CLINICAL TRIALS – REGULATORY DOCUMENT REQUEST FORM

Revised April 2, 2024

(Sponsor/CRO to complete this form)

Sponsor: _____ CRO (if applicable): _____ Date: _____

Protocol Name: _____

	Comments
Sponsor Main Contact Information Name: _____ Email address: _____ Phone number: _____	
CRO/CRA Main Contact Information (if applicable) Name: _____ Email address: _____ Phone number: _____	
CTA/contract (draft): Sponsor Version	
Budget (draft): Sponsor Version	
Protocol Information Number: _____ Protocol Version: _____ Protocol Date: _____	
Study Drug Information Study Drug Name: _____ IND#: _____ NCT#: _____ Will study drug be provided by sponsor? _____ Study drug route (e.g., IV, oral, injection, etc.): _____	
Supplemental/Additional/SOC drug Name(s): _____ Will additional drug(s) be provided by sponsor, procured by site, or provided by patient's insurance/SOC? _____	

If procured by site, will sponsor reimburse site? _____	
Central IRB information Central IRB of record: _____ Central IRB/External study ID: _____ Central IRB Contact: _____ Does Sponsor/CRO have a dedicated central IRB point of contact? _____ _____	
Requested <u>mandatory</u> documents/manuals from sponsor *Please send the following documents upon returning this form to site.* ☐ Protocol ☐ IB ☐ Central IRB Study Approval Letter ☐ ICF/consent form: Central IRB draft template ☐ Lab Manual (if lab draws are involved) ☐ Lab processing flow chart (if not included/incorporated into Lab Manual) ☐ Pharmacy Manual (if study drug is involved) ☐ Imaging Manual (if CT/MRI/scans are involved) ☐ Patient Material (if applicable): study surveys, questionnaires, IFU/information sheets, etc. ☐ Safety/DMC/DSMB Charter (if applicable; if not finalized, a draft charter will suffice) ☐Regulatory documents ☐ 1572 ☐ Signature pages (protocol, IB, etc.) ☐ FDFs	

Other Required Information from Sponsor

Will the study involve central labs? ☐Yes ☐No

If so, which ones? _____

_____

Will the study involve local labs? ☐Yes ☐No **If so, which ones?** _____ _____
Will the study involve PKs? ☐Yes ☐No **PK timepoints:** _____
How long is subject's approximate participation duration on study? (E.g. # of visits, # of months/years): _____
What is the anticipated # of global study participants?: _____
Status of study recruitment timeline *(towards the start, middle, or end)*: _____

Notes: Sponsor Name: _____ Contact Name: _____

Contact Email: _____Contact Phone: _____