**Tips for completing**

**R&A form for Clinical Trial Agreements**

**Guidance for Completing the R&A form for Industry Sponsored Clinical Research Projects**

*UTHealth’s Clinical Trial Budget Template & Coverage Analysis Grid is an excel document in which information regarding the coverage analysis and internal budget is documented. In SPA, we refer to this document as the “CAIB”*

1. **Coverage Analysis-** Each clinical research study requires a coverage analysis that is approved by SPA/CRF**.**
2. **Complete the internal budget- Do not start on R&A form until internal budget is complete.**
	1. The internal study budget is captured within the same excel worksheet tool as the coverage analysis..(CAIB tool)
		1. Once the Coverage analysis is final, and approved by SPA, your next step is to complete the internal budget. The internal budget is completed by entering applicable data within the following tabs:
			1. “Effort “”
			2. “Costs”
			3. “Study Start up “ ( if applicable)
			4. The worksheet will automatically calculate the internal budget.
	2. It is critical that all costs to the best estimate possible are captured within the budget so that you know how much revenue is needed from Sponsor.
	3. *Costs not included in the budget but incurred puts UTHealth in position of subsidizing for- profit Industry Sponsors*
	4. Note: Do not negotiate budget with sponsor until internal budget has been completed and all costs identified.
3. **Direct Costs and Indirect Costs matches between these documents:**
	1. The R&A form
	2. The “Summary” tab within the CAIB
		1. Use the totals titled “Total Direct Costs for R&A”, “Total Indirect Costs for R&A”, and “Total Costs for R&A”
4. **Time and Effort for PI and study personnel listed on the R&A form matches between these documents:**
	1. The R&A form
	2. The “Summary” tab within the CAIB
		1. Note, the CA and Budget tool automatically calculate the effort based upon the data entered into the “Effort” and “Start Up” tab..
		2. PI’s are no longer are required to list 2% effort on industry sponsored clinical research studies.
		3. The effort listed is for the entire life of the project, so it may appear to be more than expected. You can divide by the number of anticipated years to get an annual estimate.
5. **The number of patients to be enrolled onto the study matches between these documents:**
	1. The R&A form
	2. The Coverage analysis/Internal budget worksheet (CAIB)
	3. The ICF
	4. The contract (if applicable)
6. **The patient stipend matches between** **these documents:**
	1. The final budget inserted into the agreement
	2. The internal budget within the CAIB
	3. The ICF
7. **Submit a copy of the internal budget along with the R&A form when requesting DMO approval and signature.**
8. **The R&A Package is required for routing Clinical Trial Agreements for signature and financial account set up. The R&A packet includes:**.
	1. Final R&A form accurately completed and signed by DMO (see check list above)
	2. Internal budget competed on UTHealth’s Coverage analysis/Internal budget tool (CAIB)
	3. IRB approval letter
	4. IRB approved Consent form
	5. Research Conflict of Interest
	6. Coverage analysis approval