

CTO Study Feasibility Form

Please use this form as a tool to identify the resource requirements and risks of the clinical trial. The answers provided on this form will also assist in the creation of the study budget.

Complete Study Title:

Department:

Study Information

- Type of Study: Clinical Trial Registry Observational
 Chart Review Epidemiological
- Phase of Study: I II III
 IV (post market) Other: N/A

Investigational Product:

Is the Investigational Product being supplied by the Sponsor?: Yes No

- IND; IND # IND Held by:
 IDE; IDE # IDE Held by:

Please note that if this is a device study, a charge code will have to be generated.

Study Procedures

What is the expected length of the overall study?:

How many cycles/years is it expected that this study will run?:

Do you have all of the equipment necessary to complete the study procedures? Yes No

If not, will the sponsor supply the equipment and necessary training? Yes No

Are the procedures realistic, and in line with current standard of care practices? Yes No

Is the study complicated? Yes No

Do you anticipate protocol compliance issues? Yes No

Is this study likely to be audited by the FDA? Yes No

- Will PIs and/or study coordinators need to be available after hours? Yes No
- Will a central lab be used? Yes No
- Will any of the labs being sent out need to be conducted and read at DHMC? Yes No
- Do any of the labs need to be ordered as STAT? Yes No
- Will you need the services of other departments? Yes No

Laboratory

Phlebotomy Labs processed here

Shipping Freezer storage

Dry Ice Other:

Pathology

Specimen ship out Other:

Investigational Pharmacy

Dispensing Mixing/compounding (e.g. chemo) Other:

If the Investigational Pharmacy is not being used, where will the drug be stored?:

Are there any pre-meds?: Yes No

If yes, please list:

Radiology

CT MRI

Copies of films Other:

EKGs done by DHMC Techs

M2S for 3D rendering

Infusion Suite

Endoscopy Suite

OR / Recovery Room

In-patient Room

Can the other departments meet the protocol requirements? Yes No

If you have seen the Case Report Forms (CRFs), are they complex? Yes No

Is the turnaround time for the CRFs adequate? Yes No

Study Population

How many patients do you anticipate enrolling per year?:

How many patients do you anticipate enrolling in total?:

How long do you expect the average patient to stay in the study?:

How many screen failures do you anticipate?:

Are there competing studies already open to enrollment?

Yes No

Do you have access to the patient population?

Yes No

Is it a vulnerable population?

Yes No

Will participants come from your clinic?

Yes No

Will you need to recruit from other clinics?

Yes No

Will you need to recruit from outside of DHMC?

Yes No

Is the enrollment goal realistic?

Yes No

Is the enrollment timeline realistic?

Yes No

Do you foresee problems with recruitment (e.g. rigid or complicated inclusion/exclusion criteria, too many visits/too much of a time commitment)?

Yes No

Do you anticipate problems with subject retention (e.g. too inconvenient, painful, difficult, or expensive for the participants)?

Yes No

Do you anticipate participant compliance issues (e.g. complicated dosing, diaries, etc.)?

Yes No

Are there excessive costs that will be charged to the participants?

Yes No

Do you anticipate a lot of AEs/SAEs?

Yes No

Will participants be paid?

Yes No

Travel Meal Reimbursements Overnight Stays Other:

If any of the above will be required, at what frequency?:

If a drug study, will the drug be available to the participants after the study?

Yes No

Sponsor and Contract Research Organization (CRO)

Sponsor Name:

Do you have experience with this Sponsor?

Yes No

If you do, has your experience been satisfactory?

Yes No

If you do not, have you checked the Sponsor's reputation with colleagues?

Yes No

CRO Name (if applicable):

Do you have experience with this CRO?

Yes No

If you do, has your experience been satisfactory?

Yes No

If you do not, have you checked the CRO's reputation with colleagues?

Yes No

Research Team

Principal Investigator:

Phone/Pager:

Research Nurse:

Phone/Pager:

Study Coordinator:

Phone/Pager:

Does the research team have experience with this type of study? Yes No

Do you have adequate clinic space to complete study procedures? Yes No

Do you have time in your clinic schedule to see study participants? Yes No

Do you have adequate office space to store study supplies (e.g. binders)? Yes No

Using the event schematic in the protocol, do the PI and the research team have adequate time to complete all of the tasks in light of current workloads? Yes No

Will any additional training be needed? Yes No

If so, how will the training be obtained?:

Budget Considerations

Items to consider when reviewing the preliminary budget:

Will the Sponsor pay start up fees as outlined by the CTO? Yes No

Does the budget cover all of the research nurse/coordinator time (considering scheduling, visits, CRFs, AEs, monitoring, queries, etc)? Yes No

Does the budget cover database mining/recruitment time? Yes No

Does the budget cover screen failures? Yes No

Does the budget cover advertising? Yes No

In light of these considerations, does the preliminary budget seem reasonable? Yes No

Do you feel that it is feasible to pursue opening this study at DHMC? Yes No

FOR CTO USE:

CTO Study Number:

Date of Resource Meeting:

Draft MCA completed Date:

Is this study a Qualifying Clinical Trial?: Yes No