Thomas Jefferson University

MULTI-SITE CLINICAL STUDY REVIEW FORM

The purpose of this form is to guide Principal Investigators (PI) through the Multi-Site Clinical Study Review Process. This purpose of this process is to review all multi-site clinical studies initiated by a Thomas Jefferson University PI's for feasibility and compliance. The goal of this review process is to ensure that TJU-sponsored studies are designed to minimize risk and maximize data integrity and quality. This review will also help to ensure that adequate funding is available to implement the proposed study. The Jefferson Clinical Research Institute (JCRI) will review this form and facilitate communications between PI and designated representatives from relevant departments as applicable. Depending on the scope of your trial, this form may be subject to the following reviews:

- **Export Control**
- **Privacy**
- **Budget Review**
- **Data Management**
- **Monitoring**

Submission Instructions: Please email the completed form to melissa.mccarey@jefferson.edu. The multi-site trial will work with the PI to obtain the required approvals for this protocol concept. Bring a copy of this form to any meetings requested.

Oncology Protocol Concept Instructions: Any protocol concepts involving cancer (including pre-cancerous lesions) must also be approved through the SKCC Oncology Study Start-Up process, which includes SKCC cancer leadership approval. Visit http://isley.kcc.tju.edu/intranet/clinicaltrials/start-up.php for detailed instructions.

Protocol Concept Overview

Instructions: Investigators at Jefferson who wish to initiate a multi-site study must complete this section and, if applicable, the international research section. Each question (e.g., funding source, study procedures, etc.) should be answered based on the ANTICIPATED study.

Oncology Study *(Use SKCC Cancer Trial Decision Tree at http://isley.kcc.tju.edu/intranet/clinicaltrials/documents/SKCC%20Clinical%20Trial%20Decision%20Tree%20(2017-11-9).pdf)*	☐Yes ☐No
Protocol Title	
Principal Investigator (PI)	
Project Manager	
Clinical Research Coordinator	
Statistician	
Funding Source *(Select all that apply)*	☐ Industry Support, specify organization: _____ ☐ Federal Grant, specify FOA: _____ ☐ Non-Federal Grant, specify: _____ ☐ Other, specify: _____
Funding Application Deadline	____/_____/_____
Study Type	☐ Retrospective only ☐ Prospective only ☐ Both retrospective and prospective
Study Category	☐ Interventional *(Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed)* ☐ Observational *(Studies that focus on patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.)* ☐ Ancillary *(Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies*

	must be linked to an active clinical research study and should include only patients accrued to that study.) ☐ Correlative *(Laboratory-based studies using specimens to assess disease risk, clinical outcomes, response to therapies, etc.)* ☐ Other, specify: _____
Study Phase *(Select all that apply)*	☐ Pilot ☐ Feasibility ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ N/A *(epidemiological, cancer control/behavioral, observational, ancillary, correlative, or other biological)*
Number of External Study Sites *(Note: TJU controlled affiliates, e.g., Abington, Aria, and Kennedy, are <u>NOT</u> considered external sites)*	
International Study Sites	☐ Yes – Complete International Research section ☐ No
External Study Sites – International *(List all international external study sites – specify country and institution)*	
External Study Sites – Domestic *(List all domestic external study sites)*	
Primary Objectives/Endpoints	
Study Population *(Specify disease, disease-state, age, etc.)*	
Sample Size Estimate Per Site	
Study Activation Date Per Site	
Enrollment Period	
Study Duration *(Include description of participant follow-up time)*	
Study Procedures *(Describe any planned interventional procedures, devices, or drugs)*	

IND or IDE *(Select "Yes – Current" if there is an existing IND or IDE application. Select "Yes – Pending" if the IND or IDE application is currently pending with FDA)*	☐ Yes – Current, specify IND/IDE number: _____ ☐ Yes – Pending ☐ Unknown/To Be Determined ☐ No
Specialized Equipment/Labs *(Specify any specialized study equipment, other devices, or labs required by protocol)*	
Required Biospecimens/Research Materials *(Describe any biospecimens or other research materials required for this protocol)*	☐Yes - standard of care, specify: _____ ☐Yes – research materials, specify: _____ ☐Yes – material transfer agreement, specify: _____ ☐No
Domestic Shipment of Biospecimens/Research Materials (study drug, study device, study-related equipment)	☐Yes, specify storage plan/transport plan: _____ ☐Yes – material transfer agreement, specify: _____ ☐No ☐N/A

Data and Safety Monitoring Plan

If Jefferson is considered the sponsor for this trial, plan for verifying data integrity and monitoring safety must be included

Data & Safety Monitoring Plan *(Briefly describe the anticipated data & safety-monitoring plan (DSMP). Note: a DSMP is now required for NIH grants)*	
Does the study budget include regulatory CRO and/or monitoring costs? *(Describe local regulatory/monitoring plan and associated costs. If local regulatory CRO/monitoring will not be included in the budget, specify reason)*	☐Yes, specify plan and anticipated costs: _____ ☐No, specify reason: _____ ☐N/A

Data Management Plan

All data management plans must be reviewed and approved by IS&T before study initiation

Describe the PHI that will be collected as part of this study.	
How will data be shared between sites?	
How will study data be stored?	
List the software programs that will be used to share and store data for this study.	
Please list other non-patient data that will be shared between sites. *(Please include any personally identifiable information for site faculty and staff including CVs, names, dates of birth, email addresses, etc.)*	

International Research (If Applicable)

Instructions: Investigators at Jefferson who wish to initiate a multi-site study with international components must complete this section.

Disclaimer: Research, privacy, and data requirements may vary between countries. Jefferson may not be aware of all applicable requirements for each country participating in research. Additional costs resulting from country-specific regulations or requirements are the responsibility of the principal investigator and his/her department.

Export Control Standards: Investigators **MUST** consult with Jefferson's Export Control Officer to answer the following questions.

Will this study require Export Control? *(Use the Export Control questionnaire at https://www.jefferson.edu/content/dam/tju/international_affairs/files/Questionnaire_Export%20Control.pdf*	☐Yes ☐No
Will there be any international shipments of either human, zoonotic or plant pathogen/non-pathogen or toxin/non-toxin materials (including blood, chromosomes, genomes, plasmid,	☐Yes, specify materials to be shipped and describe materials storage plan/transport plan: _____ ☐Yes – material transfer agreement, specify: _____ ☐No

transposon, hazardous material, drugs, food, chemicals, live animals or anything with dry ice) or any other research materials?	
Will this study involve any international data sharing?	☐Yes, specify type of data that will be shared and describe data sharing mechanism: _____ ☐No
Regulatory Oversight Standards: Evidence of local approval by an IRB, Ethics Board, or Independent Ethics Committee (IEC) familiar with the local research context and local law is generally required.	
Are there government standards for review of research at the external locations? *(To describe applicable local human research standards, please check with your international partner institutions, and consult the OHRP International Compilation of Human Research Standards on https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html)*	☐Yes, specify standards for each country outside of the United States where research is taking place: _____ ☐No
Local IRB/EB/IEC Review Expected *(If local IRB/EB/IEC review is not possible, specify reason)*	☐Yes ☐No, specify reason: _____
Local IRB/EB/IEC Requirements *(Please describe the requirements, documentation, local timeframe for review, and costs for review by a local IRB/EB/IEC)*	
Local Endorsement *(If no local IRB/EB/IEC approval will be in place, at a minimum, there must be endorsement (letter of support) of the project by the local authority/institution involved in the research)*	☐Yes ☐No, specify reason: _____
Data Privacy and Security Standards: Evidence of understanding of local regulations regarding data privacy and security is required.	
Are there local data privacy/security regulations at the external location? *(Describe applicable local data privacy/security regulations)*	☐Yes, specify standards: _____ ☐No

Are there adequate data privacy/security protections that meet local regulations built into the protocol? *(Describe protections based on local data privacy/security regulations)*	☐Yes, specify protections: _____ ☐No
Is there going to be any data storing, sharing, and transmitting? *(Describe how research data will be stored and transmitted between international sites)*	☐Yes, specify plan: _____ ☐No
Budget Standards: Evidence of understanding of additional costs related to conducting international research is required.	
If Jefferson will distribute or receive investigational products (as defined above in Export Control Standards), does the study budget include international taxes (VAT; Import/Export) and/or international shipping costs?	Export: ☐Yes, specify plan and anticipated costs: _____ ☐No, specify reason: _____ ☐N/A Import: ☐Yes, specify plan and anticipated costs: _____ ☐No, specify reason: _____ ☐N/A
Does the study budget include increased general liability insurance coverage costs?	☐Yes, specify plan and anticipated costs: _____ ☐No, specify reason: _____ ☐N/A

- PROTOCOL CONCEPT COMPLETE, STOP HERE –

Email completed form to
melissa.mccarey@jefferson.edu