Clinical Trials Information Sheet

Name of Principal Investigator	
Name of Coordinator	
Contact Telephone **Contact Email**	

STUDY INFORMATION

Study Title	
Sponsor	

Protocol No.	
Short Title/Acronym	

Type of Study: ___ PI-Initiated Study ___ Sponsor Initiated Study

__ Observational
__ Retrospective Chart Review
__ Clinical Trial
Phase: _____
__ Lab Services
__ Material Transfer
__ Data Transfer
__ Other

Type of Sponsor:

___ Corporation
___ Government Agency
___ Academic Institution
___ Consortia (such as Children's Oncology Group)
___Philanthropic Organization
___ Investigator Initiated

Which support services will be used for the study?

____ Clinical Research Unit
____ Research Pharmacy
____ Research Lab
____ Cardiology
____ Medical Imaging
____ Physical Therapy
____ Ophthalmology

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Location of Research and Study Personnel

Where will research activities take place? List location(s): _____

Are all study personnel institution employees? If not, please list other affiliations_____

Will any off-site vendors or service providers be used? If so, please list:

Are there any contemplated subsites? If so, please list potential subsite location(s): _____

Will there be a "co-principal investigator" involved? If so, please provide name: _____

Patient Care:

List procedures and assessments that will conducted for research purposes only: _____.

How likely are AEs/SAEs?

Pharmacy:

Does the study require use of drugs other than the investigational drug, such as a placebo or control drug? Does the research pharmacy stock it or will it need to be purchased?

For inpatient studies, are there particular non-investigational drugs that may be required that the PI is concerned about? Ex: PI may be aware of expensive drug that will be required, or if there is a shortage, manufacturing issue etc.

Is the study drug a controlled substance?

Enrollment

Approximately how many subjects will be enrolled at Lurie?

Will it be difficult to enroll subjects?

Are subjects local or will subjects come to Lurie from out-of-town to participate in the study?

Do you have plans to open a competitive study in next year or two?

Equipment:

Is sponsor providing any equipment for use in the study? ___Y/ ___N

If yes, please list: _____

Is PI interested in purchasing or keeping equipment when the study ends?

CRF Completion Timeline:

What is the department's data entry timeline policy? If no policy, what is the preferred timeline in which the CRFs will be completed after the subject visit?

Sponsor Monitoring Visits:

Are there any considerations you need your contract officer to keep in mind when negotiating the Sponsor's right to monitor the study? (e.g. timing, duration, etc.)

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Final Study Report:

Are there any conflicting obligations that will prevent the PI/study team from providing the final study report to Sponsor within 60-90 days after study completion?

Please provide any additional information regarding this study that you would like your contracts office to be aware of during negotiations:

_____