Departmental Guidance Document:

Creating and submitting a Proposal Record for Clinical Trial Agreements

Contents

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.
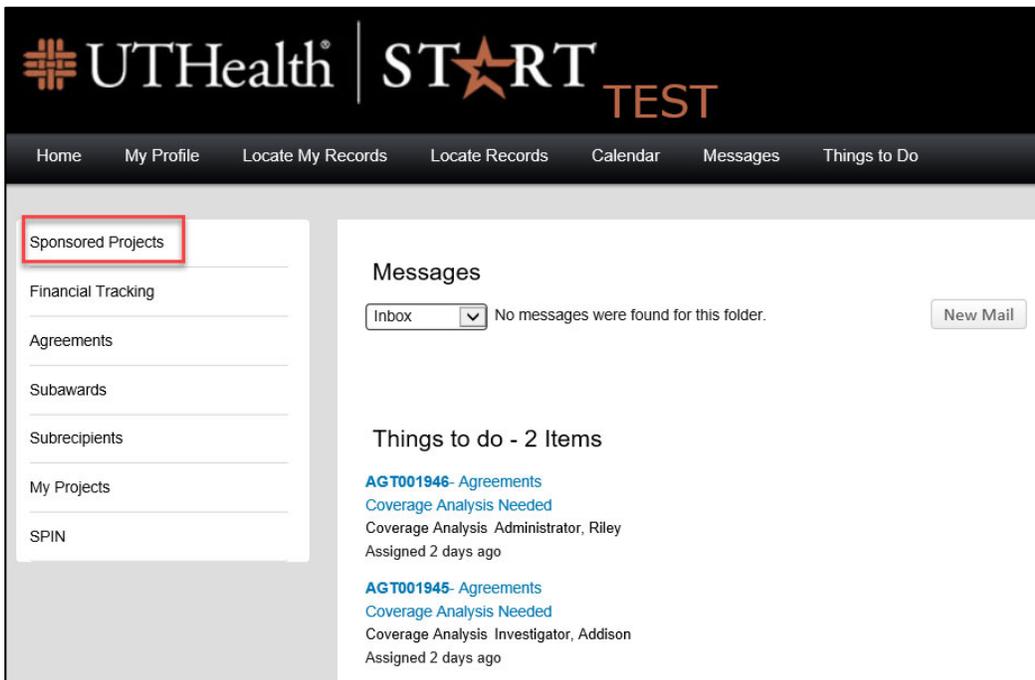
Proposal Type

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.
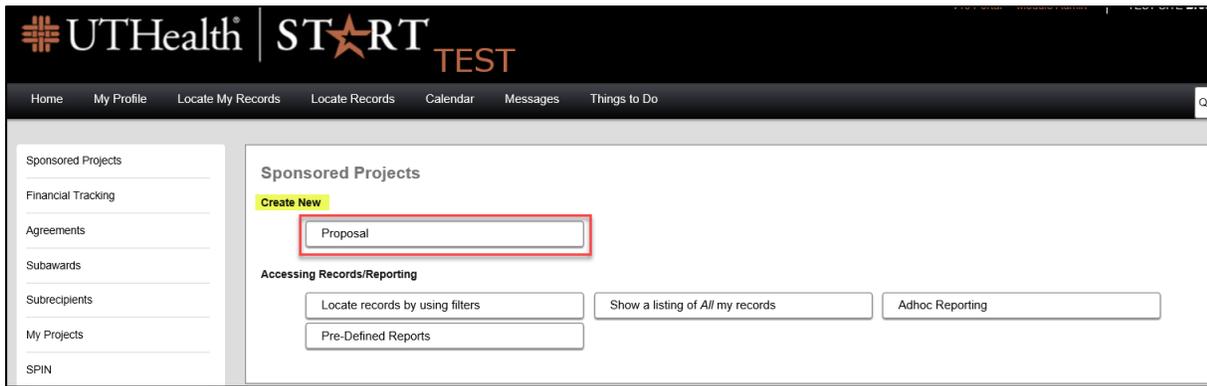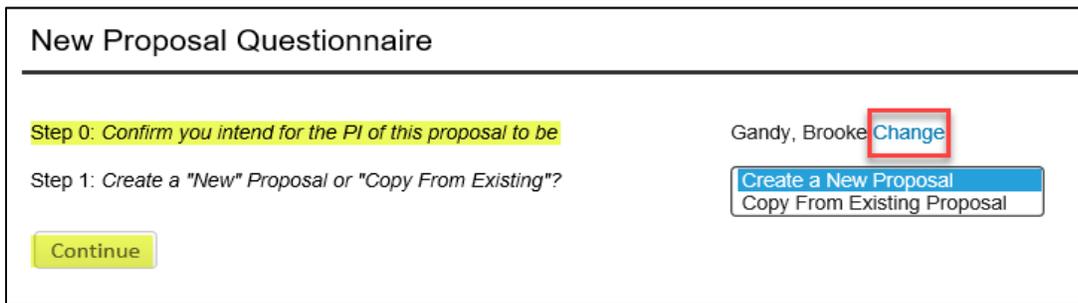
   https://uthealthstart.uth.edu

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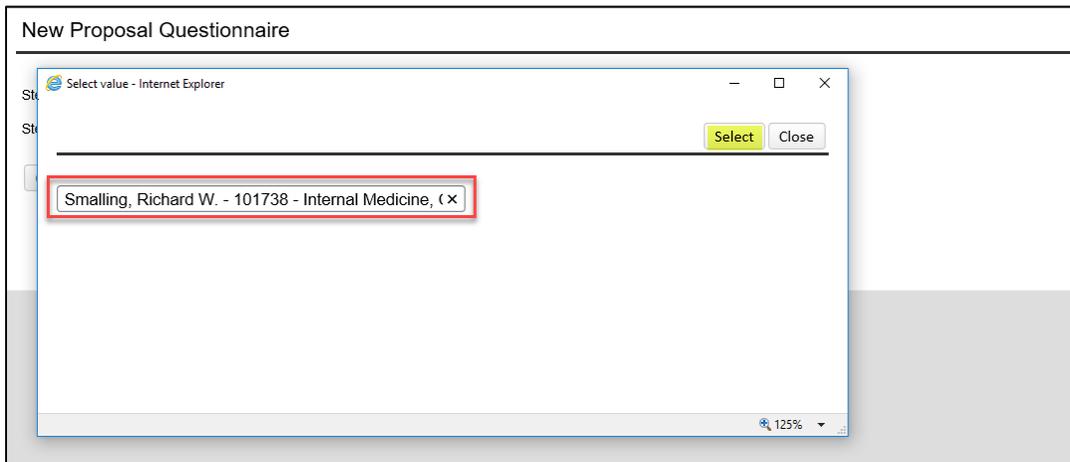
6. Once the PI name is changed, Step 1 requires you to select **Create a New Proposal** and click **Continue.**

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.**

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.)*

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.**

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

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.)

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**.

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

New Proposal Questionnaire

Step 0: *Confirm you intend for the PI of this proposal to be*	Gandy, Brooke Change
Step 1: *"New" or "Copy From Existing"?*	Create a New Proposal
Step 2: *Proposal Type*	Monetary Agreement
Step 3: *Selected Sponsor*	Pfizer, Inc. (PFZ)
Step 4: *"Tracking" Number or "Proposal" Number*	This proposal will be automatically numbered.
Step 5: *Proposal's Title*	ABCD
Step 6: *Project Start and End Dates*	*01-Mar-2020* to *01-Mar-2021*
Step 7: *How many years and/or budget periods would you like?*	[1 ▾]
	*NOTE: If you need additional years/periods beyond 7, you may add them as neede 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.

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: *Proposal Type*	Monetary Agreement
Step 3: *Selected Sponsor*	Pfizer, Inc. (PFZ)
Step 4: *"Tracking" Number or "Proposal" Number*	This proposal will be automatically numbered.
Step 5: *Proposal's Title*	Comparison of study drug ABCD vs. study drug XXXX
Step 6: *Project Start and End Dates*	*01-Mar-2020* to *01-Mar-2022*
Step 7: *Number of Budget Periods*	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**.
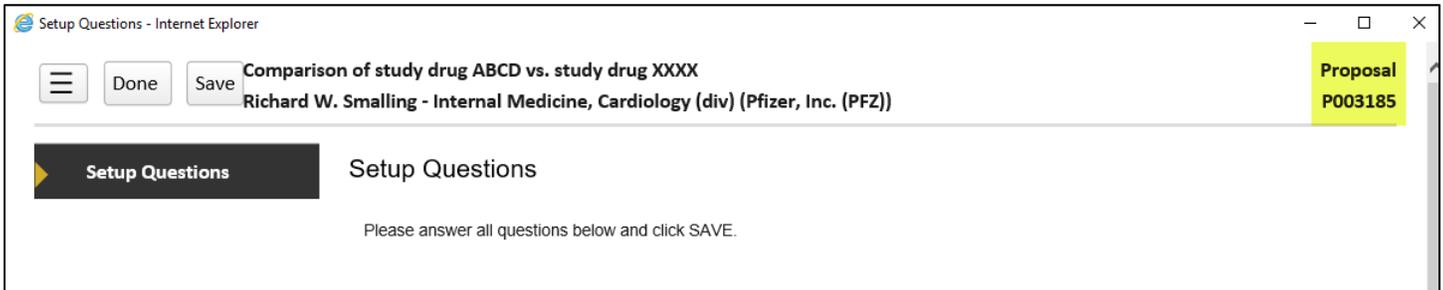
16. Once you scroll down on the Setup Question page, select **Monetary Agreement**. Once selected, an alert pop-up box will confirm the change of submission mechanism of the proposal.
    Note: Since the Proposal is for an Internal budget (IB), the submission mechanism/screen template will change to 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
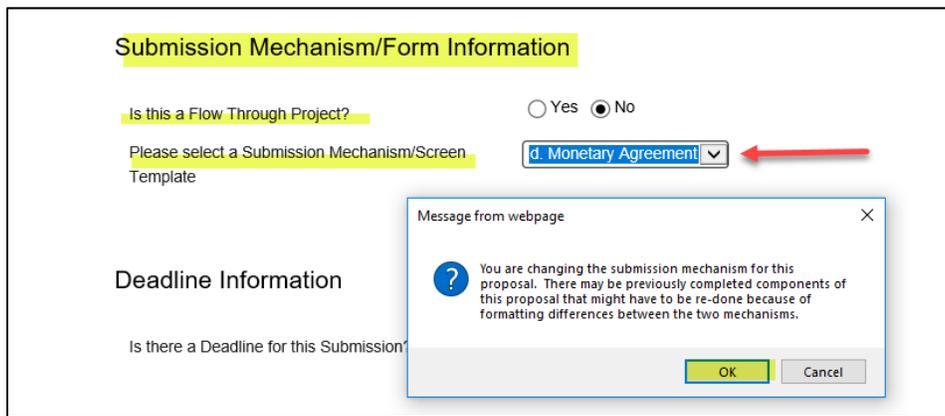
17. Next, enter the Deadline Information, General Proposal Properties and Budget Setup Information.
    Select the **Clinical Research (non-Federal)** option for industry-funded studies on the drop-down menu.
    Click **Save and Continue**.
    Note: Deadline Information will always be selected as "No" 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.

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

Sponsor Information:
a. Verify Sponsor
b. Add the CRO name if applicable
c. Click on the **Yes/No** boxes to answer the sponsor-related questions

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: [Approved ▼]
                                                        * protocol #: [HSC-MS-19-0056]

Yes ☑ No☐ * Does this research include enrollment of patients/participants?
            * Target Enrollment: Estimated [25]   * Est Clinical Research/Trial End Date: [21-Dec-2030]

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:
                                        [UT Physicians Internal Medicine
                                         UT Physicians CARE Clinic]

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 cleary 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)
[123456]

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.

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

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)

Section 2:   Creating & Submitting a Clinical Trial Agreement (CTA) to Sponsored Projects Administration (SPA)
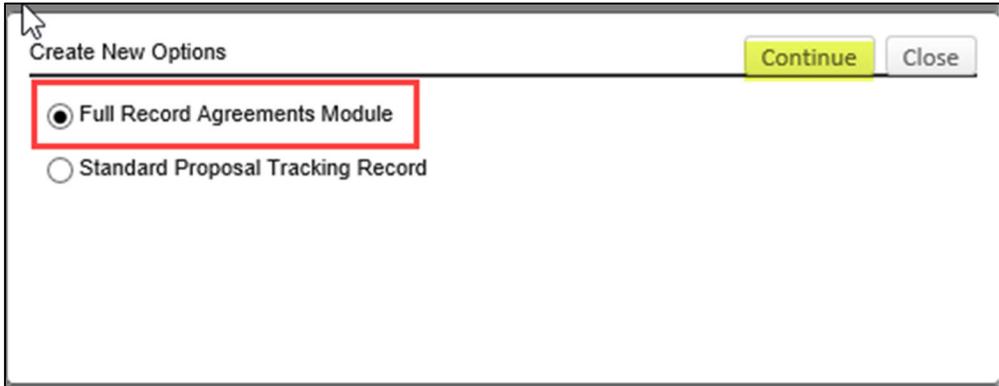
1. **Create a New Agreement Record (AGT) from within the Proposal Record:**
   *Note: Creating a new AGT record within the Proposal will **automatically** link to the Proposal record*
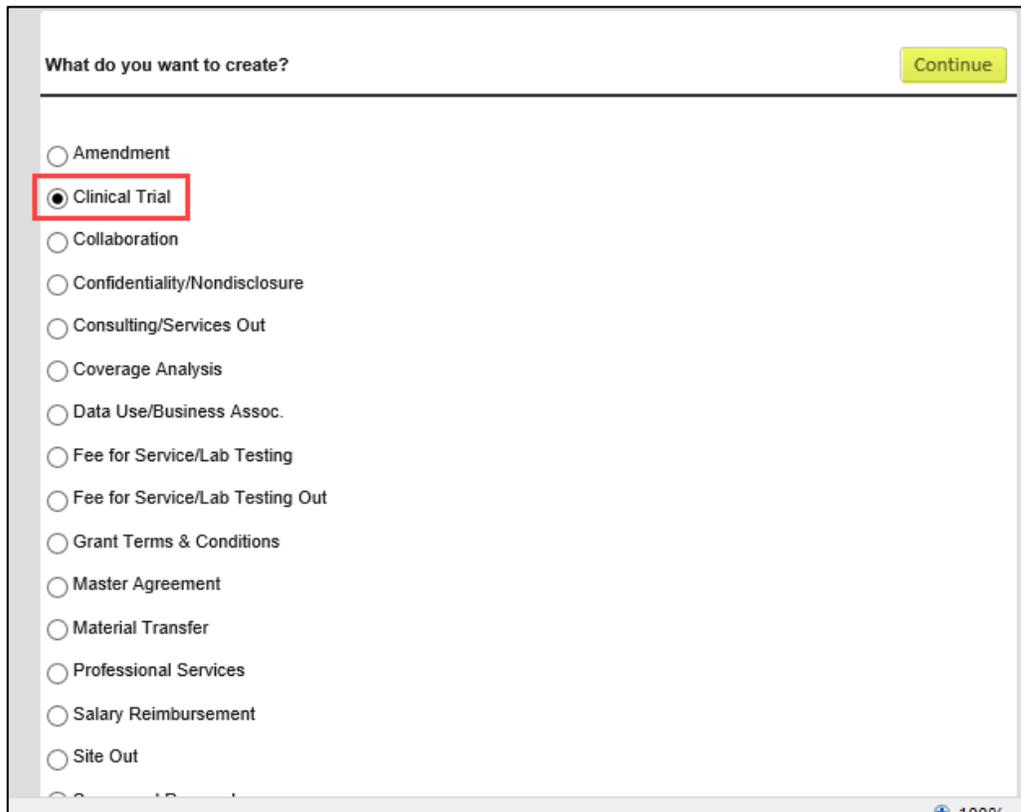
   a. Once you have clicked on the **Agreements** Tab, click on **Create New.**

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. <u>Add the requested information in the appropriate fields:</u>
   * 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.

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:
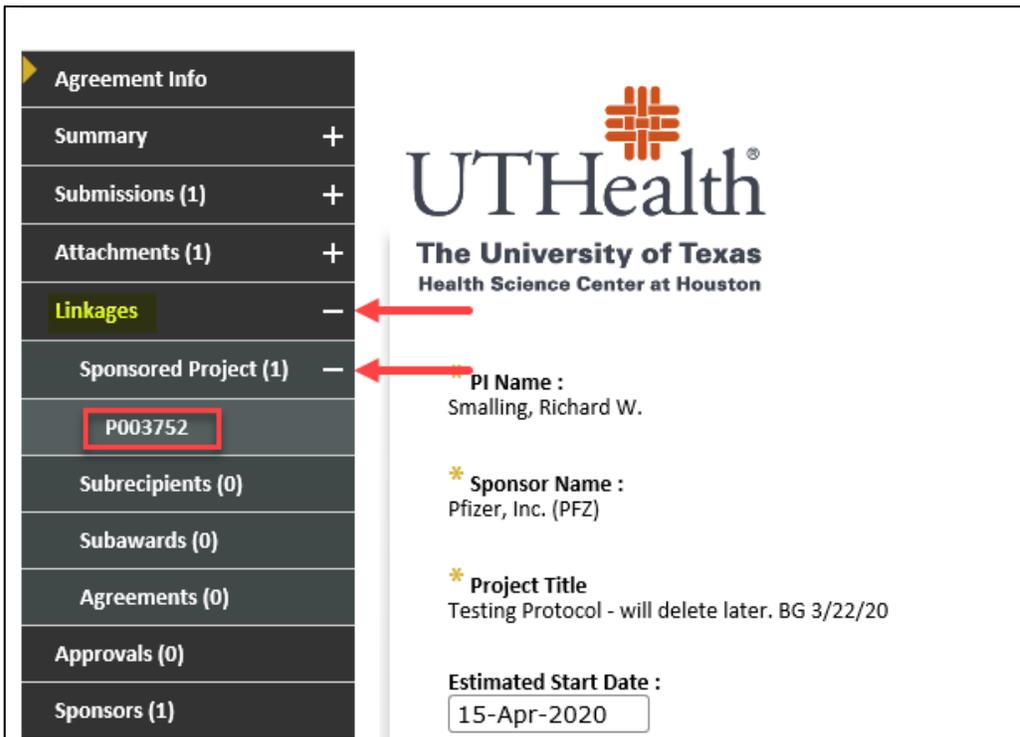
g. Click on the **Summary** Tab (click on the word "Summary")
   * Add the **Agreement Title/Study Title.** <u>Again, enter the full title. You can copy and paste it from the Agreement info tab.</u>
   * Click **Save**
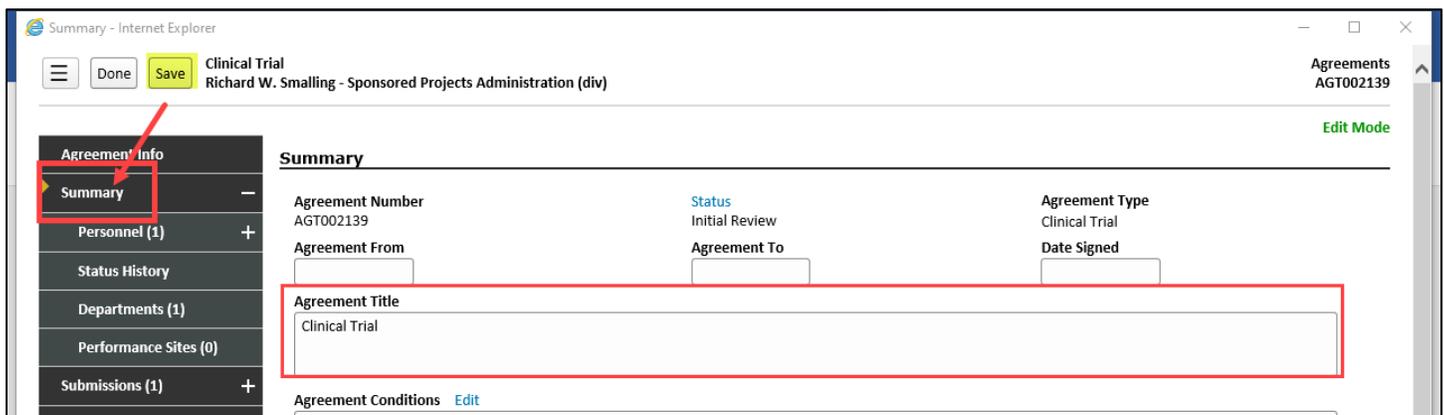
2. **Attaching the Clinical Trial Agreement:**

* 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**
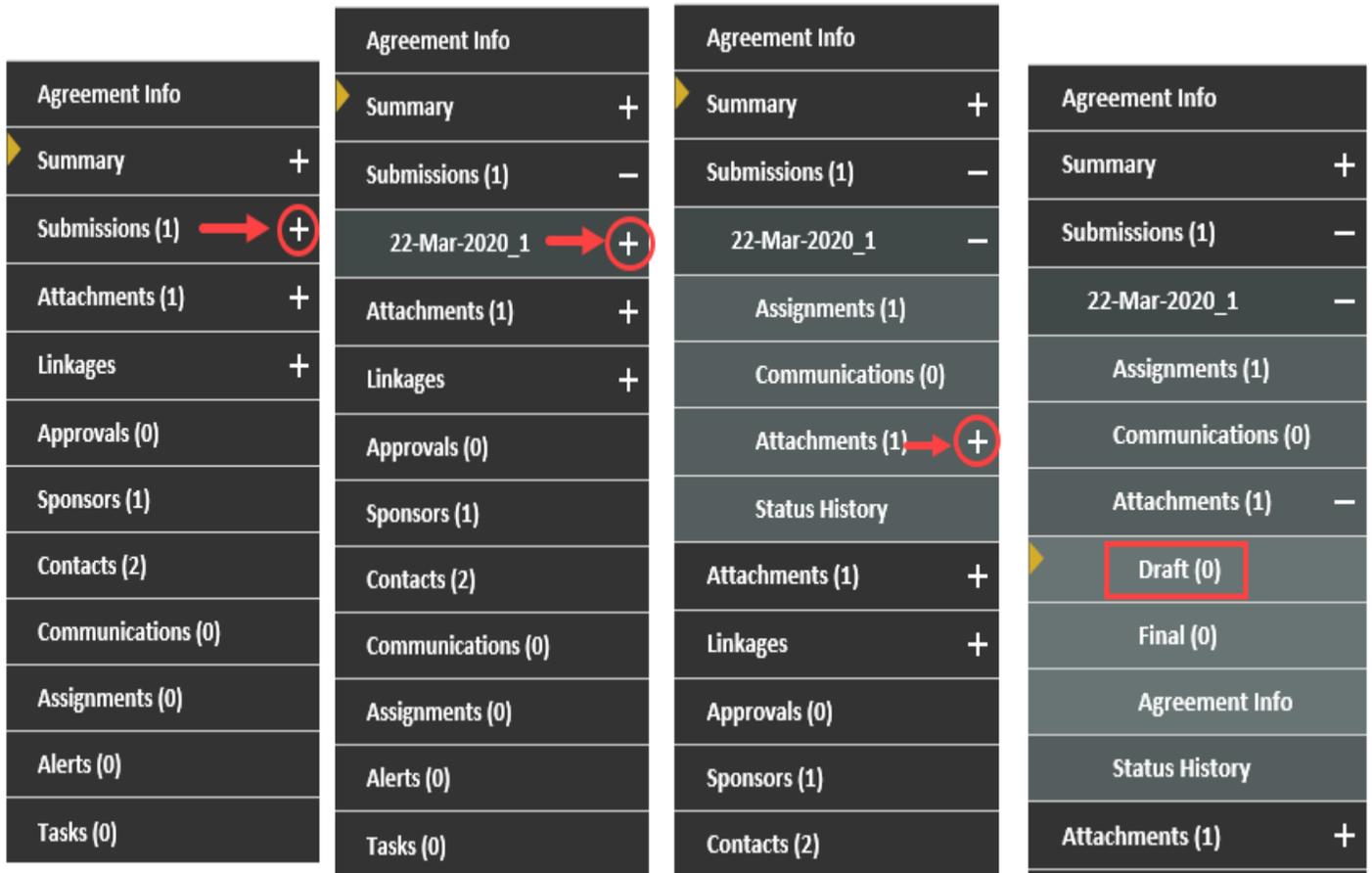
a. You are now in the Draft tab under Attachments and are able to attach the CTA.
   *Click on "**Add Documents**"
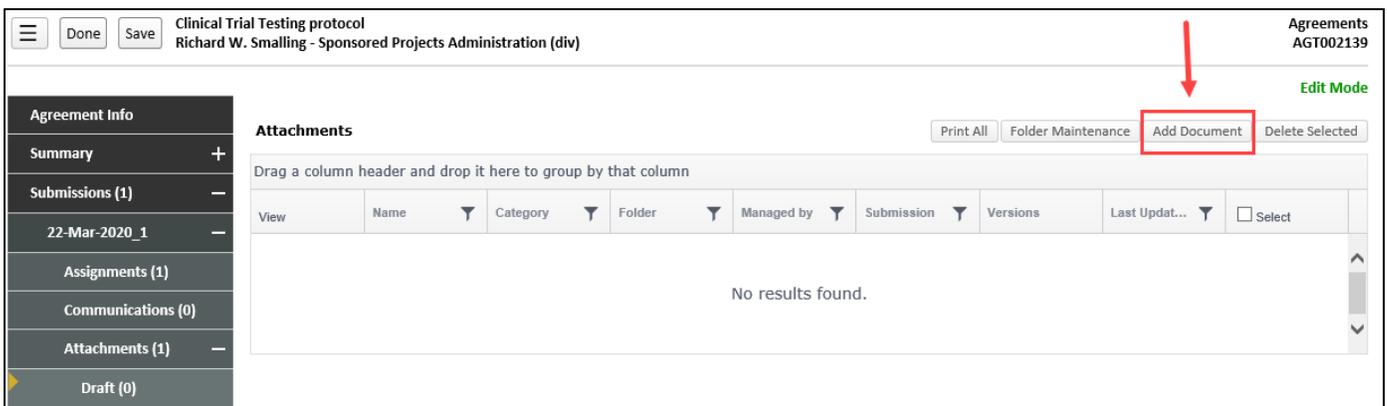
b. Insert the following information to upload the CTA:
   * Insert Name: **"CTA initial draft"**
   * Category: select **Agency Funding Document** in the drop-down menu
   * Folder: select **Draft** in the drop-down menu
   * Click on **Upload**

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

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**

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

c. First, click on **Add**
d. Then, click on **Save**
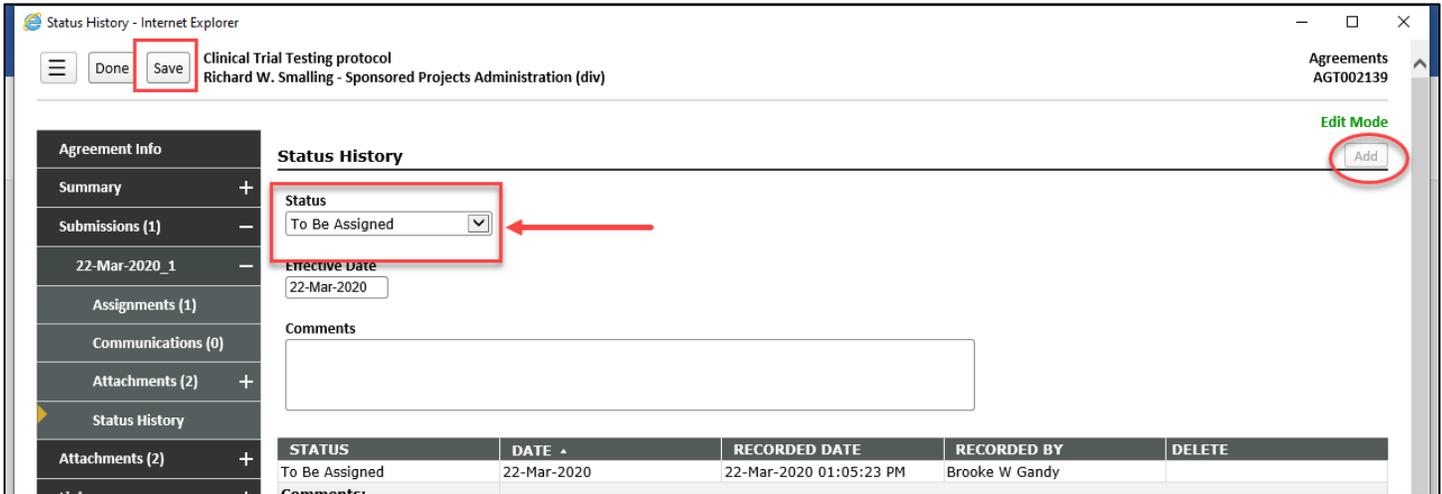
Please note: CTA review in SPA will be prioritized <u>based upon how actively the Departmental study team is working to finalize the Proposal Record.</u> This will ensure SPA priorities are aligned with the Departmental study teams.

- *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 <u>prior</u> to negotiating budget with sponsor. All of the tabs within the <u>C</u>overage <u>A</u>nalysis <u>I</u>nternal <u>B</u>udget 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. <u>No additional amount needs to be added.</u>
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

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**.

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

Edit Mode

Project Period:
07-Feb-2020 to 07-Feb-2021

Source View: Sponsor ▼

Rollup subprojects: Not Rollup ▼

| Proposal Structure | Import/Export | Complete Budget |

Budget Summary [Hide]

		Periods [hide]				Sponsor [show]	Cost Sharing [show]	Project [hide]		
YEAR/PERIOD	INCREMENT	START	END	TYPE	STATUS	TOTAL	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
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 |

Add Bulk Entry

Non-Personnel [hide]

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

| 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:	$ 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 Invoiciable procedures within the calculation***

$1,040,000

h. Expand the **"+"** for Period 1 tab and click on the **F&A tab**.
    Verfiy 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%)

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

    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.

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 appliable to project)
2. Negotiated Sponsor Budget – Final

If the below items (as applicable) are availble you should attach now. If the below items are not yet avaible, move to next steps and attach them after the budget is aprpoved 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.

	Attachments	Sequence	Original	PDF	Completed ☑
✓ Setup Questions					
Data Collection	Approved CA_Internal Budget_(CAIB tool).xlsx	1	View	View	
Personnel	Sponsor Budget_Final.docx		View	View	
Budget					
Uploads & Reviews					
✓ Attachments					

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:

a.   Click on "Add"
b.   Select "Type"
c.   Select "Not Attached" for Protocol
d.   Select "Continue"

Add/Edit Approvals   Save   Close

Approvals   Continue

Type: IRB ▼
Protocol: ○ Attached   ⦿ Not Attached   ○ Create New

e.   Enter protocol specific IRB approval information
   a.   "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.

Uploads & Reviews Tab:

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

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

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

Finalize Tab:

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

b. Click on **Assemble Application.**

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

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.

3. PI clicks on "Approve" the proposal and routes it to the DMO.
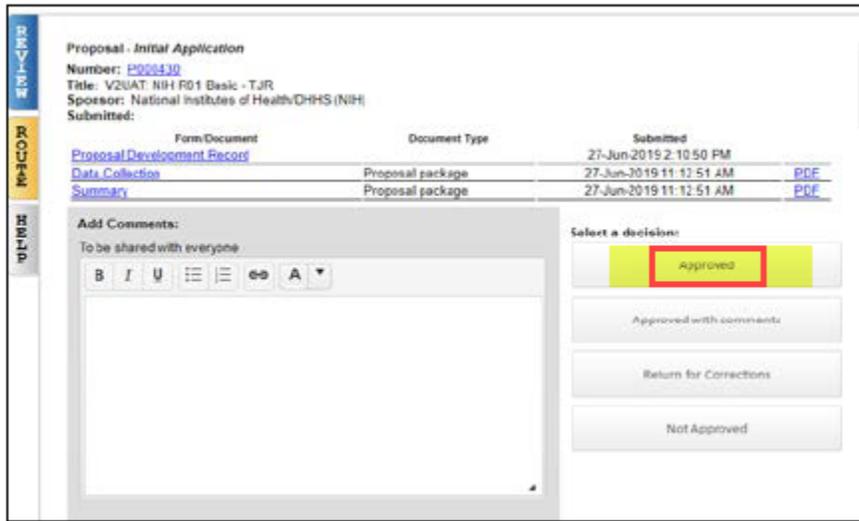
4. The DMO approves the proposal. (same manner as above)
5. After the DMO has approved the proposal, anyone in the department (creator of proposal or DMO) clicks on the **Final review "thumb" icon**.
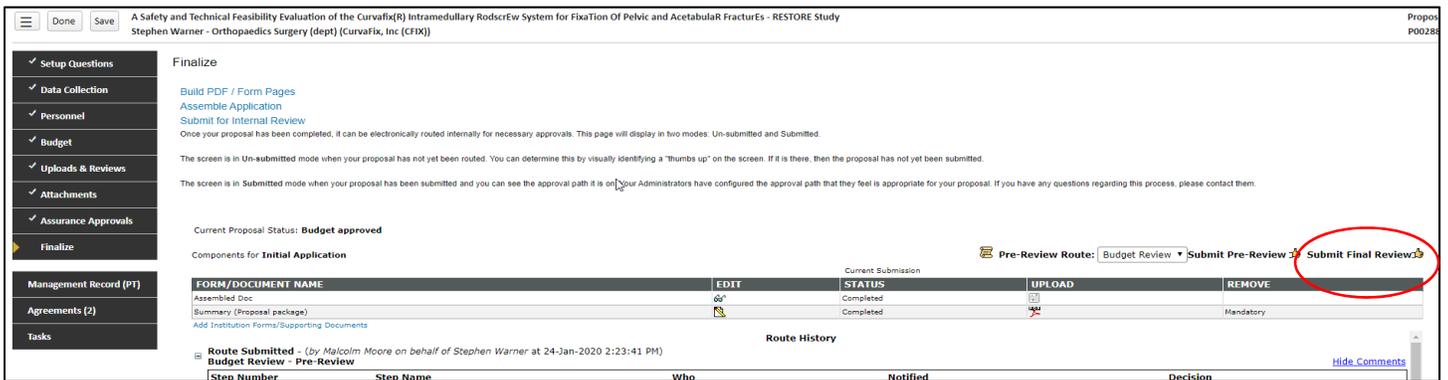
6. The proposal is routed to SPA Intake Pre-Award group.
7. The SPA Intake group routes to the SPA Financial group.
8. The SPA Financial group completes a congruency check and approves the Proposal Development (PD) Record (Budget).
9. The SPA Financial group routes the Proposal to the SPA Contract group

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

P003188
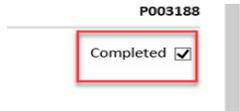
Completed ☑

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**

Finalize				
✓ Setup Questions				
✓ Data Collection	Build PDF / Form Pages			
✓ Personnel	Assemble Application			
✓ Budget	Submit for Internal Review			
✓ Uploads & Reviews	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.			
✓ Attachments				
✓ Assurance Approvals	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.			
✓ Finalize				

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**

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				

Management Record (PT)

Tasks

Agreements (2)

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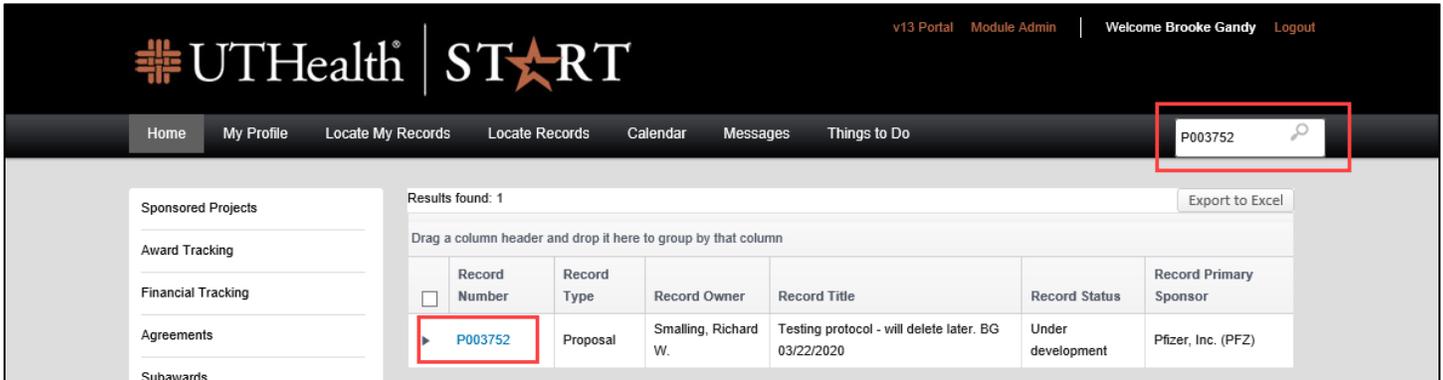
     c. Once in the Proposal Development (PD) record:
        * Click on the **Agreements Tab**
        * Click on **Link to Existing**

     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 Go Clear All

Browse By

Sponsor/Scheme		Set	Sponsor Type	- Select -	
Primary Center/Program		Set	Center/Program		Set
Principal Investigator		Set	Investigator		Set
Primary Assoc. Dept.		Set	PI Department		Set

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**

1

Number	Title	Sponsor/Scheme	PI	Select
AGT002139	Clinical Trial Testing protocol	Pfizer, Inc. (PFZ)	Smalling, Richard W.	☐

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**

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

d. Click on **Link to Existing**

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

Add Agreements

Select by
Number   [   ]   Go

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

Apply Filters   Go   Clear All

Browse By

Sponsor/Scheme	[ ] Set	Sponsor Type	- Select - ▼
Primary Center/Program	[ ] Set	Center/Program	[ ] Set
Principal Investigator	[ ] Set	Investigator	[ ] Set
Primary Assoc. Dept.	[ ] Set	PI Department	[ ] 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	Select
AGT002139	Clinical Trial Testing protocol	Pfizer, Inc. (PFZ)	Smalling, Richard W.	☐