**FINANCIAL CONGRUENCY CHECKLIST IN UTHEALTH START**

# Initial CHECK TO confirm CRFA team Should Review Proposal Record budget

Protocol was NOT written/Co-written by UTHealth PI.

Sponsor is paying UTHealth based upon completed Patient visit milestones (payment is based upon enrolment and work completed)

If yes to both of the above CRFA Financial Analyst should review the budget

*If the answer is “no” to either of the above CRFA financial reviewer will contact Kristin Parks to discuss which team in SPA should review the proposal record budget.*

# Quality Review

**Ensure** CA & CTA AGT records are both linked to each other and Proposal record (if CA is applicable)

Ensure the IRB number is added/linked to IRIS within the “Assurances and Approvals tab.

# Verify the Attched Documents in Proposal Record

Completed Internal Budget on CAIB tool

Negotiated Sponsor Budget- Final

*The below items are not required for Budget approval BUT they are required for Contract to be routed for signature and proposal record is not considered final until they are attached. Notate which of these are still pending within approval notes.*

**IRB a**pproved Informed Consent (ICF)

RCOI

IRB Approval letter (If outside IRB is approving IRB)

# Internal Budget CAIB tool Reivew

1. **Is the Internal Budget complete (does it appear that all applicable fields in all tabs completed/filled in)?**

Yes No *(if no, notify department additional fields/ tabs need to be complete.)*

**Effort Tab**

1. **Does the amount of time entered appear appropriate?**

Yes No N/A

**Coverage Analysis Tab**

1. **Has anything changed on the CA tab from the “Approved” CA? (Compare against the CA AGT record)** *If inappropriate changes have been made return for corrections. If changes are appropriate update final CA AGT record.*

Yes No N/A

**Cost-Expense Tab**

1. **Does the patient stipend/reimbursement in the ICF match the amount in the Contract?**

Yes No N/A

1. **Are all costs listed? (Fields Highlighted yellow typically require costs to be added)**Note in some case the cost will be zero such as when sponsor is providing drug at no charge or venepuncture is effort based, sponsor is paying research stipends, etc.

Yes No N/A

1. **Did the department copy the cost dollar amounts from the final sponsor budget?**  *The department should use the MHH fee schedule/pricing, UTP Fee schedule and quest pricing for these fields*

Yes No N/A if “yes” return for corrections

**START UP and Invoiceables Tab**

1. **Is the “Start-up Effort Calculator” on Row 52 completed?**

Yes No

1. **Are the SC and PI noted at least 3 hours to be spent on “Protocol Review” within the start-up effort calculator?**

Yes No (if less than 3 hours return for corrections)

1. **Is “Coverage analysis Fee” noted on the START UP fee table?**

Yes No

if the answer is “no” CRFA financial analyst has two options here:

Option 1 -return for corrections to have the department add this fee to the start-up cost table.

Option 2 - If the study appears to make a large profit that will cover the CA fee you can approve the record with a note “*Although ‘Coverage Analysis Fee ‘was not listed on the internal budget as a separate lined item SPA has confirmed the budget will cover these costs*.

**Summary Tab**

1. **Ensure all fields are completed if some are missing from the top section as it could negatively impact the lower sections. Ensure all needed information is there.**
2. **Is “Study Coordinator – Administrative Time and effort completed by the department?**

Yes No

1. **If yes to #9 above, Is the SC admin time % effort noted sufficient?** 
   1. **Rule of thumb –**
      1. **Minimum 5% per project.** *(If less there should be a note describing why so low)*
      2. **Minimum should be 5% effort per 10 patient increment (example 30 patients would be at least 15% admin time and effort.** *(Note this is low end. Many studies have extensive CRF forms to complete /queries so typically is higher.)*
      3. *Some of the tools have a formula in the SC Admin if the tool you are reviewing has a prebuilt formula calculating the SC Admin Effort then it is OK to approve.*
2. **Is the “Total Amount Funded by Sponsor” correct? Review the Final Sponsor budget to verify?** *(Total anticipated revenue/Total Amount funded by Sponsor is calculated as follows: Total per patient amount multiplied by # of anticipated patients, plus Start-up fees and guaranteed to receive invoiceables. We do not include the Invoiceable* *procedures within the calculation because they may or may not happen therefore are not guaranteed.)*

Yes No

* 1. **TAR too High---Is the Total Anticipated Revenue = to or greater than 35% above the costs to conduct the study – Typically this identifies that costs are under estimated. It is most likely due to under estimated salary costs or clinical charges being paid for by the department.** *(Return for corrections to the department)*

Yes No

* 1. **TAR in Deficit (Red font)—Red font indicates the Total Anticipated Revenue is less than costs to conduct the study?** 
     1. *If the deficit is small, (less than 15%) send to Kristin Parks to review to see if “padding” will cover.*

Yes No

* 1. **TAR LOW--Does the Total Anticipated Revenue barely cover the costs to conduct the study?** 
     1. **If the TAR is 10% or less of the Total costs to conduct the study, this does not leave much wiggle room for underestimated/unexpected costs.** 
        1. *SPA to add to “Low Revenue Generating Studies” tracking sheet. (To provide information to Leadership regarding those departments/Study teams needing guidance on budget negotiations and/or being more selective in study selection.)*

# Proposal Record START BUdget TAB REview

1. **Does the “Personnel Section within the budget tab show costs as Zero?**  **(this section lists the PI name / staff member’s** **names) (**Personnel Subtotal should be zero. If there are $ amounts showing in this section of the budget, CRFA Financial analyst will need to, return for corrections and instruct the department to remove the % effort from the “Personnel “tab and follow guidance in “Clinical Trial PD “ START guidance document) Key Personnel are mandatory to be listed in START- staff optional. However, no effort % should applied in START for Industry studies. (CT SAL recharge will utilize data within the CAIB tool)

Yes No

1. **Are all costs (minus IDC) listed within the Non-Personnel, Category “Other Costs” 60006 M&O?** (CAIB tool provides this amount on cell H35. if older version of CAIB tool was used, this data may not available- in these cases please defer the department to “Clinical Trial- PD START guidance document details how to separate IDC from Total amount funded by sponsor”.

Yes No

1. **Does the “Total Costs” within the Proposal record Budget tab match the Internal Budget CAIB excel tool “Total Amount Funded by Sponsor” cell G39 on summary tab?** If no, you should send back to department noting the amount listed in Proposal record budget does not match the amount listed in the Internal budget CAIB excel tool please reassess.

Yes No

1. **Does the budget have only one project period?** (start date /end date can span multiple years)

Yes No (if “no” return for corrections. There should be only one budget period for these studies in START.)

# APPROVE or Return for corrections

**If all items were answered correctly above, The Proposal record budget is ready to approve and route to CRFA Contract Analyst for final approval/pass off to PAF for award financial account set up.**

**If any item was noted as incorrect, CRFA Financial Analyst will need to return for corrections –** see template responses for department on SPA shared drive.

**1.. Notify Contract Analyst the financial Review complete:**

* **P Record approval on To Do list Open to Approve**
* **Click on Route**
  + **Click on “Insert”**
  + **Add contract analyst to route**
* **Approve with Comments/Return for Corrections**