

# Navigating the Research Start- Up Process: What should come first?

ITHS Research Coordinator Networking &  
Education Day

April 25, 2014

Amy Deyle RN, BAN, CCRC  
Research Coordinator Core  
ITHS, University of Washington

# Overview

- What is involved in the start-up process?
- Where to start in the process?
- What are the steps for completing the budget, IRB, other committees and regulatory process?



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Overview

- What are the differences between institutions that need to be taken into account during the start-up process?

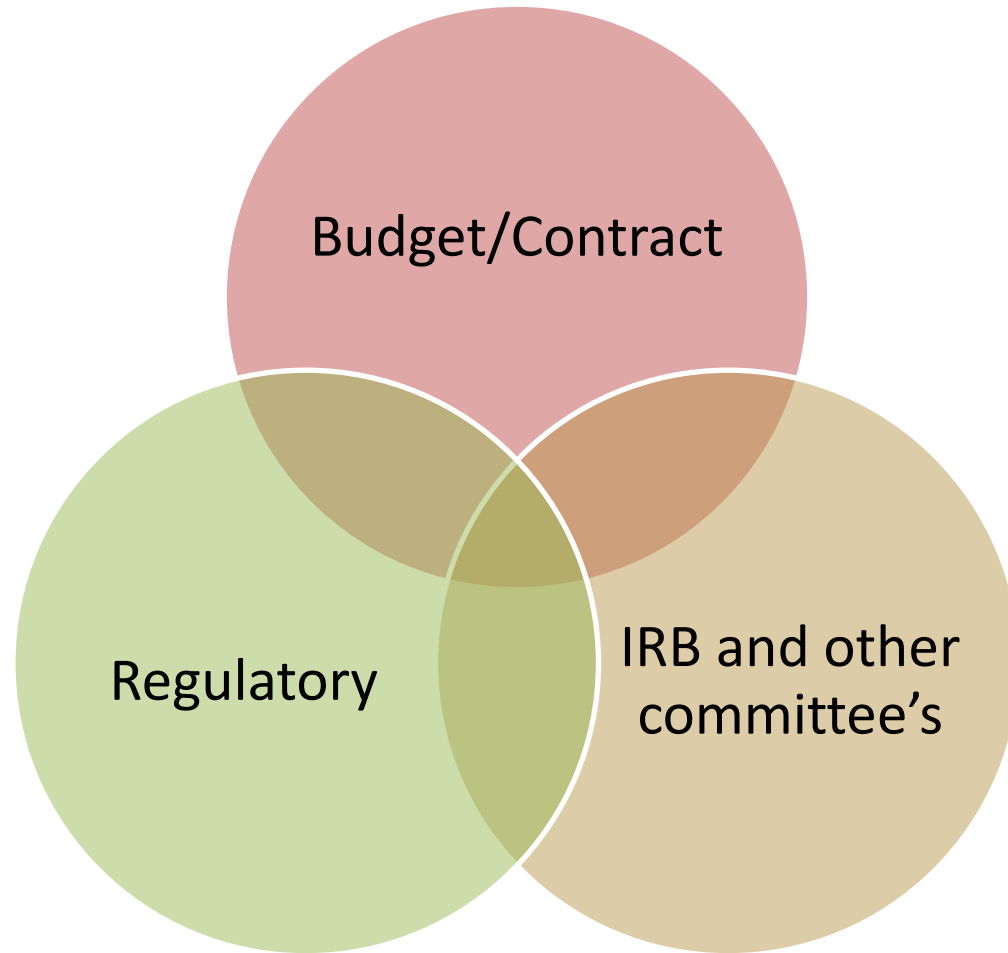


**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Parts to Study Start Up



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Pricing Pages

- UW/HMC - RRR Packet
- SCCA – CTAS (clinical trial assessment summary) and CTPI (clinical trial planning and implementation form)



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Consent

- What institution you work in may dictate when you work on the consent

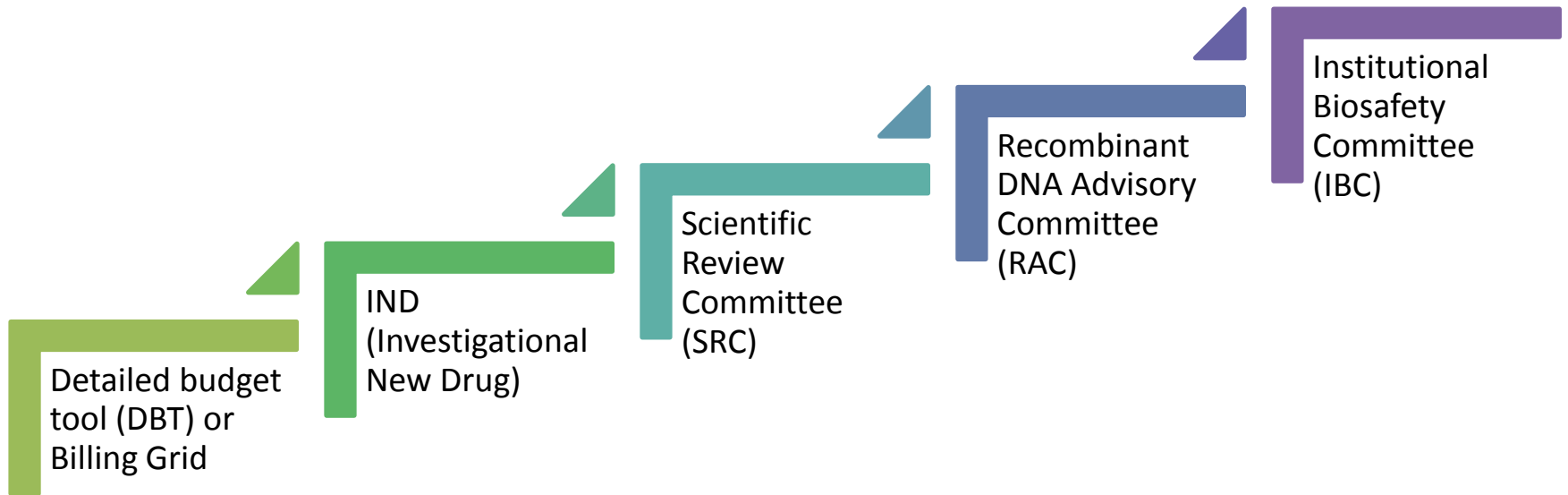


**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Next Three to Four Steps



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Assignment Email from CRBB

Submit the DBT  
or billing grid to  
CRBB

You will receive  
an assignment

You can initiate  
the eGC1



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health



# Sample Assignment Email

CRBB [crbb@uw.edu]

## Actions

To: @uw.edu

Cc: @uw.edu

Attachments:

PSST\_study\_2014-04-25.pdf (313 KB)

Thursday, January 16, 2014 11:10 AM

You forwarded this message on 1/16/2014 2:22 PM.

Attached please find the Project Status Summary Transmittal (PSST) form for Dr. Jane Doctor's STUDYMM study. This study is ready for budget review and has been assigned to Barb Budget's portfolio. She will contact you with details and assist in obtaining the signed pricing pages from UWMC and HMC Eye Clinic since you have not yet received these documents from the service center.

[Study Long Title: *Open-Label, Randomized, Multi-Center Study Comparing the Sequence of Study Drug and Study Drug in Patients with Metastatic Melanoma*]

Our records show CRBB first triaged your study on 4/24/2014, and all documents required for review were received on 4/24/2014.

If your study is an industry sponsored clinical trial, you may now submit for OSP concurrent review. To submit your study for concurrent review:

1. Enter budget as \$0 in your eGC-1: In the budget section of the eGC-1 form, enter "\$0" in Total Direct Costs and "\$0" in Total Costs. Also add the F&A rate, 27%, in the Indirect Cost line item of the budget section.
2. Include the CRBB assignment email in your eGC-1 package. For School of Medicine industry-sponsored clinical trials, the initial eGC-1 package is composed of:
  - The completed eGC-1 Form with the \$0 budget/27% F&A rate noted
  - The sponsor's proposed contract
  - This CRBB "assignment email"
  - The study protocol
  - The completed Significant Financial Interest Disclosure Form (if required)
3. When the budget negotiation is complete, the CRBB budget specialist will send you a "summary review" email. When you receive this email, withdraw the eGC-1 form in SAGE, insert the budget information, attach the summary review email, and re-submit the eGC-1 form. This step does not require a second round of signatures.
4. When OSP has received the final eGC-1 form with the budget information included, the clinical trials group can proceed to finalize the research agreement.

If you have any questions or need additional assistance in the interim, please let us know.

Best regards,  
CRBB

Clinical Research Budget & Billing Office (CRBB)  
University of Washington Medicine | Box 358048  
Main (206) 543-7774  
Fax (206) 543-8501  
<https://depts.washington.edu/crbb/>



# ITHS

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Radiation Safety Committee

- There is now one committee between UW and the SCCA
- FHIRB and HSD require approval prior to approving the study to open for enrollment
- Specific language in the consent



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Institutional Review Board

- Western Institutional Review Board (WIRB)
- Human Subjects Division (HSD)
- Cancer Consortium Institutional Review Board (CCIRB)



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Regulatory

1572

Curriculum Vitae

Lab normals

CAP

CLIA

Protocol or Investigational  
Brochure signature page

Financial Disclosure Forms



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Final Items

- RU/RS/RH study code and RRR number
- Coverage Analysis (CTP) checklist
- Pre-printed orders (maybe CPOE)



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Final Items

- Site Initiation Meeting
- Staff in-service
- Laboratory and pathology set up
- Radiology central imaging



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Review

Start with pricing and consent form

Always make sure to pull the most current documents when filling out forms for all items of start up

Regulatory documents can be pulled together when you have time, but it is your time if the study does not open.



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

# Links

- <http://www.seattlecca.org/Research-Staff-Resources.cfm>
- <http://www.cancerconsortium.org/en/support/study-management/study-start-up.html>
- [https://depts.washington.edu/crbb/About CRBB.shtml](https://depts.washington.edu/crbb/About_CRBB.shtml)



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health



# Links

- <http://extranet.fhcrc.org/EN/index.html>
- <http://www.washington.edu/research/hsd/>
- <http://www.ehs.washington.edu/rso/>
- <https://www.washington.edu/research/clinical-research-handbook/>



**ITHS**

Institute of Translational Health Sciences

Scientists helping scientists improve health

