Clinical Oversight Committee – Study Information Sheet

PI(s):

Medical Investigator: | **Has the MI reviewed this protocol?** ◯ Yes ◯ No

Sponsor:

Sponsor Type: ☐ Federal/Non-Profit ☐ Pharma/For-Profit | **Study Type:** ☐ Phase I ☐ Phase II, III, or IV ☐ N/A

Study Title:

Desired Start Date	
Approximate Screening Time	
Approximate Completion Date	
# of Volunteers Expected to Screen	
# of Volunteers Expected to Enroll and Randomize	

Location of Study ☐ PBRC only ☐ Other_____ ☐ Both

Please check if you will be using the following (service units must review entire protocol to confirm):

- ☐ Study Coordinator (Shipp)
- ☐ Outpatient Clinic Services/Staff (Shipp)
- ☐ PBRC Data Management (Murla)
- ☐ Dietary Assessment/Dietary Counseling (Champagne)
- ☐ Preventive Medicine (Johannsen)
- ☐ Psychological Assessment Lab (Newton)
- ☐ Research Kitchen (Brock)
- ☐ Clinical Chemistry (Rood)
- ☐ Recruiting/Advertising (Bourgeois)
- ☐ Exercise Testing Core (Lupo)
- ☐ Imaging (Murray)
- ☐ Pharmacy (Hazlett)
- ☐ Mass Spectrometry (Rood)
- ☐ Biostatistics (Johnson)
- ☐ Nutrition Research Group (Allen)
- ☐ Inpatient Unit (Waguespack)
- ☐ IDRP (Keller)
- ☐ Ingestive Behavior (Martin)
- ☐ MSSP & FPQ Intellectual Property (Geiselman)

Is this a draft or incomplete protocol? ***If yes, final version must be routed before final budget is submitted to Sponsor.***	◯ Yes ◯ No

PI requests use of negotiable budget rate: ◯ Yes ◯ No

Justification for use of negotiable budget rate:

PI hereby agrees not to discuss price/budget with a potential sponsor without Sponsored Project Services involvement. PI further agrees to abide by all PBRC policies related to budget and contract negotiation, including, but not limited to, Clinical Study Budget, Resource & Initiation Policy and Indirect Cost Allowances policy. PI initials_____

RESET FORM

Please attach additional pages as necessary