OU Health Stephenson Cancer Center

A Department of University of Oklahoma Medical Center

February 22nd, 2023

Dear Sponsor,
We are excited to have the opportunity to work with you on your clinical trial. As a NCI Designated Cancer Center, our mission is to improve patient outcomes and reduce the burden of cancer in Oklahoma and the nation. We are one of the premier cancer centers for the state of Oklahoma and we take pride in our facility as well as the many opportunities for treatment we offer.

We would like to provide some information about our facilities and site practices. This study start-up packet should provide you with a general overview of our site. Please review the attached documents. If you have any questions or need any information, please do not hesitate to contact us. Your regulatory specialist will be your main contact throughout the study start up process.

We look forward to working with you.

Sincerely,

Regulatory Affairs Department
Stephenson Cancer Center
SCCCTOREG@ouhsc.edu

Site Feasibility

1.1 Facility Background

The Stephenson Cancer Center at the University of Oklahoma is Oklahoma's only National Cancer Institute-Designated Cancer Center. As a nationally recognized leader in research and patient care, Oklahomans no longer need to travel out of state to receive state-of-the-art clinical care.

The experts at the Stephenson Cancer Center are exploring new treatments and breakthroughs with advanced research and clinical trials right here at home.
The Stephenson Cancer Center cancer care teams focus on treating people, not patients.
The Stephenson Cancer Center leads the nation for patients participating in National Cancer Institute-sponsored clinical trials and it is one of 30 designated lead centers nationally in the NCI's National Clinical Trials Network.

To learn more about the Stephenson Cancer Center, please visit:
https://stephensoncancercenter.org/

1.2 Facility Equipment

Our facility is equipped with state of the art equipment that is monitored on a daily basis. Our facility houses the following items:

- -80 degrees Celsius freezers for sample storage
- -20 degrees Celsius freezers for sample storage
- Temperature regulated and monitored storage for investigational drugs
- Infusion center that houses public, semi-private, and private infusion areas
- Crash carts in infusion center
- Clinics for disease types
    - Clinics hold between 8-16 clinic rooms
    - All clinics have basic equipment such as scales, blood pressure machines, heart rate monitors
- Designated Phase I infusion center for early phase and first-in-human trials

1.3 Facility SOPs

SOPs will be provided upon written request during the study start up process. Please contact SCCCTOReg@ouhsc.edu or the regulatory specialist assigned to the study.

1.4 Start-Up Procedures

Our site has procedures in place for study start-up. **Please note that completed study activation (from site selection to patient enrollment) can take about 6 months.** Please see our procedures below:

1. Principal Investigator/Site is contacted about potential new study

2. If PI is interested, PI will forward information to Regulatory department.

3. Clinical Trials Budgets Team will route Confidential Disclosure Agreement (CDA) if applicable with our Office of Research Administration (ORA). ORA staff will work with you to negotiate the CDA before finalizing it for our site. CDA's typically cover all OUHSC personnel, as they are usually institution-wide agreements.

4. Sponsor and Regulatory Specialist will schedule Pre-Study Visit (PSV) if required by sponsor.
    a. Site encourages PSVs be conducted virtually.
    b. If your company has conducted an on-site PSV within the last year for other studies, it is encouraged that the PSV be conducted virtually.
    c. PI will be present at PSV for approximately 30 minutes as availability permits
    d. Study staff including regulatory, data managers, and study coordinators will be present for PSV as availability permits.

5. Study is sent to Disease Site Review for approval
    a. Study may be turned down by disease site due to competing studies or unavailability of study patient population
    b. A protocol or a detailed protocol synopsis is required for review purposes.

6. Feasibility Questionnaires/Surveys (FQ's) will only be completed after Disease Site Review approval.
    a. A PDF or Word version of the FQ will be required. We are unable to complete FQs in sponsor portals or websites.
    b. Please send email or letter regarding site selection for documentation.

7. If study is approved by Disease Site, study will move forward to the following committees:
    a. Feasibility Review Committee (FRC)
    b. Protocol Review and Management Committee (PRMC)

8. The following documents are required in order for FRC and PRMC submission.
    a. Draft Budget and Clinical Trial Agreement
    b. Full Study Protocol
    c. Informed Consent Form (Template/draft acceptable)

d. Pharmacy Manual (Draft acceptable)
e. Lab Manual (Draft acceptable)
f. Investigator Brochures, QOLs, Surveys etc., if applicable

9. Feasibility Review Committee: Reviews budget, schedule, and requirements of study to see if study is feasible to operationalize at our site.

Turnaround time depends on sponsor communication and committee workload. Please note that studies may be tabled to future meetings

a. Study may be turned down due to discrepancies with budget, or site operational challenges
b. Once deemed FRC feasible, study moves forward to PRMC

10. Protocol Review and Monitoring Committee: Reviews protocol to check scientific integrity, available study data, and patient risk.

Turn-around time depends on sponsor communication and committee workload. Please note that studies may be tabled to future meetings.

a. Study may be turned down due to insufficient data from previous phases, or concern for patient safety
    i. PRMC may request more information from sponsor about the study before granting approval.

11. FRC and PRMC meet twice a month. Submission deadlines are a week prior to the FRC meeting.

12. In order to improve our start up timelines, the Clinical Trials Agreement (CTA) will be routed to our Office of Research Administration (ORA) by your regulatory contact concurrent with our submission to the FRC and PRMC committees. **Please note: if the PRMC Committee decides to disapprove your study, all further negotiations on the CTA will halt**. Staff from ORA will reach out to negotiate CTA once it goes through their internal process.

13. IT Risk Assessment Review Process will take place concurrently with the CTA review.
    i. OUHSC IT requires any medical device on trial to go through an IT risk assessment review. The reverse feasibility questionnaire should be filled out to get the process started (if applicable). This process can take several weeks and the review has to be conducted in order for contracts to be finalized and before our site can begin to use the equipment.

14. If study is approved by both FRC and PRMC, the following will take place:
    a. Regulatory documents will be routed for signature (FDFs, 1572, etc.)
    b. Study will be prepared for submission to Institutional Review Board (IRB). **Please note: Our institution requires all new studies submitted after January 2019 to incorporate Common Rule language. Having this language already embedded will expedite the ICF negotiation process. Our site will provide a common rule worksheet to sponsor for completion in advance of IRB submission.**
        i. We can submit to either local IRB (OUHSC IRB) or central IRB (WIRB or Advarra)
            1. **If using WIRB, sponsor must work with WIRB directly for payments**
            2. We must submit to our local IRB to get approval to utilize WIRB (turn-around time of 5-7 business days). This approval is required prior to submitting to an external IRB.
            3. WIRB turn-around time for approval is approx.14 business days
        ii. If using WIRB, sponsor may submit to WIRB on site's behalf **or** Regulatory Specialist will submit documents for site to WIRB
        iii. If using local IRB, Regulatory Specialist will negotiate Informed Consent with sponsor
            1. Turn-around time for local IRB approval is 6-8 weeks
            2. OUHSC IRB meets once a month

15. Study is submitted to IRB for approval
    a. Both local and central IRB may send stipulations that must be addressed before study is approved.

16. When study is approved by IRB, sponsor and Regulatory specialist can schedule Site Initiation Visit (SIV).

    a. SIV can last no longer than 4 hours and can be conducted virtually.
    b. PI portion will be scheduled for approximately 30 minutes to 1 hour dependent on PI availability.
    c. Study staff such as regulatory, data management, study coordinators, and pharmacy will be present, dependent on availability.

17. Sponsor will activate site for patient enrollment.

18. Study team will ensure all operational needs are met prior to enrolling patients on study.

1.5 Start-up Procedures for Studies Managed by Sarah Cannon SMO

Early Phase and first-in-human studies have the opportunity to be managed by Sarah Cannon

Site Management Organization (SMO). Our site and Sarah Cannon have procedures in place for study start-up. **Please note that completed study activation (from receipt of all study documents, including trial agreement and budget drafts, to patient enrollment) can take 8-12 weeks.** As a result, timelines and sequence of events as stated above may differ due to SCRI involvement.

1.6 Monitoring and Parking Information

Our site policy is to conduct most all monitoring visits remotely.

If you are interested in learning more about our monitoring process or need parking information for Site Visits, please visit the following website for more information. https://stephensoncancercenter.org/monitor