug ABCD vs. study drug XXXX
Step 6: <i>Project Start and End Dates</i>	01-Mar-2020 to 01-Mar-2022
Step 7: <i>Number of Budget Periods</i>	2

Is all of the above information correct?

*NOTE: Clicking "Create Proposal" will create a new proposal with the properties you have indicated above. There is one final screen of questions to be completed before you can start entering your new proposal. Again, you will be able to change the properties of the proposal once it has been created if need be.

[Step back through responses](#) [Create Proposal](#)

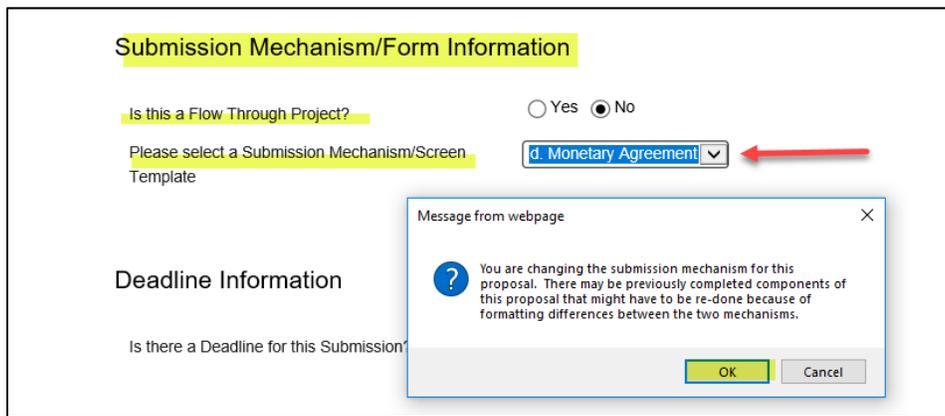
15. A new pop-up screen will appear to indicate the creation of a Proposal. Located at the top right corner of the screen is the Proposal number “P003185.” Proceed with answering the **Setup Questions**.



16. Once you scroll down on the Setup Question page, select **Monetary Agreement**. Once selected, an alert pop-up box will confirm the change of submission mechanism of the proposal.
Note: Since the Proposal is for an Internal budget (IB), the submission mechanism/screen template will change to reflect the format for a “Monetary Agreement.”

Vipul patel 3d core basic routine MRI—CAT Scan

Why go to MHH? OPID- hospital building outpatient imaging department 16th floor plaza building



17. Next, enter the Deadline Information, General Proposal Properties and Budget Setup Information. Select the **Clinical Research (non-Federal)** option for industry-funded studies on the drop-down menu. Click **Save and Continue**.
Note: Deadline Information will always be selected as “No” since deadlines do not apply to monetary agreements.

☰
Done
Save

Comparison of study drug ABCD vs. study drug XXXX

Richard W. Smalling - Internal Medicine, Cardiology (div) (Pfizer, Inc. (PFZ))

Proposal
P003187

Deadline Information

Is there a Deadline for this Submission?

Yes No

General Proposal Properties

Will your proposal involve the use of Human Subjects?

Yes No

Will your proposal involve the use of Laboratory Animals?

Yes No

Budget Setup Information

Select the Program Type

Clinical Research (non-Federal) ▼

Additional Information

Keywords (Select up to three)

Set Clear

Save and Continue

Note: Once **Setup Questions** are complete, all the required tabs for proposal development will appear. To finish your proposal, you will need to visit each tab, supply the information requested (if any), and then click the **Completed** box (top right corner). Completed tabs will display a check mark in the navigation panel. Clicking **Completed** will lock that tab from changes. However, you can still make changes to previously completed pages by first “uncompleting” it (i.e. toggling the “Completed” check box off). Uncompleting the **Setup Questions** tab will also uncomplete all other completed tabs- the displayed warning is provided. No data is lost by doing this but you **WILL** have to re-visit each tab, confirm that the data are still relevant given the changes made to **Setup Questions**, and recomplete the tab.

Setup Questions - Internet Explorer

Comparing study drug ABCD vs. study drug XXXX
Richard W. Smalling - Internal Medicine, Cardiology (div) (Pfizer, Inc. (PFZ))

Proposal P003188

Setup Questions

Completed

Setup Questions

Data Collection

Personnel

Budget

Uploads & Reviews

Attachments

Assurance Approvals

Finalize

Tasks

Agreements (0)

Done

Completed

Setup Questions

This proposal is for a **Monetary Agreement**. In order to finish the proposal, complete all items in each tab that appears after completing this page. Once the required items in each tab are finalized, you must check the "Complete" box in the top right corner of each tab. This will add a check mark next to the tab name.

When Exiting a tab or screen, always click DONE in the upper-left corner.

To turn on Field Help, click the Icon with three lines in the upper left corner, then click Show Tool Tips. A question mark will appear next to each field where help is available. Click on the question mark to view field help.

The Proposal will need to be submitted into each of the following routes.

Budget Review: This is the first review.

Required items: Set Up Questions, Data Collection, Personnel with effort, draft Scope of Work (SOW), Cost Share and IDC Waiver justifications (if applicable).

Submit to budget route by clicking Uploads and Reviews tab, Selecting Pre-review Route "Budget Review" and clicking "Thumbs Up" Icon. The approval route will pop-up, click "Submit".

SPA Review: This route is skipped for monetary agreements.

Final Review: This is the third review.

Overview of Proposal Tabs and Status History

Setup Questions: Proposal overview; impacts future data on tabs that will display once this page is complete.

Data Collection: Internal form to gather UTHealth study-specific information

Personnel: Only the PI will be listed. You can add personnel on the Budget Tab but this is not required.

Budget: Reflects total estimated revenue based on full enrollment at a summary level. It shall include # of patients x amount per patient plus start up fees. A completed CAIB tool with budget details will be attached.

Uploads & Reviews: Any supporting documents (i.e. Data Collection, summary). Documents loaded here will remain with the proposal indefinitely and will be visible in the Proposal Tracking module.

Attachments: The required uploaded documents (i.e. Informed Consent Form, Internal Budget, Research Conflict of Interest, IRB approvals, Coverage Analysis Approval)

Assurance Approvals: Tracks IRB # and status.

Finalize: Use Build PDF and assemble the proposal and submit for Internal Review; View current proposal status.

Tasks: Used to assign a task to another user to complete and the system will track tasks

Agreements: Create and link the agreement record. The CA and CDA records can also be linked here.

Data Collection Tab:

Verify and enter all of the appropriate data collection fields.

General Information:

- Click on **Monetary Agreement** for Proposal Type
- Click on **Clinical Trial Agreement** for the Expected Award Type
- Click on **Sponsor** for the Protocol/Research Plan Developed by
- Enter the Short Title/Project Nickname. Please do not use the protocol # as the short title.
- Click on **submission not needed** for who is responsible for proposal submission to sponsor
- Enter Other party's contact name. Add the phone number next to the name
- Enter Other party's email address

Sponsor Information:

- Verify Sponsor
- Add the CRO name if applicable
- Click on the **Yes/No** boxes to answer the sponsor-related questions

✓ Setup Questions

✓ Data Collection

✓ Personnel

✓ Budget

✓ Uploads & Reviews

✓ Attachments

✓ Assurance Approvals

Finalize

Management Record (PT)

Tasks

Agreements (2)

Data Collection

Validate Complete 

GENERAL INFORMATION

* Proposal Type
Monetary Agreement

* Expected Award Type
Clinical Trial Agreement

* Protocol/Research Plan Developed by
Sponsor

* Short title/Project Nickname
RELIEVE-HF
(max 20 chars)

* Who is responsible for proposal submission to sponsor?
submission not needed

Attach abstract

* Other party's contact name
[REDACTED]

* Other party's email address
[REDACTED]

SPONSOR INFORMATION

* Direct Sponsor/PTE
V-Wave Inc. (VWAVE)

List CRO (if applicable)

Link/URL to Guidelines (if not Federal)

Yes No * Has the proposal already been submitted to the sponsor?

Yes No * Continuous submission?

Yes No * Did the Development Office alert you to this RFP?

Institutional compliance:

- a. Click on the **Yes/No** boxes to answer the appropriate questions.
Based on your **Yes/No** responses, additional text boxes will automatically populate to be answered.

INSTITUTIONAL COMPLIANCE

Yes No * Does project involve human subjects (or material or data from human subjects)?
* protocol status:
* protocol #:

Yes No * Does this research include enrollment of patients/participants?
* Target Enrollment: Estimated * Est Clinical Research/Trial End Date:

Yes No * Does this research involve clinical services, procedures, or visits?

Yes No * Will visits occur at any of the UTPhysicians (UTP) clinic sites?
* List sites to be used:

Yes No * Does project involve stem cells?

Yes No * Does project involve vertebrate animals?

Yes No * Does project involve biological agents, infectious agents, or recombinant or synthetic nucleic acid?

Yes No * Does project involve radioactive materials?

Yes No * Does project involve toxic or physically dangerous chemicals or carbon or silica based nanochemistry?

Financial Information:

- a. **Enter the Department ID for FMS account set-up, do not enter "0." Since these are industry sponsored clinical trials, there should not be any cost share or indirect cost waiver. If there are extreme circumstances where these are needed, then the justification needs to clearly indicate why.**
- b. Click on the **Yes/No** boxes to answer the appropriate questions
- c. If **Yes** for Cost sharing, answer the additional questions and provide justification
- d. Click on the **Completed** check box at the top right corner when finished with this section

FINANCIAL INFORMATION

* Enter Department ID for FMS account set-up (if awarded)

Yes No * Does project budget request waiver of indirect costs?

Yes No * Is there cost sharing included?
* Type: Mandated by Sponsor Voluntary
* Source of Cost Sharing:
* Chartfield String:

* Enter Cost Share Justification

Personnel Tab:

In this tab, the personnel will automatically pull the PI name and info for this section.

- Verify the PI's name. No additional personnel are required to be added (only PI for this section).
- Zeros (0) should also appear into the Person Months (calendar, academic, summer)
- Click on the **Completed** check box when finished with this section

Setup Questions	Personnel Completed <input checked="" type="checkbox"/>										
Data Collection	You have opened this proposal in view mode										
Personnel	Person Months <input type="text"/>										
Budget	Senior/Key										
Uploads & Reviews	PI	NAME/ROLE	MAIL	ALERT	ORGANIZATION / DEPARTMENT	PERSON MONTHS			CV/BIOSKETCH	CURRENT/PENDING SUPPORT	REMOVE
Attachments		Sachin Kumar PD/PI * Certifications and Training			The University of Texas Health Science Center at Houston ACTAT (dept)	CALENDAR	ACADEMIC	SUMMER			
Assurance Approvals						0	0	0			
Finalize	Legend: <input type="text"/> Prime										

After completing the Personnel Tab, skip to the **Agreements** tab as shown below to proceed to Section 2: Linking Records, Creating & Submitting a CTA to Sponsored Projects Administration (SPA)

Setup Questions
Data Collection
Personnel
Budget
Uploads & Reviews
Attachments
Assurance Approvals
Finalize
Management Record (PT)
Tasks
Agreements (0)

Section 2: Creating & Submitting a Clinical Trial Agreement (CTA) to Sponsored Projects Administration (SPA)

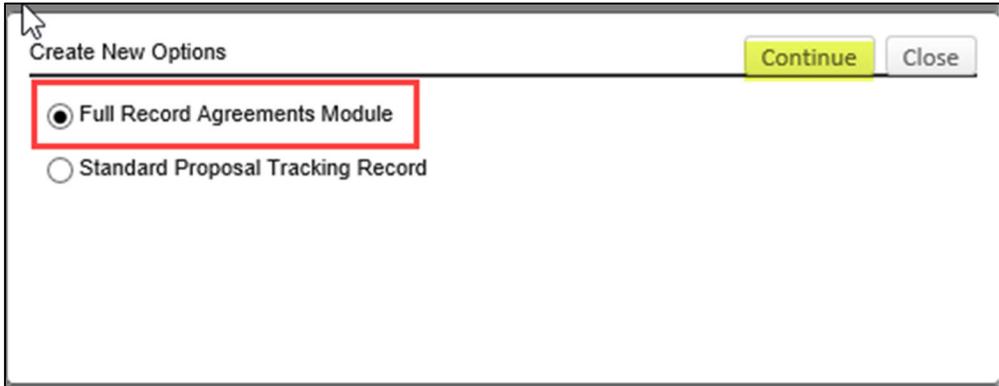
1. Create a New Agreement Record (AGT) from within the Proposal Record:

*Note: Creating a new AGT record within the Proposal will **automatically** link to the Proposal record*

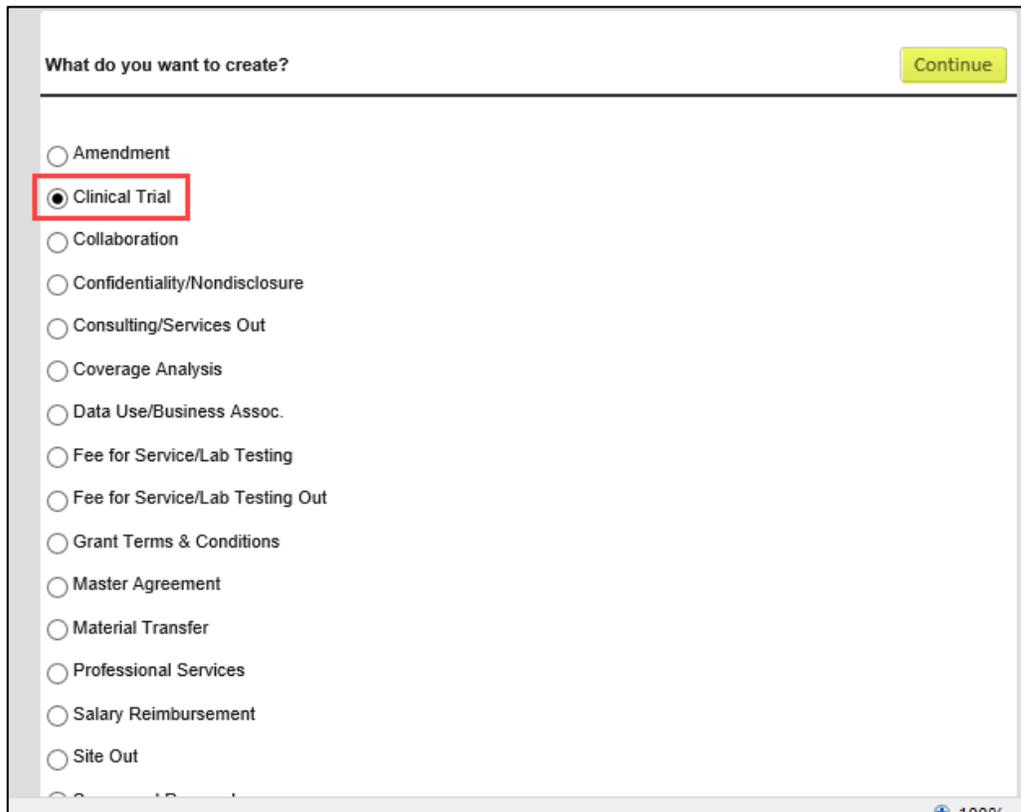
- a. Once you have clicked on the **Agreements** Tab, click on **Create New**.

The screenshot shows a web interface for a clinical trial. At the top, there is a header with a menu icon, 'Done', and 'Save' buttons. The main title is 'Comparison Clinical Trial study regarding Drug ABCD vs. Drug XXXX' and the subtitle is 'Brooke Gandy - Sponsored Projects Administration (div) (Pfizer, Inc. (PFZ))'. On the left is a sidebar with a list of tabs: 'Setup Questions', 'Data Collection', 'Personnel', 'Budget', 'Uploads & Reviews', 'Attachments', 'Assurance Approvals', 'Finalize', 'Management Record (PT)', 'Tasks', and 'Agreements (0)'. The 'Agreements (0)' tab is highlighted with a red box. The main content area shows 'Agreement Summary (0 Found)' with a 'Create New' button highlighted by a red box and a 'Link To Existing' button. Below this is a table with columns 'Number', 'Institution', and 'Type'. A red arrow points from the 'Create New' button to the 'Institution' column header.

- b. A pop-up box appears, click on **Full Record Agreements Module**
- c. Click on **Continue**



- d. Another pop-up box will appear. Click on **Clinical Trial Agreement**
- e. Click on **Continue**

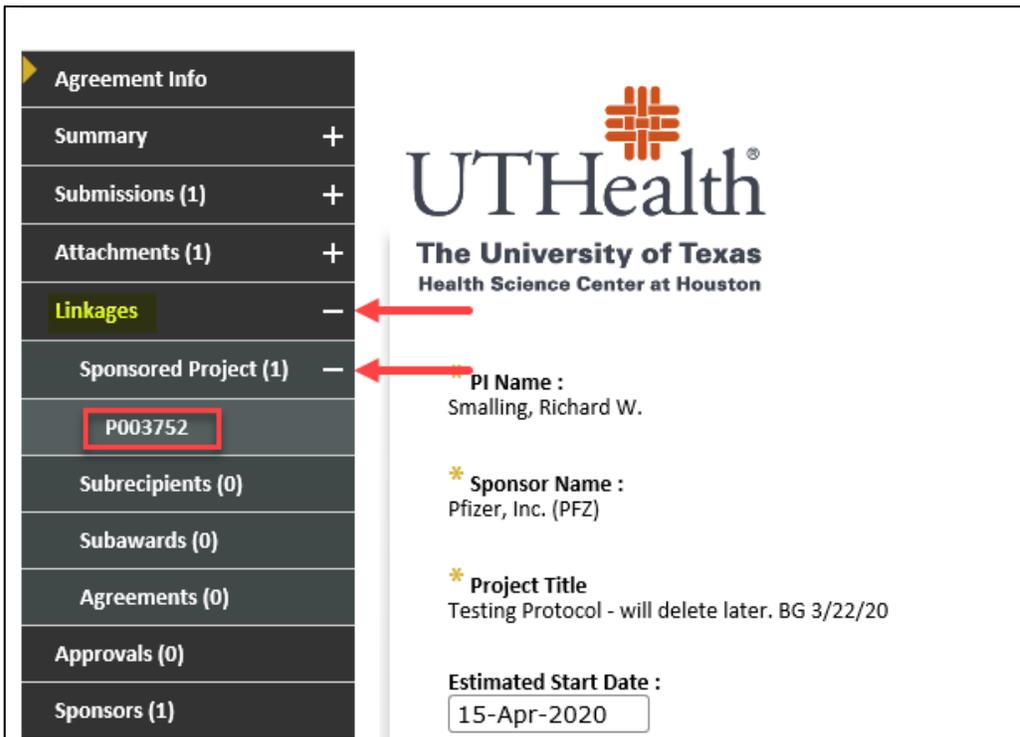


- f. At this stage, you have created the Clinical Trial Agreement (AGT #), located in the top-right corner.
Add the requested information in the appropriate fields:
- * Update the PI's Name
 - * Add Sponsor's Name
 - * Add Project Title
 - * Add Estimated Start & End Date
 - * Add Other Party's Contact info
 - * Click **Save**, then **Submit**

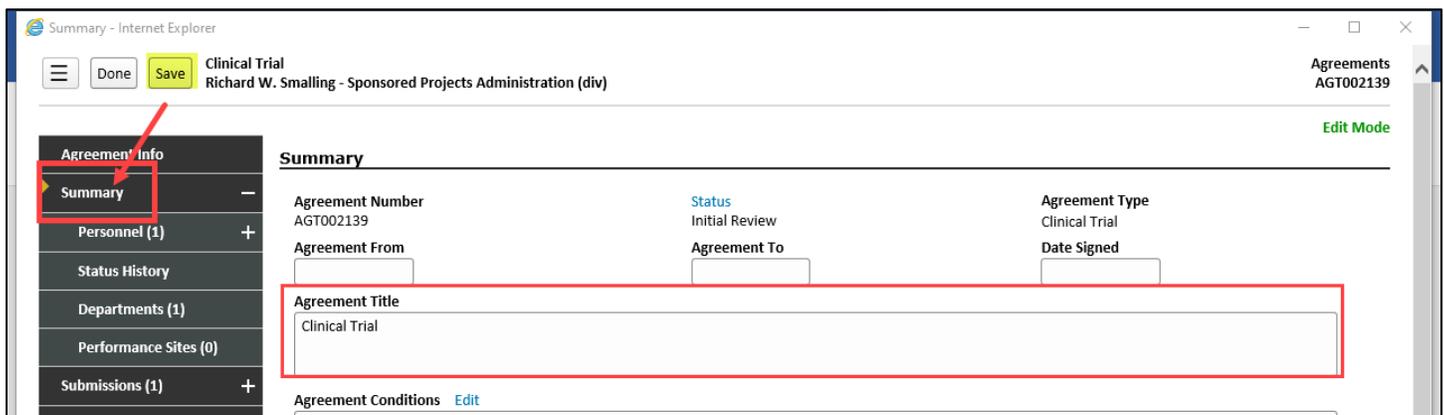
Note: Once you click Submit, the information has been saved in the **Agreement Info** tab.

The screenshot shows a web application interface for managing Clinical Trial Agreements. The top navigation bar includes 'Done' and 'Save' buttons. The main content area is titled 'Clinical Trial' and 'Brooke Gandy - Sponsored Projects Administration (div)'. On the left, there is a sidebar with a list of tabs: Agreement Info, Summary, Submissions (1), Attachments (1), Linkages, Approvals (0), Sponsors (0), Contacts (0), Communications (0), Assignments (0), and Tasks (0). The main content area displays the UTHealth logo and the text 'The University of Texas Health Science Center at Houston'. The form fields include: PI Name (Smalling, Richard W.), Sponsor Name, Project Title, Estimated Start Date, Estimated End Date, Other Party's Contact Name, and Other Party's Contact Email. A red arrow points to the 'Submit' button with the text 'Click Save, then Submit!'. The top right corner shows 'Agreements AGT002023' and 'Edit Mode'.

Tip: If you navigate down the tabs to **Linkages** and expand the “+” sign, and also expand **Sponsored Projects**, you will notice that this Clinical Trial Agreement has been automatically linked to the Proposal record, as indicated by the Proposal number below:

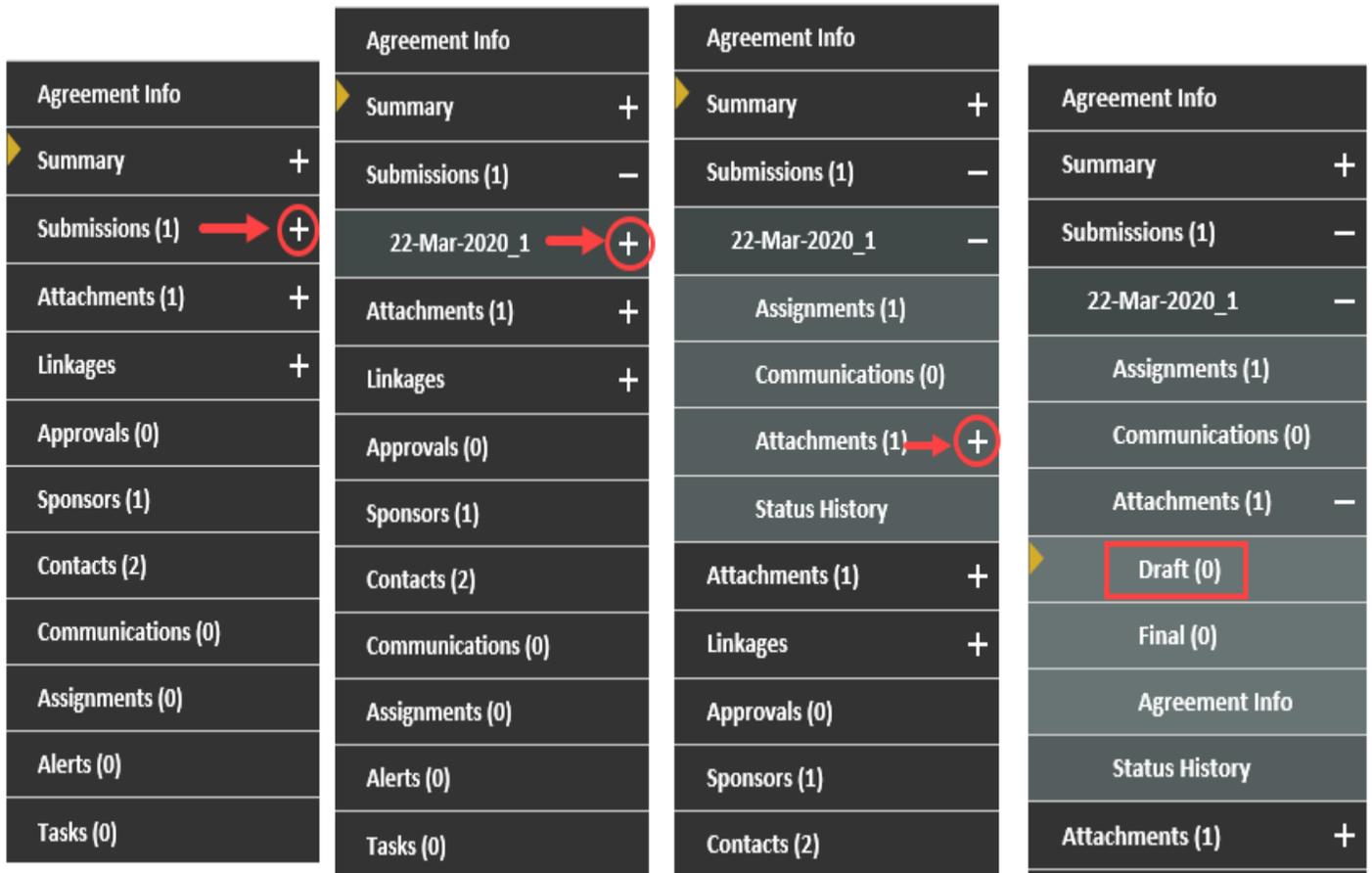


- g. Click on the **Summary** Tab (click on the word "Summary")
- * Add the **Agreement Title/Study Title**. Again, enter the full title. You can copy and paste it from the Agreement info tab.
 - * Click **Save**

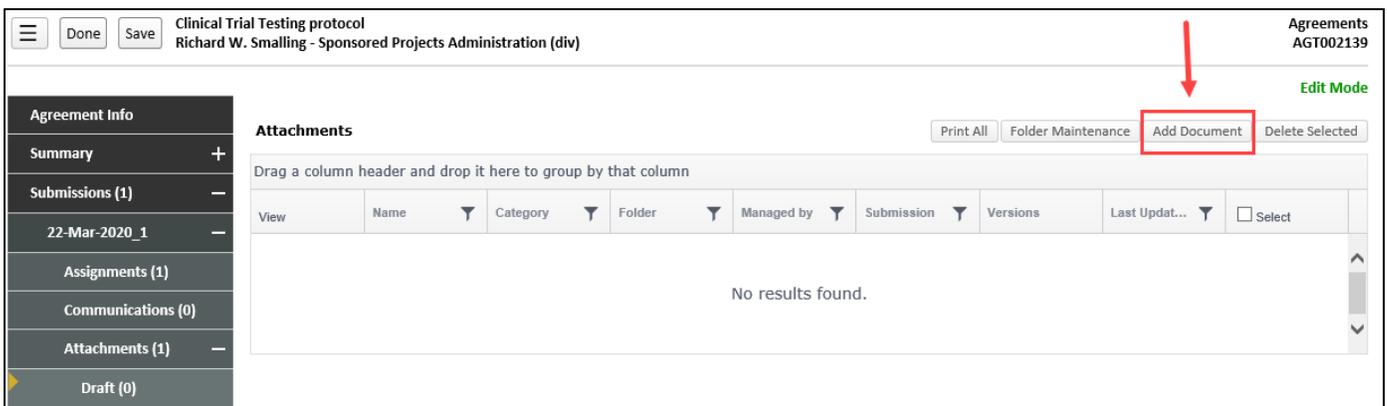


2. Attaching the Clinical Trial Agreement:

- * Click on the **Submissions (+)** sign to expand
- * Click on the **date of submission (+)** sign (i.e. 22-Mar-2020) to expand
- * Click on the **Attachments (+)** sign to expand
- * Click on **Draft**



- a. You are now in the Draft tab under Attachments and are able to attach the CTA.
 *Click on “**Add Documents**”



- b. Insert the following information to upload the CTA:
- * Insert Name: “**CTA initial draft**”
 - * Category: select **Agency Funding Document** in the drop-down menu
 - * Folder: select **Draft** in the drop-down menu
 - * Click on **Upload**

Upload Upload Close

Upload new document

Name

Location Browse...

Category ▼ ←

Folder ▼ ←

c. Now the CTA has been uploaded and attached as indicated in the Draft tab (1).

Done Save Clinical Trial Testing protocol Richard W. Smalling - Sponsored Projects Administration (div) Agreements AGT002139 Edit Mode

Attachments Print All Folder Maintenance Add Document Delete Selected

Drag a column header and drop it here to group by that column

View	Name	Category	Folder	Managed by	Submission	Versions	Last Updat...	Select
View	CTA initial draft	Agency Funding Document	Draft	Record	Clinical Trial	1	22-Mar-2020 3:3...	<input type="checkbox"/>

Agreement Info Summary Submissions (1) 22-Mar-2020_1 Assignments (1) Communications (0) Attachments (2) **Draft (1)** CTA initial draft Final (0)

Next: Please attach a copy of the proposed/draft budget from the Sponsor. If the Sponsor has provided the proposed budget within a separate document (typically excel), follow the steps above to attach the draft budget. The name for the document "Initial Draft Budget." *This draft budget is utilized by SPA during the coverage analysis process.*

3. Submitting the CTA to Sponsored Projects Administration (SPA):

a. Under the **Submissions** tab, click on **Status History**

Agreement Info **Status History**

Summary +

Submissions (1) -

22-Mar-2020_1 -

Assignments (1)

Communications (0)

Attachments (2) +

Status History

Status ▼

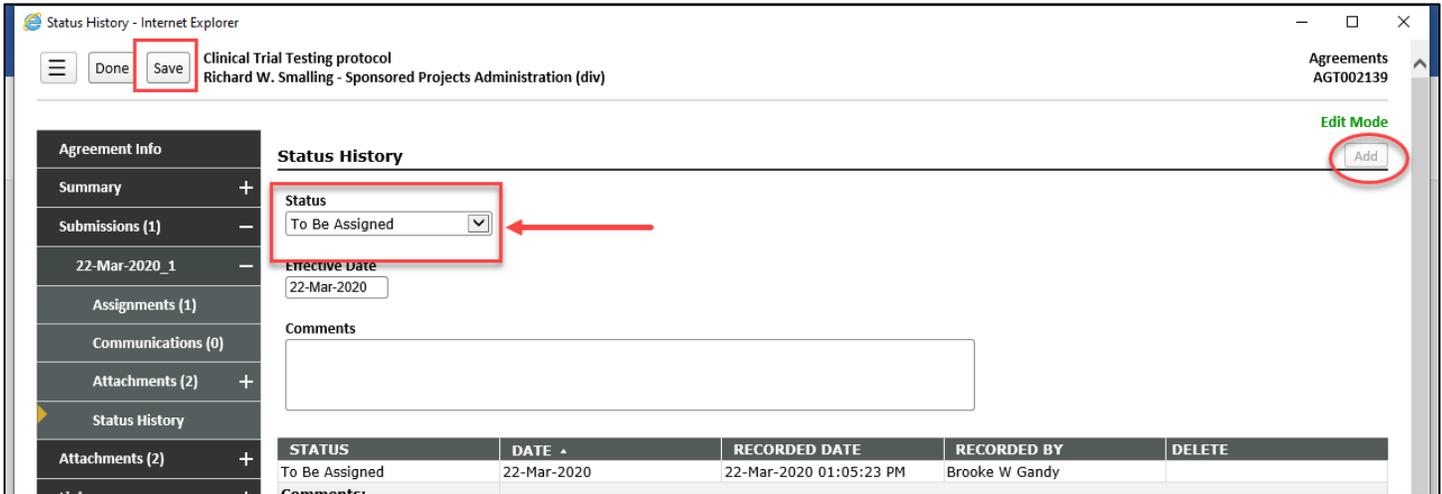
Effective Date

Comments

STATUS DATE RECORDED DATE RECOR

b. Change status to **To be assigned** in the drop-down menu

- c. First, click on **Add**
- d. Then, click on **Save**



Please note: CTA review in SPA will be prioritized based upon how actively the Departmental study team is working to finalize the Proposal Record. This will ensure SPA priorities are aligned with the Departmental study teams.

- **SPA gives higher priority ranking to those CTAs in which the budget has been finalized and routed for approvals in START to ensure SPA is focusing on the projects deemed high priority by the departments..*
- *SPA will place CTA on “Hold” status if the department is not actively working to finalize proposal record.*



Do not proceed to Section 3 until you have completed budget negotiations with the sponsor and have the following documents required for financial account set up:

1. Coverage Analysis: AGT record has “Approved” status
2. Completed Internal budget: Utilizes the same excel file/tool as Coverage Analysis

3. Finalized Sponsor Budget

You should have a clear understanding of all costs involved to conduct the study prior to negotiating budget with sponsor. All of the tabs within the Coverage Analysis Internal Budget tool (CAIB) should be completed prior to budget negotiations.

NOTE: Proposal Records are automatically deleted after 6 months. Please contact CRF if delays are experienced.

Section 3: Submitting the Proposal Record for Budget Approval

Once you have completed budget negotiations with the sponsor and you will now be able to complete the budget tab. The budget tab tracks anticipated revenue, not costs. The Coverage Analysis is a separate but linked AGT record that the Clinical Research Finance Team would have created when the protocol was submitted to the IRB.

Budget Tab:

Another pop-up box will appear for the budget section. The information for this tab provides the overall summary for study-related anticipated revenue.

- a. **The Non-Personnel “Maintenance & Operation” is the only direct cost amount to be entered in this section.**
- b. The Subtotal Personnel (PI) cost is always \$0.00. No additional amount needs to be added.
- c. Notice that the Year/Period is 1 (prior selection on the Set-Up questions)
- d. The Budget Summary includes the Directs, F&A, Total amounts, and total estimated revenue

Budget — Edit Mode

Project Period: 14-Feb-2020 to 20-Feb-2021 Source View: Sponsor Rollup subprojects: Proposal Structure Import/Export Complete Budget

Period 1 + Not Rollup

Budget Summary [Hide]

YEAR/PERIOD	INCREMENT	Periods [hide]				Sponsor [show]	Cost Sharing [show]	Project [hide]		
		START	END	TYPE	STATUS	TOTAL	TOTAL	DIRECTS	F&A	TOTAL
1	1	14-Feb-2020	20-Feb-2021	Funding*	Proposed	-	-	-	-	-
Total:						\$ 0	\$ 0	\$ 0	\$ 0	\$ 0

Subproject Summary [Show]

Personnel [Hide]

	NAME	PERIOD 1	DIRECT COSTS
Detail	Gandy, Brooke PD/PI	-	\$ 0
Subtotal Personnel:		\$ 0	\$ 0

Add New Profile Begin typing to select Personnel Name... -- Select Type -- -- Select Role -- Add Person

Non-Personnel [hide]

CATEGORY	PERIOD 1	DIRECT COSTS
No records to display.		
Subtotal Non-Personnel:		\$ 0

Select Budget Category Select Object Code Add Item

** Un-mapped object codes will not reconcile into budget categories **

SubAwards [show]

Subprojects [show] Import as Subproject

	PERIOD 1	TOTAL COSTS
Total Sponsor Direct Costs:	-	\$ 0
Sponsor F&A:	0	0
Total Sponsor Costs:	\$ 0	\$ 0

- e. To enter the anticipated direct revenue (Non-Personnel section) select **Other Costs** from the drop-down menu and then select **61006-Maintenance & Operation** from the additional drop-down menu. Click **Add Item**.

Non-Personnel [hide]

CATEGORY	PERIOD 1	DIRECT COSTS
No records to display.		
Subtotal Non-Personnel:		\$ 0
Other Costs	61006 - MAINTENANCE & OPERATION	

Add Item

** Un-mapped object codes will not reconcile into budget categories **

- f. A new pop-up box will appear to enter the cost for the Maintenance & Operation.

The Total anticipated revenue/Total Amount Funded by Sponsor is:
Start Up Fees + (Total contracted participants x Amount paid per participant)

This will give you total contracted revenue. You can increase or decrease as needed based on what the PI deems realistic and appropriate but, the total revenue must match the anticipated amount from sponsor on the summary tab of the CAIB tool.

Take the total revenue and divide by 1.3 to back out the 30% indirect revenue.

For example: \$10,000 start up fees + (\$10300/participant x 100 participants) = \$1,040,000

\$1,040,000 / 1.3 = \$800,000 direct revenue

g. Enter the total direct revenue amount in the text box and click **Save and Continue**.

Non-Personnel Costs

Detail Justifications Cost Sharing Show Calculations **Save and Close** Save Close

Costs by "Budget Period" Annual Inflation *Manual Entry* Description Other Costs

Budget Category Other Costs Object Code 61006 - MAINTENANCE & OPERATION

PERIOD	START DATE	END DATE	TOTAL
1	07-Feb-2020	07-Feb-2021	800,000
Total			\$ 800,000

NOTE: The system will automatically calculate the Sponsor F&A/Indirect Revenue.

Project Period: 07-Feb-2020 to 07-Feb-2021 Source View: Sponsor Rollup subprojects: Not Rollup Proposal Structure Import/Export Complete Budget Edit Mode

Budget Summary [Hide]

YEAR/PERIOD	INCREMENT	START	END	TYPE	STATUS	Sponsor TOTAL	Cost Sharing TOTAL	DIRECTS	F&A	TOTAL
1	1	07-Feb-2020	07-Feb-2021	Funding*	Proposed	\$ 1,040,000	-	\$ 800,000	\$ 240,000	\$ 1,040,000
Total:						\$ 1,040,000	\$ 0	\$ 800,000	\$ 240,000	\$ 1,040,000

Subproject Summary [Show]

Personnel [Hide]

NAME	PERIOD 1	DIRECT COSTS
Gandy, Brooke PD/PI	-	\$ 0
Subtotal Personnel:		\$ 0

Non-Personnel [hide]

CATEGORY	PERIOD 1	DIRECT COSTS
Other Costs 61006 - MAINTENANCE & OPERATION	\$ 800,000	\$ 800,000
Subtotal Non-Personnel:		\$ 800,000

SubAwards [show]

Subprojects [show] Import as Subproject

	PERIOD 1	TOTAL COSTS
Total Sponsor Direct Costs:	\$ 800,000	\$ 800,000
Sponsor F&A:	240,000	240,000
Total Sponsor Costs:	\$ 1,040,000	\$ 1,040,000

Total Amount Funded by Sponsor ** Total is calculated as follows:
 Total per patient amount multiplied by # of anticipated patients (inclusive of OH) , plus Start-up fees. Please do not include the Invoicable procedures within the calculation**

\$1,040,000

h. Expand the "+" for Period 1 tab and click on the **F&A** tab.
 Verify the **Base** category needs to indicate **TDC** from the drop down menu, and the **Rate** category

needs to indicate **Clinical Research** in order to capture the IDC (Indirect Costs of 30%)

BUDGET CATEGORY - ITEM	TOTAL	BASE	RATE (%)	F&A (\$)
Salaries & Wages Gandy, Brooke	Cost Sharing	0	0	0
Other Costs Other Costs	Cost Sharing	800,000	800,000	240,000
Total		\$ 800,000	\$ 800,000	240,000

i. If **Cost Sharing** is applicable to the study, click on the **Cost Sharing** tab, then click **Add Source**.

	PERSONNEL	SPONSOR	INSTITUTION	OVER CAP/UNALLO	TOTAL
Subtotal Personnel:	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
	NON-PERSONNEL	SPONSOR	INSTITUTION	OVER CAP/UNALLO	TOTAL
Subtotal Non-Personnel:	\$ 800,000	\$ 0	\$ 0	\$ 0	\$ 800,000
	SUBPROJECTS	SPONSOR	INSTITUTION	OVER CAP/UNALLO	TOTAL
Subtotal Subprojects:	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
Total Direct Costs:	\$ 800,000	\$ 0	\$ 0	\$ 0	\$ 800,000
F&A:	\$ 240,000	\$ 0	\$ 0	\$ 0	\$ 240,000
Total Costs:	\$ 1,040,000	\$ 0	\$ 0	\$ 0	\$ 1,040,000

j. A new pop-up box will appear. Enter the applicable information regarding sources, percentages, and account number. Click on **Save** once the information has been entered.

SOURCE	CHARGE TO	SHORT NAME	ACTUAL %	AMOUNT	ACCOUNT NUMBER	DELETE
SRC 1	Pfizer, Inc. (PFZ)	Sponsor	100.000	800,000		
SRC 2	Sponsored Projects Administration (div)	Institution	0.000	0		
SRC 3	Sponsored Projects Administration (div)	Over Cap/Unallo	0.000	0		
Total			100.000%	\$ 800,000		

Attachments Tab:

The following documents are required to be attached for financial approval:

1. Approved CA & with Internal Budget tabs completed (all tabs must be completed if applicable to project)
 2. Negotiated Sponsor Budget – Final
- If the below items (as applicable) are available you should attach now. If the below items are not yet available, move to next steps and attach them after the budget is approved and finalized. (Discussed in more detail on page 32 “Finalize Proposal Record”)
3. CPHS IRB Approval Letter (IRIS interface pending)
 4. RCOI (Research Conflict of Interest for each person listed on the budget)
 5. IRB approved Informed Consent document(s)
 6. IRB approval letter from 3rd party (if applicable)

*Note the contract can not be routed for signatures until all of the above items (as applicable) are attached .

I. Click on the **Completed** check box when finished uploading all of the appropriate documents.

	Sequence	Original	PDF
Approved CA_Internal Budget_(CAIB tool).xlsx	1	<input type="button" value="View"/>	<input type="button" value="View"/>
Sponsor Budget_Final.docx		<input type="button" value="View"/>	<input type="button" value="View"/>

Assurance Approvals Tab:

The Approvals page contains information regarding compliance requirements. If your proposal requires any of the listed approvals (IRB, IACUC, IBC, etc.), you should add a corresponding protocol record. This is accomplished by clicking ADD, selecting the desired approval type from the dropdown list, then clicking CONTINUE. UTHealth has interfaced iRIS to the START system. Once an IRB C number is entered, it will pull the proposal status from iRIS and will update the status on a nightly basis. This interface cannot occur until the IRB or IACUC number is entered. Any additional regulatory approvals (such as commercial/central IRB and/or the biosafety committee) must be entered manually.

To manually add approval:

- Click on “Add”
- Select “Type”
- Select “Not Attached” for Protocol
- Select “Continue”

Save Close

Approvals

Type:

Protocol: Attached Not Attached Create New

- Enter protocol specific IRB approval information
 - “IRB Approved To date”- if applicable (some IRB approvals do not have end date)

_Reference number is the ID number assigned to specific protocol.

_Approval PI (UTHealth PI) use the SET link – see below following the screenshot – to do this)

When setting the Approval PI, a popup window will appear. On that window, click the first letter of the person’s last name. THEN, either click the dropdown icon and scroll to the desired name or type the person’s name in the Search For box until the desired name is highlighted. (You can also combine these methods by typing the first few letters of the name in and then clicking the dropdown. This will start the dropdown list at the letters you typed, rather than at the beginning.) Once the desired name is highlighted, click **Select**.

As you are looking at the dropdown list of names, you may notice that most names are listed two or more times. Choose the first occurrence of the person you are seeking. Note that each person’s UTHealth id and assigned organization(s) are included to aid in identification.

- f. (Add new approval record for each Assurance committee approval required for protocol-example IRB approval, Biosafety Committee approval, etc.)
- g. Check the **Completed** check box to complete this section.

Setup Questions Approvals Completed

Data Collection

Personnel

Budget

Uploads & Reviews

Attachments

Assurance Approvals

Finalize

Note: The Approval Date of the highest sequenced LA and/or HS record will map to Other Project Info.

Approvals Add

[Associate Protocols to Proposals \(PD\)](#)

Uploads & Reviews Tab:

- a. Click on the **EDIT** icon.

Setup Questions Uploads & Reviews Completed

Data Collection

Budget

Personnel

Uploads & Reviews

Attachments

Assurance Approvals

Finalize

Current Proposal Status: Under development

Components for Initial Application Pre-Review Route: Budget Review 👍

Current Submission

FORM/DOCUMENT NAME	EDIT	STATUS	UPLOAD	REMOVE
Summary (Proposal package)		Completed		Mandatory

[Add Institution Forms/Supporting Documents](#)

- b. A new pop-up box will appear. Click on the **Complete** check box.

UTHealth
The University of Texas
Health Science Center at Houston

Validate Complete

PROJECT INFORMATION

Proposal Nbr: P003243
Project Type: Clinical Research (non-Federal)
Proposal Type: Monetary Agreement
Sponsor Deadline:

Project title: 1234

Primary Sponsor: Pfizer, Inc. (PFZ)
Original sponsor: Pfizer, Inc. (PFZ)

Opportunity/Program:

BUDGET INFORMATION

Budget Summary

Start Date	End Date	Direct Costs	Subawards	Indirect Costs	F&A Rate	Total Project
14-Feb-2020	20-Feb-2021	\$0.00	\$0.00	\$0.00	0%	\$0.00
14-Feb-2020	20-Feb-2021	\$0.00	\$0.00	\$0.00	-	\$0.00

No IDC waiver is being sought
No cost sharing is being sought

c. Then, click on the **Completed** check box on the Uploads & Review Tab.

Setup Questions Data Collection Budget Personnel **Uploads & Reviews** Attachments Assurance Approvals Finalize

Uploads & Reviews Completed

Current Proposal Status: Under development

Components for Initial Application Pre-Review Route: Budget Review Submit Pre-Review

Current Submission

FORM/DOCUMENT NAME	EDIT	STATUS	UPLOAD	REMOVE
Summary (Proposal package)		Completed		Mandatory

Finalize Tab:

a. Click on **Build** to Build PDF/Form Pages.

Setup Questions Data Collection Personnel Budget **Uploads & Reviews** Attachments Assurance Approvals **Finalize**

Finalize

[Build PDF / Form Pages](#)

Form Page	Build	Last Built	Built By
Budget Summary Form	<input type="button" value="Build"/>		

Warning: Once these pages are built, uncompleting any of these "Tabs" will require that you re-build these pages.

[Assemble Application](#)
[Submit for Internal Review](#)

b. Click on **Assemble Application**.

The screenshot shows a sidebar on the left with menu items: Setup Questions (checked), Data Collection, Personnel, Budget, Uploads & Reviews, Attachments, Assurance Approvals, and Finalize (selected). The main content area is titled 'Finalize' and includes a 'Build' button. Below this is a table with columns 'Form Page', 'Last Built', and 'Built By'. The table contains one row: 'Budget Summary Form', '14-Feb-2020 11:37:49 AM', and 'Gandy Brooke'. A red warning message states: 'Warning: Once these pages are built, uncompleting any of these "Tabs" will require that you re-build these pages.' Below the warning, the 'Assemble Application' button is highlighted with a red box, and the 'Submit for Internal Review' link is visible below it.

c. Click on **Submit for Internal Review**.

This screenshot is identical to the one above, but the 'Submit for Internal Review' link is highlighted with a red box instead of the 'Assemble Application' button.

Routing:

The routing process is triggered anytime a submit button is clicked in the system. Routes are built for proposal reviews, when an agreement is submitted to SPA, as well as initiating and processing the Coverage Analysis. “Things to do” assigned via a Route are completed on the Reviewer Dashboard.

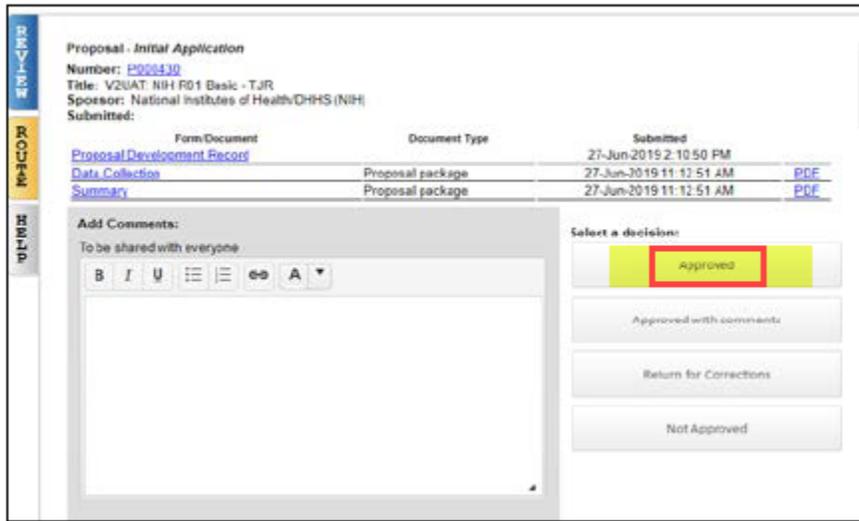
1. The department clicks on **Submit Pre-Review “thumb” icon** to send to PI for approval.

Submit Pre-Review 

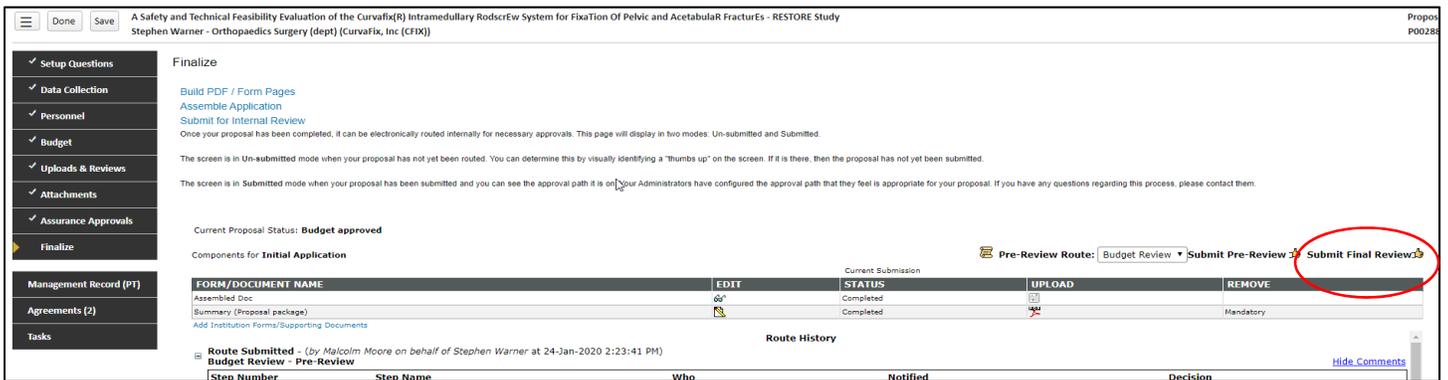
2. The Approval request is immediately available on PI’s START Dashboard.

The screenshot shows a 'Things to do - 31 Items' dashboard. At the top right, there are controls: 'Filter by Area', 'Show Completed Items', 'Display Options/Sorting', and 'Page 1 of 4'. A task is listed: 'P000327 (Sponsored Project) - Your action is required'. Below the task title, it says 'Grants gov for 6/7/19 Investigator, Paula' and 'Action Item Assigned 4 days ago'.

3. PI clicks on “Approve” the proposal and routes it to the DMO.



4. The DMO approves the proposal. (same manner as above)
5. After the DMO has approved the proposal, anyone in the department (creator of proposal or DMO) clicks on the **Final review “thumb” icon**.



6. The proposal is routed to SPA Intake Pre-Award group.
7. The SPA Intake group routes to the SPA Financial group.
8. The SPA Financial group completes a congruency check and approves the Proposal Development (PD) Record (Budget).
9. The SPA Financial group routes the Proposal to the SPA Contract group

SPA (Director or AVP) “Approval” noted here signifies that the Proposal Record Budget has been approved by SPA

Section 4: Finalizing the Proposal Record

The CTA will be routed for institutional signature after the Proposal Record has been fully completed and all required documentation has been uploaded. In order to proceed with finalizing the Proposal Record for the CTA for institutional signature), the remaining documents (as applicable) will need to be attached into the **Proposal Tracking (PT)** record:

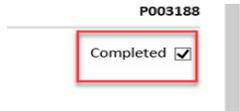
- CPHS IRB Approval Letter (IRIS interface pending)
- RCOI (Research Conflict of Interest for each person listed on the budget)
- IRB approved Informed Consent document(s)
- IRB approval letter from 3rd party (if applicable)

- a. From the Proposal Development (PD) record, click on the **Attachments** tab:
- b. Uncheck “Completed” box (Upper right hand corner)
- c. Click on **Add Document**.
- d. A pop-up box will appear, enter the following information for each uploaded document:

* Enter the name of the document (i.e. RCOI)

* **Browse** your files and then select **Upload**

- e. Once all documents have been uploaded check the “Completed” box in the upper righthand corner of the page



Once the remaining documents have been uploaded into the PD record, the SPA Contract group will complete their congruency check and route to the Director for institutional signature/Approval.

To view the status of the Proposal route:

- a. Click the “**scroll**” icon to view status and route history
- b. Notice the Approval status: **SPA Approved**

- ✓ Setup Questions
- ✓ Data Collection
- ✓ Personnel
- ✓ Budget
- ✓ Uploads & Reviews
- ✓ Attachments
- ✓ Assurance Approvals
- ✓ Finalize

- Management Record (PT)
- Tasks
- Agreements (2)

Finalize

[Build PDF / Form Pages](#)
[Assemble Application](#)
[Submit for Internal Review](#)

Once your proposal has been completed, it can be electronically routed internally for necessary approvals. This page will display in two modes: Un-submitted and Submitted.

The screen is in Un-submitted mode when your proposal has not yet been routed. You can determine this by visually identifying a "thumbs up" on the screen. If it is there, then the proposal has not yet been submitted.

The screen is in Submitted mode when your proposal has been submitted and you can see the approval path it is on. Your Administrators have configured the approval path that they feel is appropriate for your proposal. If you have any questions regarding this process, please contact them.

Current Proposal Status: **Active**

Components for **Initial Application**

Current Submission

FORM/DOCUMENT NAME	VIEW	STATUS	UPLOAD	REMOVE
Assembled Doc		Completed		
Summary (Proposal package)		Completed		Mandatory

Step 2 Kyle L Jernigan 04-Dec-2019 9:36:20 AM Approved - Approved with comments

Comments: **Kyle L Jernigan (12/5/2019 11:08:18 AM)** - "Financial concurrency was approved first time around. KJ "

Step 3 Daniel DeLeon 05-Dec-2019 11:08:20 AM Approved - Approved

Comments: **Daniel DeLeon (12/17/2019 11:24:07 AM)** - "SPA approved. "

Step 3 Approved (SPA submits) Victor Samuel Lopez Rivera 17-Dec-2019 11:24:19 AM Informed -

Comments: none

Additionally, once the contract has been signed, SPA CRF routes the proposal to PAF for account/award set up. Then, PAF sets up the Award in FMS and changes the status of the proposal to Awarded/Active.

Appendix I: Linkages- How to link Records in START

As noted previously the Proposal Development (PD) module is used in conjunction with the Agreement (AGT) module to Submit Clinical Trial Agreements to SPA for processing. Each Clinical Trial Agreement will have a Proposal record in START. In many cases each Clinical Trial agreement will have two Agreement records in START (1. A CTA Agreement record; and 2.a Coverage Analysis Agreement record.)

The Proposal module is used for:

Submitting Project information to SPA for project and budget review and approval, regulatory approvals, and financial account set up.

The Agreement module is used for:

Submitting the Agreement itself to SPA for review and negotiations of legal terms.
Submitting and tracking the status of the Research billing Coverage Analysis (CA)

All records in START related to a particular Project should be linked.

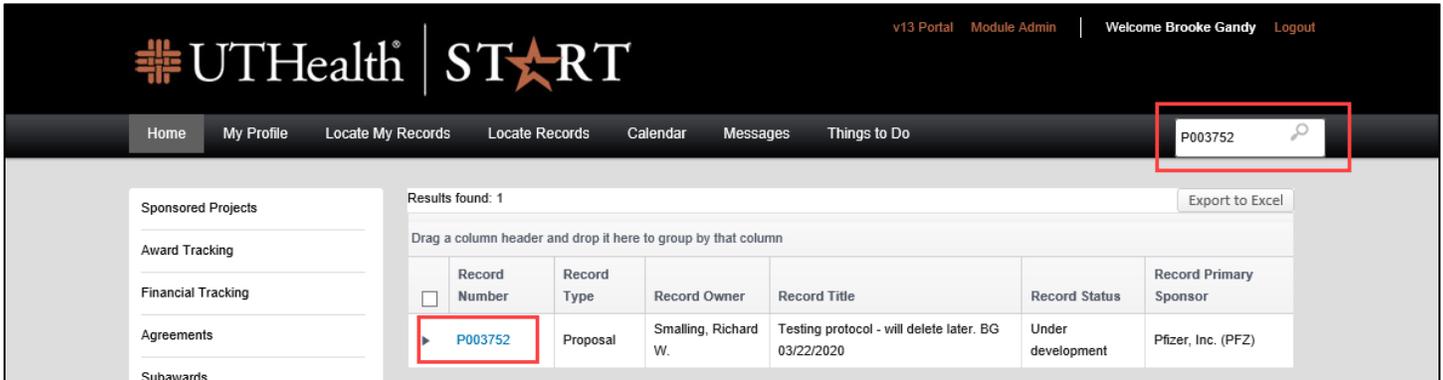
Examples of linking existing records for Clinical Trial Monetary Agreements include:

1. Linking CTA Proposal Record to CTA Agreement record (Proposal Record # to AGT Record)
2. Linking CTA Proposal Record to CA Agreement Record (Proposal Record # to AGT #)
3. Linking Clinical Trial Agreement to the Clinical Disclosure Agreement: (AGT# to AGT#)
4. Linking Clinical Trial Agreement to Coverage Analysis: (AGT# to AGT#)

The remainder of this page is intentional left blank move to next page

1. **Linking Proposal Record to AGT record** (Linking Proposal to CTA Record and /or Linking Proposal Record to CA record)

- a. From the Home Page, enter and locate the Proposal record in the **Quick Find** section
- b. Click on the P number and navigate to **Proposal Development > Edit**



- c. Once in the Proposal Development (PD) record:
 - * Click on the **Agreements Tab**
 - * Click on **Link to Existing**



- d. If the Agreement Number is known, enter the AGT number into **Select by Number**
 - *Click **Go**



- e. If the Agreement Number is unknown, use filters to locate record
 - * Once filters have been selected, click **Go**

Apply Filters

Browse By

Sponsor/Scheme <input type="text"/>	Sponsor Type <input type="text" value="- Select -"/>
Primary Center/Program <input type="text"/>	Center/Program <input type="text"/>
Principal Investigator <input type="text"/>	Investigator <input type="text"/>
Primary Assoc. Dept. <input type="text"/>	PI Department <input type="text"/>

- f. Scroll Down to the bottom of the screen
 - * Click on the box of the Agreement
 - * Click **Select**
 - * Click **Save** on the PD record

2 Records Found. Displaying pages 1 through 1 of 1

Number	Title	Sponsor/Scheme	PI	Select
AGT002139	Clinical Trial Testing protocol	Pfizer, Inc. (PFZ)	Smalling, Richard W.	<input type="checkbox"/>

1. Linking an Agreement Record to an existing Agreement Record: (linking CTA record to CA record and /or linking CTA record to CDA record)

- a. From the Home Page, enter and locate the Agreement record in the **Quick Find** section
- b. Click on the AGT number and navigate to **Edit > Master Record**

UTHealth | **START TEST** v13 Portal | Module Admin | TEST SITE Brooke Gandy | Logout

Home | My Profile | Locate My Records | Locate Records | Calendar | Messages | Assignments | Quick Find 🔍

Sponsored Projects

Award Tracking

Financial Tracking

Agreements

Subawards

Results found: 1 Export to Excel

Drag a column header and drop it here to group by that column

	Record Number	Record Type	Record Owner	Record Title	Record Status	Record Primary Sponsor
▶	AGT002282	Agreements	Selvaraj, Sudhakar	TMS-EEG INVESTIGATION OF PREFRONTAL CORTICAL EXCITABILITY IN DEPRESSION AND RTMS TREATMENT RESPONSE	Initial Review	National Institutes of Health/DHHS (NIH)

- c. Once in the Agreement record:
 - * Expand the **Linkages Tab**
 - * Click on **Agreements**

Coverage Analysis Info Form

Summary —

Personnel (1) +

Status History

Departments (1)

Performance Sites (0)

Submissions (1) +

Attachments (1) +

Linkages ➔ +

Approvals (0)

Linkages —

Sponsored Project (0)

Subrecipients (0)

Subawards (0)

Agreements (0)

Approvals (0)

- d. Click on **Link to Existing**

Coverage Analysis Info Form

Summary +

Submissions (1) +

Attachments (1) +

Agreements Edit Mode

Create New Link to Existing

Number	Title	PI	Status		

- e. If the Agreement Number is known, enter the AGT number into **Select by Number**

*Click **Go**

Add Agreements

Select by

Number

- f. If the Agreement Number is unknown, use filters to locate record

* Once filters have been selected, click **Go**

Apply Filters

Browse By

Sponsor/Scheme <input type="text"/> Set	Sponsor Type <input type="text" value="- Select -"/> <input type="button" value="v"/>
Primary Center/Program <input type="text"/> Set	Center/Program <input type="text"/> Set
Principal Investigator <input type="text"/> Set	Investigator <input type="text"/> Set
Primary Assoc. Dept. <input type="text"/> Set	PI Department <input type="text"/> Set

- g. Scroll down to the bottom of the screen

*Click on the box of the Agreement

*Click **Select**

*Click **Save** on the Agreement record

2 Records Found. Displaying pages 1 through 1 of 1

1

Number	Title	Sponsor/Scheme	PI	<input type="button" value="Select"/>
AGT002139	Clinical Trial Testing protocol	Pfizer, Inc. (PFZ)	Smalling, Richard W.	<input type="checkbox"/>

