Stephenson CANCER CENTER
The UNIVERSITY of OKLAHOMA

Protocol Review and Monitoring System
New Study Submission Form

This form will not autosave your information.
Please save this document as a pdf on your computer so that you don't lose your work!

Study Details (must also be entered in Velos)

Principal Investigator

Study Contact

Study Number

Study Title

NCT #

Studies linked to this protocol
(ex: master protocol for basket trials)

Primary Purpose

- (•) Basic Science (BAS)
- ( ) Device Feasibility (DEV)
- ( ) Diagnostic (DIA)
- ( ) Health Services Research (HSR)
- ( ) Prevention (PRE)
- ( ) Screening (SCR)
- ( ) Supportive Care (SUP)
- ( ) Treatment (TRE)

Other (OTH)

- ( ) Retrospective Chart Review
- ( ) QOL/Survey/Long Term follow up
- ( ) Specimen Research
- ( ) Tissue banking/lab collection

Disease Site

- (•) Anus
- ( ) Bones & Joints
- ( ) Brain & Nervous System
- ( ) Breast-Female
- ( ) Breast-Male
- ( ) Cervix
- ( ) Colon
- ( ) Corpus Uteri
- ( ) Esophagus
- ( ) Eye and Orbit
- ( ) Hodgkins Lymphoma
- ( ) Ill-Defined Site (multi-site)
- ( ) Kaposi's Sarcoma
- ( ) Kidney
- ( ) Larynx
- ( ) Leukemia, other
- ( ) Leukemia, not specified
- ( ) Lip, Oral Cavity, Pharynx
- ( ) Liver
- ( ) Lung
- ( ) Lymphoid Leukemia
- ( ) Melanoma, Skin
- ( ) Multiple Myeloma
- ( ) Mycosis Fungoides
- ( ) Myeloid & Monocytic Leukemia
- ( ) Non-Hodgkins Lymph.
- ( ) Other Digestive Organs
- ( ) Other Endocrine System
- ( ) Other Female Genital
- ( ) Other Hematopoietic
- ( ) Other Male Genital
- ( ) Other Respiratory & Intrathoracic Organs
- ( ) Other Skin
- ( ) Other Urinary
- ( ) Ovary
- ( ) Pancreas
- ( ) Prostate
- ( ) Rectum
- ( ) Small Intestine
- ( ) Soft Tissue
- ( ) Stomach
- ( ) Thyroid
- ( ) Unknown Sites
- ( ) Urinary Bladder
- ( ) N/A

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Study Details (must also be entered in Velos)	
Accrual Targets	SCC Projected Total Accrual SCC Projected Annual Accrual National Planned total Accrual Duration of Accrual
Phase	◉ Phase I ○ Phase I/II ○ Phase II ○ Phase II/III ○ Phase III ○ Phase III/IV ○ Phase IV ○ Phase IV/V ○ Phase V ○ Pilot/Feasibility
Research Type	◉ Cooperative Group ○ Industrial ○ Institutional ○ None ○ Other Externally Peer Reviewed
Category	◉ Interventional ○ Observational ○ Ancillary/Correlative
Feasibility Review Committee	Funding Organization (if applicable) Grant Number (if applicable) Which SCC CTO Staff will be assisting with activities for your study? ☐ Regulatory ☐ Research Nursing ☐ Data management ☐ Informatics ☐ Biospecimen
Protocol Review and Monitoring Committee	YES / NO ◉ ○ Does this meet the operational definition of a clinical trial? ◉ ○ Is this a research protocol dealing with healthy human subjects? ◉ ○ Does the research protocol deal with the population sciences? ◉ ○ Is this a retrospective study?
Institutional Biosafety Committee	◉ ○ Does the Sponsor recommend IBC Review? ◉ ○ Does this study involve gene therapy? ◉ ○ Does this study involve the use of a viral vector or plasmid?
Data and Safety Monitoring Committee	◉ ○ Is this study reviewed by an external (non-SCC) Data and Safety Monitoring Committee?

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Steps to submit your study for PRMS review:

1. Enter the Study in Velos by completing relevant fields on the Study Summary Page
    - If you do not have Velos access, email SCCSystems@ouhsc.edu to request an account.
2. Email the PRMS Submission Form & Study Documents (protocol, informed consent, QOLs, manuals, surveys) to SCC-PRMC@ouhsc.edu

Additional documents required for PRMS submission of Interventional Treatment Trials run through the Stephenson Cancer Center CTO:

Check ☑ next to each item that is complete or will be attached to your submission.
If the item will not be created for your study, leave a commen ***for the item.***

- ☐ Verify that a budget draft and contract are with ClinicalTrialBudgets@ouhsc.edu
- ☐ Full Study Protocol
- ☐ Informed Consent Documentation
- ☐ Pharmacy Manual
- ☐ Lab Manual
- ☐ Additional Sponsor documents such as IBs, QOLs, Surveys, Exhibits
- ☐ PI Signature (if no signature, attach PI approval email)

Please do not submit any study for PRMS review until all required documents have been received. Incomplete submissions will not be processed.