UNIVERSITY OF IOWA
HOLDEN COMPREHENSIVE
CANCER CENTER
University of Iowa Health Care

Clinical Research Services

HCCC Pre-Study Team
200 Hawkins Drive, 11510 PFP Research
Iowa City, Iowa 52242-1002
Phone: 319-335-2510
Email: HCCC-Reg-Prestudy@healthcare.uiowa.edu

SPONSOR QUESTIONNAIRE FOR MOG SUBMISSION

Date: Click or tap to enter a date.

NCT Number: Click or tap here to enter text.

Sponsor:Click or tap here to enter text.

Study Title:Click or tap here to enter text.

Is this a dose escalation study? ☐Yes ☐ No

Is this a first in human study? ☐Yes ☐ No

How many sites are planned to open for this study: Click or tap here to enter text.

How many of these sites are already open? Click or tap here to enter text.

Projected first subject first visit (MM/YYYY): Click or tap here to enter text.

Number of subjects currently enrolled: Click or tap here to enter text.

Number of subjects planned to be enrolled: Click or tap here to enter text.

Projected last subject first visit (MM/YYYY): Click or tap here to enter text.

Is electronic drug accountability required? Click or tap here to enter text.

CRO: Click or tap here to enter text.

IVRS: Click or tap here to enter text.

EDC: Click or tap here to enter text.

Pt Reimbursement System? ☐Yes ☐ No
If yes, please specify (Greensphire, Scout, etc.): Click or tap here to enter text.

Vendor Services: data entry, regulatory, coordination. If yes, please specify (Threewire, WCG, etc)Click or tap here to enter text.

Does this trial require SIP? ☐Yes ☐No
How will SIP be used for this study:
☐SUSARS
☐Training
☐Other, please specify: _____

Does this trial require the use of a portal to access IND SUSARs? ☐Yes ☐No
If yes, which portal: _____
If not required, it's preferred the sponsor email these reports to the primary regulatory team member managing the study.

Does this trial use a central IRB? ☐Yes ☐No
If yes, which IRB: _____

If No, our site will use our local IRB (HawkIRB) as the IRB of record.

Imaging:

a. Will the study have an imaging manual? ☐Yes ☐No

b. Will the study have a verification of scanner(s) form? ☐Yes ☐No
   i. If so, please indicate the modalities (CT, MRI, PET, SPECT, US)

c. Will the study have a phantom scan form? ☐Yes ☐No
   ii. If so, what is the frequency of required phantom scans
   iii. If so, please indicate the modalities (CT, MRI, PET, SPECT, US)

d. Will the study require radiology technological training? ☐Yes ☐No
   iv. If so, please indicate the modalities (CT, MRI, PET, SPECT, US)

e. Will the study require transfer of deidentified medical image data? ☐Yes ☐No

f. Does the study have image protocol requirements that may not be SOC? ☐Yes ☐No

Pharmacy:
a. Will drug be sourced centrally or locally? ☐Yes ☐No

Pre-Screening:
Our site has on-site clinical trial navigators who utilize Triomics PRISM, an AI-enabled patient-clinical trial matching program, as tool to match patients to clinical trials.

Lab /Cellular Therapy:
a .Does the study require a -70 freezer (or equivalent freezer?) ☐Yes ☐No
b. Does the sponsor accept plasma chemistry? ☐Yes ☐No
c. Does the sponsor have a quality assurance agreement for Cellular Therapy Trials? ☐Yes ☐No

Central lab vendor(s): Click or tap here to enter text.

Our site has multiple locations
- Main Campus, 200 Hawkins Dr, Iowa City, IA 52245
- Cancer Services-Quad Cities, 1351 Kimbery Rd #100, Bettendorf, IA 52722

- Mission Cancer + Blood 2565 SE Encompass Dr. Suite 100, Waukee, IA 50263
- Mission Cancer + Blood 110 East Court Ave, Suite 200, Des Moines IA 50309
- Mission Cancer + Blood 1950 SW Magazine Rd, Ankeny, IA 50023
- Mission Cancer + Blood 411 Laurel St. Suite A300, Des Moines, IA 50314
- Mission Cancer + Blood 12495 University Ave. Suite 200, Clive, IA 50325
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As part of our feasibility review (TREC), we evaluate which locations can accommodate each trial and open at those locations. This allows for greater patient access to trials.

a. Will Sponsor allow for multiple site locations? ☐Yes ☐No

a. Will Sponsor ship Investigational Product to 2 addresses? ☐Yes ☐No
   If no, will sponsor allow site to contract a courier to transport IP to different addresses? ☐Yes ☐No

b. Will Sponsor ship study supplies (lab kits, ECG machines, tablets, paper documents) to more than one address? ☐Yes ☐No
   If no, will sponsor allow site to contract a courier to transport study supplies to different addresses?
   ☐Yes ☐No

d. Does the sponsor require a different site number for satellite locations due to shipment logistics?
   ☐ Yes ☐No

Documents Required from Sponsor:

MOG review:
☐ Protocol

TREC review:
☐ Protocol
☐ Lab and tissue/biopsy Manual (Draft OK)
☐ Pharmacy Manual (Draft OK)
☐ Imaging Manual (Draft OK)
☐ Budget

Needed for Activation:
☐ Final Protocol
☐ Final Lab and tissue/biopsy manuals
☐ Final Pharmacy Manual
☐ Final Imaging Manual
☐ Budget
☐ CTA/contract
☐ ICF Template(s)
*See Sponsor Packet for standard
☐ Investigator brochure(s)

☐ Patient-facing materials requiring IRB review
☐ DSMB Information