



**Departmental Guidance Document:
Understanding the Coverage Analysis/Internal Budget
Tool**

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Introduction

This document addresses how to Navigate through and complete the Coverage Analysis/Internal Budget tool. (CAIB tool) The Coverage Analysis (CA) and Internal Budget (IB) should be completed **before** negotiating the budget with sponsor. *This ensures there is a clear understanding of UTHealth costs to conduct the study before negotiations with sponsor begin.*

The CAIB Tool serves **two** purposes:

- 1. Billing Coverage Analysis (CA):** The Coverage Analysis tab is required per HOOP policy to ensure compliant research billing at UTHealth.
 - a. Coverage Analysis tab lists out all procedures detailed in the study protocol and notes
 - Will this service or procedure generate a bill in billing system?
 - If yes-
 1. Should it be billed to the patient/patient insurance?
 2. Should it be billed to the study account?
- 2. Internal Budget (IB):** The remaining tabs are utilized to determine costs to conduct the study. (Effort, Startup, Expenses, and Summary tabs).

Coverage Analysis/Internal Budget (Hence the name “CAIB Tool”)

THE CA and the IB ARE TWO SEPARATE ITEMS

SPA combined the CA and IB into one tool (CAIB Tool) to reduce work for the department. Combining these items into one tool allows the information entered into the Coverage Analysis tab to auto populate into the internal budget tabs thereby saving time for the person completing the internal budget.

*Billing grid/Coverage analysis (CA)- Has separate AGT record in START

*Internal budget(IB) - Should be uploaded as an attachment to Proposal Record in START

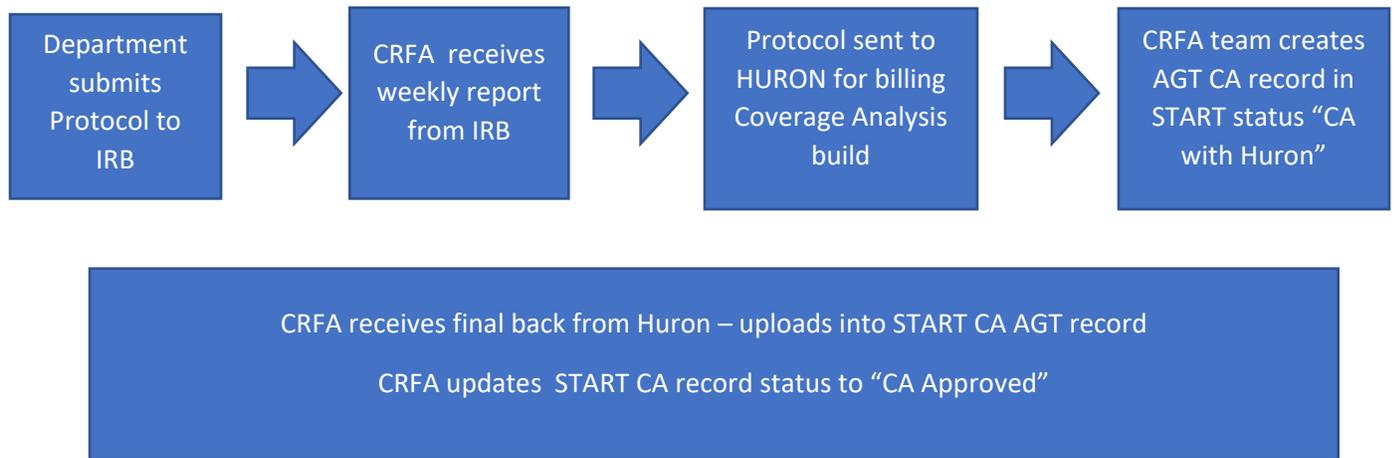
Analyzing the Costs to Conduct a Clinical Study is Complex!

SPA designed the CAIB tool in an effort to make creating an internal budget for a clinical study as straightforward as possible for the study team.

Question: How Does the CA-IB Process Get Started?

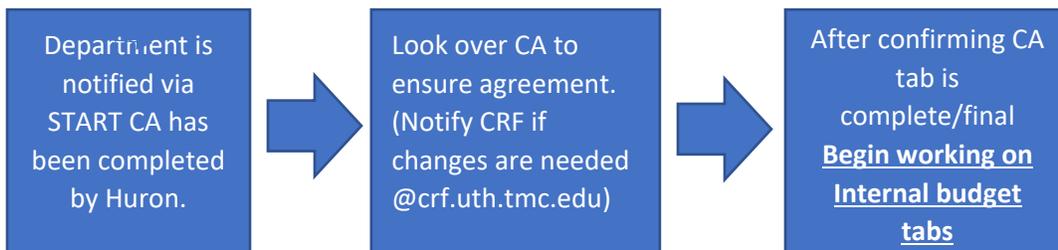
Answer: Department Submits Protocol to IRB.

This process begins when the study team submits the protocol to the IRB. The below flow chart is a high-level overview of the process at UHealth.



Question: When does the Department start working on the CAIB tool?

Answer: After the billing “Coverage Analysis “ tab has been completed and noted as final.



The START CA record is marked “Final/ CA Approved” immediately upon receipt from HURON. (This is due to the fact Huron Research Office utilizes CMS’s LCDs/NCDs and published billing guidelines for Houston Texas and can be considered final upon receipt.) However, CRFA will work with you to update the final CA within the START CA record if needed and valid.

After the Coverage Analysis tab has been finalized, you are now ready to begin working on the internal budget tabs. (You should not start on the Internal Budget until after the CA is finalized.)

The first thing you should understand about the internal budget is that the purpose is to identify the actual cost to conduct the study for UTHealth.

- You are answering the question “How much will it cost to conduct this study?”
 - COMMON MISTAKE- Do **not** use the tool to show “How much Sponsor is paying to conduct this study”
 - ***You should not simply copy and paste data from the sponsor budget into the CAIB tool this is not helpful to identify real and true costs.***

*****You should not begin budget negotiations with sponsor until the internal budget has been completed.***

After you have completed the internal budget you will be able to make a more informed approach to budget negotiations. The rule of thumb is to ensure the final budget is at least 10% above the total costs calculated in the CAIB tool to allow room for unforeseen expenses that may come up during the period of the study. These unforeseen expenses could include such things as: underestimation of administrative time and effort expended (which is quite common) or, unanticipated increases in rates for procedures. This ensures UTHealth costs are covered and may result in residual funds for the PI to use on future investigator-initiated research projects.

INTRODUCTION TAKEAWAYS

Three Important Takeaways from Introduction Section:

1. The CAIB Tool Serves two Purposes:
 - a. Billing Coverage Analysis
 - b. Internal Budget
2. The CAIB process begins when a study is submitted to the IRB for review
3. Purpose of Internal Budget
 - a. Purpose is to identify the costs to conduct the study (NOT what the sponsor is paying)
 - b. You should not negotiate budget with sponsor until you have identified the costs to conduct the study first.

Section 1: Coverage Analysis Tab

The Coverage Analysis Tab is the first tab that should be completed on this tool because the data from this tab is transferred into the other tabs and guides and directs the data entry.

What is Coverage Analysis?

- Coverage Analysis is an independent review of a clinical study to determine which procedures and services are billable to insurance and which are not.
- It is a systematic review of clinical trial documents, published practice guidelines, and Local Coverage Determinations (LCD) and National Coverage Determinations (NCD) to determine the billing status of items and services that are documented in the research protocol and/or research plan.
 - What some researchers consider to be “Standard of Care” may not be the same as what insurance companies will agree to pay for.

When the analysis is complete, the investigator/study team has a study-specific billing summary to guide the study team with clinical billing for research visits.

Understanding the Billing Coverage Analysis

The Coverage analysis tab notes all services and procedures that happen during each study visits. The study visits listed horizontally across as columns, and the services and procedures listed vertically as rows.

Example

	Visit 1	Visit 2	Visit Three
Informed consent	X		
Questionnaire	X	X	X
Drug XYZ dispense		X	X
PK/PD Blood draw			X
PK/PD Analysis at central lab			X

Each service and procedure will be designated with one of the below options:

- **NB= (Non-Billable)**
 - This item will not generate a charge in the patient care billing system.
 - Items marked “NB” are effort-based items that do not generate charges in the billing system such as obtaining informed consent and/or giving a questionnaire to the patient.

- **SOC= (Standard of Care)**
 - This item will generate a charge in the patient care billing system.
 - This item is considered routine care and is allowable to be billed to patient/ patient's insurance.
- **RES= Research**
 - This item will generate a charge in the patient care billing system.
 - This item is done for research purposes and should be paid for by the research account.
- **NB-Costs for Research**, this item will not generate a charge in the patient care billing system however, the study team will receive a bill for this service. Only a few items fall into this category such as labs sent to Quest, or contracting with the CRU to complete.

Next steps after CA is complete:

Once you have obtained notification that the CA is complete, please review and determine agreement. If any discrepancies are noted, contact CRFA team via crf@uth.tmc.edu

After you have determined agreement with the CA tab, you are ready to start on the internal budget. You are now ready to begin entering data into the internal budget tabs on the CAIB tool. You should start on the **Summary Tab**.

Before you move on to the Summary Tab please see Tip1 and 2 below.

TIP 1- Find the row noted as "Participant payment" and note each visit in which payments will be made to participants as "NB Costs for Research" to enable the ability to add these costs to the Costs Expenses tab

TIP 2- If you are using the CRU- you can add an additional row to the procedures section and name it "CRU Fee". You should designate each applicable visit as "NB Costs for Research" to enable the ability to add the CRU per visit fees for into the Cost-Expenses tab.

***Note Clinical Studies that are not initiated by UTHealth Faculty and are paid per patient milestone completion with no billing compliance risk (Retrospective chart reviews etc.) will not have CA built out through SPA However, an internal budget is required for the project proposal record in START. Therefore, you will be required to enter data into the coverage analysis tab. See "SECTION 8: CAIB Tool for Sponsored Clinical Studies with No Billing Risk" for more details.*

Section 2: Summary Tab

1. Summary Tab:

- a. Step one- Enter applicable information into all of the cells highlighted yellow/peach within the summary tab **starting from the top of page**
 - i. TIP 1-Do not enter data into any cell that is not highlighted with color.
 1. Any cell with a blank/white background auto populates by pulling in data from other tabs/cells.
 - a. (Even if it appears blank at first do not worry, it will auto populate once you have completed entering all of the data into all of the tabs.)
 - ii. **TIP-2-** Do not forget to enter the anticipated number of patients into cell **D14**. *(The calculations will not work if you miss entering data into cell **D14**.)*
- b. Step Two-Adding additional personnel- list everyone working on the study.
 - i. Keep in mind that financial management time and effort should be captured on the form as well. It requires time and effort for invoicing and payment reconciliation.
 1. If the Study coordinator is also responsible for financial management his/her administrative effort should be increased to reflect the additional time spent on these activities.
 - ii. If you are unsure of anyone's salary, check with departmental administrative staff
- c. Step Three-SC Administrative time and effort (Cell G20)
 - i. This cell is highlighted bright yellow and requires department data entry on older versions of the CAIB tool ***
 - i. This is for time spent on activities that are not included in conducting patient visits
 - ii. The Yellow box to right, "What does SC Administrative time cover?" helps to clarify what types of activities this includes.
 - iii. If you are working on an older version you will manually enter the admin time and effort.
 1. If it appears too low SPA will return for corrections.
 - ii. ***The newest version of the CAIB tool auto calculates this effort (using a calculation based upon standard practices for estimating anticipated time spent on administrative duties.)
 1. If you would like to increase/decrease the auto calculated administrative effort, contact CRF @crf.uth.tmc.edu and we will make the change.

- i. ** CRFA team can override an increase upon request, however a decrease will require specific rationale.

- d. **Skip G39 for now (It is the last step in completing the internal budget tool- discussed in Section 6).**

***Note-Salary recharge is applied based upon information listed on internal budget, please ensure to enter information as accurately as possible to avoid departmental salary deficits.

Section 3: Effort Tab

1. Step One: Discuss with your study team to determine how much time will be spent at each visit, per patient for the various members of the study team.
 - a. Note-- Effort per person for each visit should include visit preparation and all administrative activities associated with each visit too. Example- Chart set up, scheduling next visit, escorting participant for imaging, etc. (*Be sure to communicate to the study coordinator that it is important to carefully think about how much time each visit will take for each patient and to be sure to include the time it takes to enter study visit data into CRF forms too= this is important!)
2. Step Two: Enter effort by hours per visit for each member listed. Example if Study Visit 1 will take 4 hours for the SC to complete you will enter "4" by the SC's name under visit 1.
 - a. Note you do not enter information into "Study Coordinator Administrative ". This row is greyed out.
3. Once the time is entered, the CAIB tool carries over the effort information to the Summary tab and auto calculates the costs and effort percentages.

EXAMPLE CASE SCENARIO:

Even simple studies take more time than you expect. SPA suggests you share the below example with SC to guide in visit time and effort estimations.

- a. This is a real study in which the SC initially thought would only take 1.5 hours to complete but after reviewing carefully she saw it was actually 4 hours. (This is real study that SC described as “very simple.”)

For Visit one the SC evaluated how much time she was spending to conduct the visit she found:

- i. **15 minutes** on study chart set up,
- ii. **1 hour** explaining the study and consenting the patient
- iii. **1 hour 15 minutes** completing visit 1 tasks, (Con med, questionnaires, etc., dispense and explain how to complete diary, collect blood and urine, general conversations with patients during the visit.)
- iv. **25 minutes** preparing the samples and arranging Fed Ex pick up,
- v. **15 minutes** scheduling next visit faxing forms (this includes ensuring the visit is scheduled, and marked as a research visit in the system. If next visit is at MHH may take longer due to the fact MHH paperwork will need to be completed and faxed.)
- vi. **35 minutes** entering data into CRF.
- vii. **15 minutes** to review charges in Epic

For the above study they ended up changing Visit 1 for SC from 1.5 hours to **4 hours**.

Section 4: Cost Expense Tab

1. Click on “Update table” to have items auto populate from other tabs and to identify which fields need to be completed.
2. You will enter costs into the fields highlighted yellow. The costs are the amount that will be billed to the study. (Typically, by MHH or Quest)
 - e. All items noted as “Research” or “Non-billable with cost” on the CA tab will be highlighted yellow because these items will generate charges that will need to be paid for by the study.
 - i. All fields highlighted yellow will require data entry.
 - f. Items marked as Non-billable and standard of care on the CA tab will be grayed out. (You do not need to enter any data into these fields.)
 - i. Example: **Study includes an MRI Spine w/o Contrast for visit 1. The CA tab notes this MRI as “Research” which means it should be paid for by sponsor**

and NOT allowable to be billed to patient/patient's insurance. You are planning to have the MRI performed at MHH.

1. MRI Spine w/o Contrast will be highlighted yellow on the Cost-Expense tab for Visit 1. You will enter the dollar amount that MHH will send an invoice for. (Found on MHH Fee Schedule or MHH Approval letter budget)
 2. MRI Spine w/o contrast -Professional-will be highlighted yellow on the Cost-Expense tab for Visit 1. When UTP Radiologists read MRIs at MHH, the UTP billing staff enter the read fee into EPIC. The read fee will be discounted for research and billed to the study. You should enter the dollar amount that will be billed for the Read fee (You can locate the fee that will be charged by looking up the CPT code on UTP Research Fee schedule)
2. Note- "Patient Stipend" dollar amount is the only item that should match the sponsor budget all other items should reflect actual charges to the study **NOT what the sponsor is paying for the service/procedure.**
 3. Charges can be identified from various sources. The sources will vary from study to study. Some examples of where you can locate charges are: UTP Research Fee Schedule, Memorial Hermann Research Fee Schedule, MHH Approval letter budget, Radiology budget, CRU budget, or Quest's Fee schedule.
 4. The total will be auto calculated on rows 44-46 and will also auto populate on Summary tab and Budget tab.
 - 1.

Section 5: Start-Up and Invoiceable Tab

Step One: Enter Start-Up costs –

*Do not enter data into row 6 (This is auto calculated from the effort table in step two.)

*Delete the non-applicable IRB from the costs (Local or Commercial).

- a. Coverage Analysis fees - are only applicable to industry sponsored studies. (Non-industry studies will not be charged a CA fee.)
- b. If there are any others that apply to the study you are working on, be sure to add them in, and/or delete those that don't apply.
 - i. Other line items that may or may not pertain to you may include Memorial Hermann IDS pharmacy fees, and Radiology fees.

Step Two: Complete the Start-Up Time and Effort calculator on row 52. Once complete, it will auto populate at the top of the Start-Up cost table on row 6.

- a. The Start-Up Effort table starts on row 52.
 - b. Similar to the Study Visit Effort table, you will enter the number of hours per person reflecting the time expended on the various start up activities listed. You need to be sure to accurately analyze the time and effort expended on each start up activity to properly capture true costs.
 - a. NOTE- A minimum of 3 hours is required for Protocol review for PI and SC. This has been pre-populated but you can increase for more complex studies that required more hours for protocol review.
 - c. You do **not** enter data into the table on row 67. This table auto calculates to show the translation from hours to dollar amounts based upon salary of the individual study staff and the information is automatically transferred to the Summary Tab and the Budget Tab.
-
- a. Step Three: Complete Invoiceable Procedures section. These are typically items that may or may not take place and will differ from study to study.
 - a. Examples: SAE reporting, Dry ice, storage, MRI, monitor visit, and protocol amendment (the protocol amendment charges may be pulled from the sponsor budget), etc.

Side note: If your research includes imaging performed for research purposes and paid for by the sponsor, be sure that you completed the form for Radiology in iRIS if you have not completed this form in IRIS, you should go back to your submission ASAP. Radiology is required to review all protocols that have imaging done for research purposes only.

- a. *The review fee is currently \$750 (\$975 with IDC.) If it is not applicable to you, please delete this line item.*
- a. *You will be notified if / when these rates change.*

Section 6: Finalizing Internal budget-

Step 1- Negotiate budget with Sponsor.

After all of the above steps have been completed you now have a clear picture of the costs to conduct the study at UTHealth. You are now ready to negotiate the budget with sponsor. During negotiations you should aim to finalize a budget that is 10%-30% above direct costs noted in L38 of the summary tab. This allows for unforeseen costs such as underestimated effort and increases in costs and helps to ensure that the study does not go into deficit.

- We have found that most departments seriously underestimate time and effort. This is why it is important to aim to finalize a budget 10-30% above identified costs.

- Remember- It is OK to make a profit! These funds will be used to grow the PI/Department's clinical study program.

Step 2- Final Sponsor Budget Complete

Once you finalized the budget with the sponsor, you are ready for the last step to complete the CAIB tool. The last step is to enter data into the "Total Anticipated Revenue" field (G39) on the Summary Tab.

- a. This is based upon the final contracted budget with sponsor. (see Directions on row 41 as to how to calculate the number to enter into this field.)
 - a. The **Total Anticipated Revenue** is also the amount you will enter into the START Proposal record budget. (see Clinical Trial PD START guidance document for directions on how to enter this into START budget tab.)

START Budget Tip

The CAIB tool separates out the Total Anticipated Revenue into Direct and Indirect costs within cells H35 and H36. Enter the number from field H35 into START as t M&O (Maintenance and Operations) under the Budget Tab. (See START Clinical Trials PD guidance document for step- by- step directions.)

START will automatically calculate the Indirect costs noted in H36 within the budget and do not need to be manually entered.

SECTION 7: Budget Tab- (Simply an FYI)

This tab does not require any data entry by the department.

Once you have completed all data entry within the below listed tabs and consider all the data final, Click on "Update table" on the Budget tab.

After you click on "Update table" the Budget tab will automatically pull in the data from the following tabs:

- Effort
- Cost expenses
- Start up and Invoiceable
- Summary

This tab provides an overview of all of the data entered by the department on one page. You are not required to use this tab as all of the information you need is available for view on the other tabs.

TIP- Clicking “Update table” too many times can cause technical issues. If you do utilize this tab, you should check to ensure all of the data has flowed through.

SECTION 8: CAIB Tool for Clinical Studies with No Billing Risk (Retrospective chart reviews, observational, etc.)

Clinical studies, that are not a billing risk (examples are retrospective chart reviews and observational studies) are not required to have a billing coverage analysis built. Therefore, these projects will not have A coverage analysis processed by SPA.

In these cases the department will need to obtain a blank CAIB tool from the SPA web page: <https://www.uth.edu/sponsored-projects-administration/tools-resources/forms-templates> to build out an internal budget for the proposal record when submitting a monetary agreement to SPA for project account set up.

SECTION 9: When CAIB tool Internal budget tabs are not required:

Question: Is there any scenario in which a clinical study does not require the CAIB tool internal budget tabs to be completed and attached to the proposal record?

Answer: Yes, if the clinical study was authored/ coauthored and initiated by a UTHealth PI the CAIB tool is typically not required.

- If the study was initiated by a UTHealth PI and is submitted to SPA as a grant proposal the department is not required to complete the internal budget tabs of the CAIB tool and attach to the Proposal record.(The grant proposal budget will be used as the project budget.) Note the Billing coverage analysis AGT record should be linked to the proposal record to confirm a billing coverage analysis has been completed.
- If the study was initiated by UTHealth PI and a pharmaceutical company or other entity has agreed to fund the project via a monetary agreement (contract) the department is typically not required to complete the CAIB tool if the internal budget was created utilizing another budgeting tool (such as a grant budget template or excel file.)
 - Please note there are some instances in which the internal budget provided is insufficient and/or does not appear to accurately capture all costs, in these cases SPA may request the PI submit the internal budget on the CAIB tool.
 - If you are unsure as to whether or not a CAIB tool will be required as part of the proposal submission to SPA, please contact crf@uth.tmc.edu to ask if a CAIB tool is needed.

SECTION 10: Cost Sharing

What to do if sponsor is not providing enough funds to cover costs to conduct the study.

Occasionally there are clinical studies that are written by a PI from another University or by a Nonprofit Collaborative group in which the contracted budget does not provide enough funds to cover costs to conduct the study. If the department agrees to cover the additional costs because there are non-monetary benefits for participation (such as future collaborations or patient care benefits). In these cases, the research team will need to submit a cost share budget. Directions on how to submit a cost share budget are located in the “Budgeting “ guidance document located:

<https://www.uth.edu/sponsored-projects-administration/tools-resources/system-access-guides/uthealth-start> .

Please note that UTHealth does **not** subsidize projects initiated by for-profit/Industry sponsored companies. If an industry sponsored study is not providing enough funds to cover costs you should request to meet with the Project manager and/or Project Monitor to discuss increasing the budget.

Upcoming:

SCREEN FAILS--In the near future we will be adding an additional tab to capture costs for screen fails, please contact CRF if you are working on a study that anticipates a medium to large number of screenfuls so we can work with you to capture these costs within the current tool until the new version is vetted.