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