PI/Study Team Tasks:
Process for Assigning Expenses to Industry Funded Clinical Trials
PI/Study Team Tasks:

1. Communicate effort and expenses to the award manager
2. Post the effort and expenses
3. Recognize that the contract signature will be withheld until effort is posted.
I. Preparation for submission to OSP

Documents to OSP
- UAB Extramural Support Checklist
- Sponsor Information required
- Responsible Personnel List (RPL)
- Agreement (editable Word version)
- Budget (draft or final)
- Informed Consent (draft or final)

Effort may be assigned to a Clinical Trials Operating Account in real-time or to the Pending Account when it is established.

Responsibilities
1. PI / Study Team
2. PI / Study Team
3. OSP – OG/CA
4. Award Manager
II. Continuing work prior to contract readiness for signature

Effort may be assigned to a Clinical Trials Operating Account in real-time or to the Pending Account when it is established.

Responsibilities:
1. PI / Study Team
2. Award Manager

Additional start-up Activities (eg, budget, approvals)

Contract negotiation with funder

Pending acc’t (Operating acc’t)

Post effort & expenses

OSP

Unit Award Manager

PI / Study Team
III. Contract ready for signature

a. Clinical Trials Operating Account or Pending Account used appropriately

Effort may be assigned to a Clinical Trials Operating Account in real-time or to the Pending Account when it is established.
III. Contract ready for signature

b. Clinical Trials Operating Account or Pending Account *has not been used*

Effort may be assigned to a Clinical Trials Operating Account in real-time or to the Pending Account when it is established.

If a Clinical Trials Operating Account or Pending Account has not been used, the Department Chair and Executive Administrator will be notified by the CTAO and contract signature will be withheld.
PI/Study Team Tasks:

1. Communicate effort and expenses to the award manager

2. Post the effort and expenses

3. Recognize that the contract signature will be withheld until effort is posted.
PI/Study Team Tasks:
Clinical Trials Budgets – Fair and Appropriate Expenses for Industry Funded Clinical Trials
What would you do with more clinical trial revenue?
The Center for Clinical and Translational Science (CCTS), in collaboration with the Clinical Trials Administrative Office, cordially invite you to join us:

*CCTS Forum featuring*

The Business of Clinical Trials: Who Pays? Who Profits?
Wednesday, July 5, 2017
4:45pm – 6:00pm
PCAMS Library
Because of the complex nature of clinical trials, research units may leave money for a number of billable activities on the table when developing a budget. This forum will

– Address the critical considerations in crafting and negotiating fair and appropriate clinical trial budgets that address the financial realities and hidden costs of implementing a trial.
– Highlight allowable costs that sponsors are willing to pay and that clinical trial teams often overlook.
– Explore justified expenses and event-triggered ‘invoiceables’ as well as the need for enterprise-wide consistency and best practices

• https://www.youtube.com/watch?v=j_Tt1hR7ics&t=744s
CCTS
The clinical trial lifecycle graphic at https://www.uab.edu/ccts/clinical-translation

CTAO
CTAO summarizes or links to key issues like standard fee schedule, pending accounts, study management fee, etc. here https://www.uab.edu/medicine/ctao/investigators/policies-procedures

Office of Research
The new umbrella site for the central admin research / VPR operations https://www.uab.edu/research/home/
There is a link Clinical Trials, which points to older pages within OSP’s website which will be updated.

OSP Homepage (https://www.uab.edu/research/administration/offices/OSP/Pages/default.aspx), from which one can navigate to “Guidance” in the top, horizontal navigation.

F&A Rates on Investigator Initiated Trials (IIT’s)
The revision in guidelines for the F&A rate on investigator-initiated trials from 30% of TDC to 36% of MTDC can be found here: https://www.uab.edu/policies/content/Pages/UAB-AD-POL-0000089.aspx

The Clinical Trials Criteria document can be found at https://www.uab.edu/research/administration/offices/OSP/Guidance/Pages/Clinical-Trial-Criteria.aspx
On that page, #5 indicates that IITs do not fall under the clinical trial rate of 30%