

CLINICAL TRIALS – REGULATORY DOCUMENT REQUEST FORM

Revised April 2, 2024

(Sponsor/CRO to complete this form)

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

Protocol Name: _____

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

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 <i>Please send the following documents upon returning this form to site.</i>	
<input type="checkbox"/> Protocol <input type="checkbox"/> IB <input type="checkbox"/> Central IRB Study Approval Letter <input type="checkbox"/> ICF/consent form: Central IRB draft template <input type="checkbox"/> Lab Manual (if lab draws are involved) <ul style="list-style-type: none"> <input type="checkbox"/> Lab processing flow chart (if not included/incorporated into Lab Manual) <input type="checkbox"/> Pharmacy Manual (if study drug is involved) <input type="checkbox"/> Imaging Manual (if CT/MRI/scans are involved) <input type="checkbox"/> Patient Material (if applicable): study surveys, questionnaires, IFU/information sheets, etc. <input type="checkbox"/> Safety/DMC/DSMB Charter (if applicable; if not finalized, a draft charter will suffice) <input type="checkbox"/> Regulatory documents <ul style="list-style-type: none"> <input type="checkbox"/> 1572 <input type="checkbox"/> Signature pages (protocol, IB, etc.) <input type="checkbox"/> FDFs 	

Other Required Information from Sponsor
Will the study involve central labs? <input type="checkbox"/> Yes <input type="checkbox"/> 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: _____