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Study start-up for industry initiated studies: Site responsibilities to seriously consider feasibility for the study at WU

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Study Start-up for Industry Initiated Studies

Site Responsibilities to
seriously consider
feasibility for the study
at WU

Phyllis Klein
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Budget/Contract

- Notify the CCS that you have a new industry-sponsored study, so that the contract can be negotiated on your behalf
- Cheryl LaRue is the contracts secretary
- She can be reached by calling 362-6953
- E-mail: laruech@wustl.edu
- She will send you 3 forms to complete and return

Forms

- **CCS Expeditor**
 - Provides contract specialists with information necessary to negotiate the contract terms in the best interests of the PI
 - **Internal Confidentiality Agreement (ICA) form**
 - Provides the contract specialist the names of the members of the study team
 - **Request for CCS Services**
 - Tells us for what services you are requesting CCS help
- No one will start on this CTA until these forms are returned!**

CCS Services

- Budget –
 - We prepare a WU budget for you to compare to the sponsor's template
 - We charge for this service, but include it in the start-up fees to the sponsor – the PI/dept. does not pay us directly
 - We negotiate the budget with the sponsor
 - We keep the PI/coordinator apprised of any major budget adjustments that may impact the conduct of the trial
 - We make sure you approve before we accept a budget that is different from what we proposed

CCS Services

- Regulatory -
 - We have 2 full time regulatory coordinators that prepare IRB submissions for you
 - We charge a fee to the sponsor for this work as part of the study budget – the PI/dept. does not pay us directly
 - For this fee, we prepare all IRB amendments and consent changes, etc. for the first year
 - We negotiate an annual fee to cover our costs for the same service for each following year, until the study is closed
 - We expect the coordinators to submit any local SAEs and the IND safety reports as needed

CCS Services

- Coordinators

- We can provide you with a coordinator, or we can have someone help *your* coordinator with specific tasks
 - ECGs, vital signs
 - Infusions, blood draws
 - Specimen shipping, etc.
- We expect to be paid for this service from the study budget
- We can charge hourly or a percentage of the budget based on the services provided

CCS Services

- Recruitment

- Our Recruitment Enhancement Core can provide your team with assistance in screening participants
- We can send you referrals from the RPR (Recruitment Participant Registry)
- We can help with recruitment by placing advertisements on radio, TV, or by creating flyers or banners, etc.
- We can prepare the IRB submission of the recruitment materials
- This assistance is also paid for by requesting funds from the sponsor of the trial

Your Site Study Feasibility

- The study team should review the protocol
- Have someone prepare an internal budget for WU eyes only
- The team needs a breakdown of costs to determine needed resources to conduct this trial according to the protocol.
- Compare internal budget to the sponsor's template

Study Feasibility

- Set-up a meeting to discuss the study conduct and the budget with the study team
- Collect input from the coordinator, PI, and any other specialty to make sure that all of the costs are *accurately accounted* for before you finalize the budget with the sponsor
- Once you have determined all costs at each visit, you have created your budget.

Study Feasibility

- It will be your responsibility to make sure all costs are covered, and overhead is applied to all (26% overhead for the university)
- You should come up with start-up fees that include:
 - HRPO fees/Pharmacy fees (if required)
 - IRB Prep fees
 - Coordinator fees to create Source documents, train on CRFs, unpack lab kits, etc.

Study Feasibility

- The start-up fees also need to have overhead applied
- Remember...the overhead is removed *before* the funds are deposited in your research account. You will only have the net amount to pay for your study expenses
- Create a budget comparison chart to compare the two budgets side by side

Study Feasibility

- If you are creating your own budget, once you have completed your review, you may revise the sponsor's template to meet the WU needs for this study
- Once this is done, you can negotiate with the sponsor by sending them your site budget
- You can get the contact name from your contract specialist assigned to the study

Study Feasibility

- The contract specialist will submit your budget template to the contact for you, but they will **not** negotiate the budget for you. As a matter of fact, they don't even review it.
- It is your responsibility to make sure you have covered everything, including the overhead!

Study Feasibility

- If the sponsor's budget and the WU budget are not in parity, negotiations will be needed
- Remember negotiations are *give & take*
- *Sometimes you have to walk away...*

Questions?

Thank you!

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