

Clinical and Translational Research Center (CTRC) Service and Budget Requisition Form

Instructions:

1. In the fields below, please fill in as much as you can below. If you wish to arrange a time to discuss the protocol in person with us, please indicate here and we will be in touch to arrange a time ☐
2. Attach the following documents with this completed form:
 1. Study Protocol, 2. Lab Manual. If you only have draft forms, please indicate that in the document title.
3. If you have not done so please submit your request through the link below for tracking purposes:
<https://tuftsctsi.my.site.com/s/>

Please contact CTRCmanagement@tuftsmedicine.org for questions. We are available to discuss the specific needs of your study either in-person or virtually and we can be contacted at CTRCmanagement@tuftsmedicine.org or 617-636-4714 to find a time. Alternatively, please drop by the CTRC Clinic in North 6.

Table 1: Study Intake	
Full Study Title:	
Short title:	
Principal Investigator (PI):	
Institution (TMC/TU):	<input type="checkbox"/> Tufts Medical Center <input type="checkbox"/> Lowell General Hospital <input type="checkbox"/> Melrose Wakefield Hospital <input type="checkbox"/> Tufts University <div style="margin-left: 20px;"> <input type="checkbox"/> School of Medicine <input type="checkbox"/> School of Dental Medicine <input type="checkbox"/> Friedman School of Nutrition <input type="checkbox"/> Other (fill in) </div>
Division/department:	
Primary Study Contact:	
Research Administrator:	
Will CTRC be the primary study coordinator for this study?	Yes <input type="checkbox"/> No <input type="checkbox"/> Not sure, would like to discuss <input type="checkbox"/> If no, please provide name of study coordinator:
Status of IRB:	<input type="checkbox"/> Not started <input type="checkbox"/> In progress <input type="checkbox"/> Submitted <input type="checkbox"/> Approved; IRB # _____
Name of IRB:	<input type="checkbox"/> Tufts HS <input type="checkbox"/> Advarra <input type="checkbox"/> WCG <input type="checkbox"/> Other:
Is the PI new to TMC/TU/clinical trials or need additional senior-level CTRC support for any reason?	<input type="checkbox"/> Yes, specify: _____ <input type="checkbox"/> No

Multi-center trial?	<input type="checkbox"/> Tufts only <input type="checkbox"/> Multi-center Number of sites planned: _____ If investigator-initiated, the coordinating center will be: <input type="checkbox"/> Tufts Medical Center <input type="checkbox"/> Other – please specify: _____
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Table 2: Funding status <i>Fill in one side of the table</i>	
<input type="checkbox"/> Grant application	<input type="checkbox"/> Funded
Industry <input type="checkbox"/> Federal <input type="checkbox"/> Foundation <input type="checkbox"/> Other <input type="checkbox"/>	Industry <input type="checkbox"/> Federal <input type="checkbox"/> Foundation <input type="checkbox"/> Other <input type="checkbox"/>
	Investigator initiated <input type="checkbox"/> Sponsored <input type="checkbox"/>
Sponsor Name (if applicable):	Sponsor Name (if applicable):
Deadline for budget development	Deadline for budget development
Indicate grant deadline _____ (MM/DD/YYYY)	Indicate deadline _____ (MM/DD/YYYY)
Indicate deadline for submission to research administration _____ (MM/DD/YYYY)	
Indicate if preliminary budget estimate within 2 to 3 day period is needed for planning <input type="checkbox"/>	

Table 3: Study Development Services		
Service Type	Yes/ NA	Specifics or comments
Protocol Development	Yes <input type="checkbox"/> No <input type="checkbox"/>	
IRB Preparation	Yes <input type="checkbox"/> No <input type="checkbox"/>	
Recruitment services and planning	Yes <input type="checkbox"/> No <input type="checkbox"/>	

Table 3: Study level details and participant visits	
Location of Study Activities Performed by CTRC Staff	
Location of study activities: <i>Please select all that apply.</i>	<input type="checkbox"/> CTRC Clinic <input type="checkbox"/> Inpatient hospital rooms <input type="checkbox"/> ICU <input type="checkbox"/> Outpatient procedure area (i.e. Interventional Radiology, Cath lab, etc.) <input type="checkbox"/> Tufts MC Adult Clinics <input type="checkbox"/> Tufts MC Pediatric Clinics <input type="checkbox"/> Melrose Wakefield Hospital <input type="checkbox"/> Lowell General Hospital <i>If other, please specify</i> _____
Estimated trial duration	Years =

Target enrollment at Tufts	n= if not sure, please indicate approximate range (eg 1-2, 5 to 10, > 100)		
Patient Services by CTRC staff <i>If you are not sure about which of the following are needed or if this will be CTRC-managed study, please indicate here and we can be in touch with you <input type="checkbox"/></i>			
Specialized Vital Signs	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Informed Consent	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Specify if virtual <input type="checkbox"/>
Height/Weight	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Electrocardiogram (EKG)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Phlebotomy	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Blood Draw via IV Line	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Sample Processing	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Sample Shipping (Local vs. Central)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Local <input type="checkbox"/> Central <input type="checkbox"/>
Post Study Drug Observation	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Concomitant Medication Reconciliation	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Adverse Event (AE) Assessment	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Short term Sample Storage	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Long term Sample Storage and Archiving	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Anticipate visits outside Mon- Fri. 8am-5pm	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Data Entry	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Auxiliary services (i.e., OGTT, CGM installation, 6-minute walk test) or specialized equipment; <i>please specify</i>			
Questionnaires or surveys <i>If yes, please specify name and approximate length of time required to complete each individual assessment tool:</i>	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Please provide any additional comments or requests here:			