OB/GYN Clinical Trial Feasibility Questionnaire for PIs

Baylor College of Medicine
DEPARTMENT OF OBSTETRICS & GYNECOLOGY

Principal Investigator: _____

Study Title: _____

Sponsor Name: _____

Estimated Study Period: _____

Study Overview

Primary Objective: _____

Investigational Item: _____

Personnel

List all Co-investigators: _____

_____

_____

_____

Number of Coordinators requested: _____

Coordinator FTE requested: _____

Number of Coordinator hours/subjec t: _____

Additional Personnel requested: _____

_____

_____

Study Site Locations

List all sites study will be conducted at:

_____

_____

_____

Human Subject Information

Target Population: _____

Total Recruitment Goal: _____

Recruitment Goal (per Month): _____

Regulatory Affairs

Name of Central IRB to be used: _____

CITI training?: _____

Additional Training required?: _____

Other Departments Involved (Check all that apply):

Anesthesiology ☐	Audiology ☐	Cardiology ☐
Dentistry ☐	Neonatology ☐	Ophthalmology ☐
Pathology ☐	BCM Pathology ☐	TCH Pathology ☐
Renal ☐	BCM Surgery ☐	TCH Pedi Surgery ☐
Pediatrics ☐	Other (Please specify below) ☐	

Other Department : _____

Dept Contact Name & number: _____

Investigational Pharmacy (IDP)

Investigation Pharmacy needed?: _____

Sites that require IDP?: _____

IDP contacted for quote(s)?: _____

Patient Follow up

Patients to be followed up: _____

Duration of follow up: _____

Specific follow up needs:

Study Budget

Standard of Care procedures involved?: _____

Per patient reimbursement (yes/no)?: _____

Estimated IRB costs? _____

Study start up costs?: _____

Overhead costs?: _____

Inpatient Stay required?: _____

Patient Stipend provided?: _____