

FAQ & Process for beginning a Clinical Trial Agreement (CTA)

Dept Coordinator or CLINICAL CORE Personnel must input to VELOS):

**Required before a CTA review can be done:

1. Study summary must be entered in Velos
 2. Study has been **SUBMITTED to IRB** for Feasibility
 3. Collect minimal required documentation and upload in VELOS
 - a. Sponsor CTA & Budget
 - b. An Approved Protocol
 - c. Informed Consent Form(s) (draft ICF(s) acceptable)
 - d. CRC Feasibility Review--submitted to IRB
 4. Upload above documentation into Documents tab in Velos study record
 5. Notify GCS at UHCRGGRANTSCONTRACTS@Uhhospitals.org
- Once all required documents are uploaded in VELOS, Dept should email Grants/Contracts: UHCRGGRANTSCONTRACTS@Uhhospitals.org

Subject line should read: Velos #XXXX-XXXX - DEPT NAME

SAMPLE: VELOS # 1234-5678 - MEDICINE

**Required before Budget Negotiations can begin:

1. Dept. Coordinator must complete Velos Forms (see Forms tab at top of study summary)
 - a. Startup-Invoiceable Fee Checklist Form
 - b. Startup - PI Compensation_Qualifying Status Form
2. Personnel time and effort calculations-completed by Dept.
3. For trials involving clinical patient care, an RFS built CA/budget draft is required
 - a. CA/budget meeting with dept, GCS & RFS
 - b. PI review of RFS developed clinical budget & dept input of personnel time
 - c. PI written approval of draft budget

IMPORTANT EMAILS/CONTACTS:

PRE-AWARD: Grants & Contracts Office ([GenI](mailto:GenI@Uhhospitals.org))
email: UHCRGGRANTSCONTRACTS@Uhhospitals.org

RESEARCH FINANCE TEAM (CA questions)
email: ResearchBiller@Uhhospitals.org

UH CLINICAL RESEARCH Support
c/o: Heather Tribout heather.tribout@Uhhospitals.org

VELOs Support:

velosupport@Uhhospitals.org

FOR OTHER AGREEMENTS:

Data Use Agreements
Material Transfer Agreements
Other
Send an email to: UHCRGGRANTSCONTRACTS@Uhhospitals.org
Once a GCS is assigned, the department will work directly with the GCS and does not need to email the general email box to avoid duplication.
Use the general email box if you do not get a response within 24 hours.

EXAMPLE where to find Velos forms:

Summary Documents Admin Schedule Study Setup Milestones Notifications Study Status Reports Study Team **Forms**

Jump to Form:
Startup - Invoiceable Fees Checklist Form

Open Form Name: Startup - Invoiceable Fees Checklist Form

Invoiceable Fees Checklist

Form Date* IRB of Record*

Will Services from the DCRU be utilized?* Will Services from IDS be utilized?*

If DCRU or IDS services are being utilized, you must request quotes from each of these business units. The DCRU quote is available in RedCap. The IDS Request Form is available under Forms in eResearch.

Start Up Costs

| | | | |
|---------------------------------|---|--|--|
| CRC Administration Fee | <input type="text" value="Yes"/> | CRC Admin Fee Amount | <input type="text" value="\$2000.00"/> |
| CRC Financial Management Fee | <input type="text" value="Yes"/> | CRC Financial Mgmt Fee Amount | <input type="text" value="\$2000.00"/> |
| Department Startup Fee | <input type="text" value="Yes"/> | Department Startup Fee Amount | <input type="text" value="\$8000.00"/> |
| IRB Initial Review Fee | <input type="text" value="Select an Option"/> | IRB Initial Review Fee Amount | <input type="text" value="\$2000.00"/> |
| IRB Initial Review Sub/Prep Fee | <input type="text" value="Select an Option"/> | IRB Initial Review Sub/Prep Fee Amount | <input type="text" value="\$2000.00"/> |

Once all of the above documents are received, the CTA process will begin.

NOTE: WITHOUT ALL REQUIRED DOCUMENTATION, THERE WILL BE NO REVIEW

Expected turn-arounds:

1. The new/original contract will have an **initial** review by Legal within 15 calendar days of receipt of CTA
2. Draft CA/budget completed by Research Finance Specialist (RFS) in 8 business days of WellSpring notification
3. The PI and dept. need to approve the budget analysis and completion of personnel effort timely
3. Grants and Contracts Specialist (GCS) will negotiate budgets
4. **CTA completion goal from Start to Finish is 90 business days**

****Note the budget negotiation and legal review may take longer depending on whether there are complications with legal language or budget items. Our teams will work expeditiously to complete the process timely.**

5. Upon final budget negotiations, GCS will obtain PI approval of budget
6. Once CTA is FE, the final budget will be input into VELOS
 - a) invoiceables budget will be entered by the GCS
 - b) Patient care budget, calendar and milestones will be entered by the RFS
7. Final copies of contracts will be emailed to PI, Department, RFS and Grants Accounting