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Stephenson CANCER CENTER
the UNIVERSITY of OKLAHOMA

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Clinical Trials Office
Protocol Review Form

Section I

1. General information:

Date: _____ PI/Study Chair Name: _____ NCT Number: _____

Protocol No. and Title: _____

_____

_____

2. Clinical Research Category:

☐ **Interventional**: Clinical Research Category in which individuals are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, 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**: Clinical Research Category in which the studies focus on cancer patients and healthy populations that involve no intervention or alteration in the status of the participants. Biomedical and/or health outcomes 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/Correlative**: ANC - Studies 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 clinical research study. Only studies that can be linked to individual patient or participant data should be reported.

COR - Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

3. Sponsor Type (Choose one of the following):

☐ **National**: NCI National Clinical Trials Network (NCTN) and other NIH -supported Clinical Trial Networks

☐ **Externally Peer Reviewed:** R01s, SPORES, U01s, U10s, P01s, CTEP or any other clinical research study mechanism supported by the NIH or an approved peer-reviewed funding organization

☐ **Institutional:** In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer-review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing and implementing the clinical research study and reporting results. It is acceptable for for industry and other entities to provide support (e.g., drug, device and other funding but the trial should clearly be the intellectual product of the center investigator. This category may also include: Institutional studies authored and implemented by another center and Multi-Institutional studies authored and implemented by investigators at your center.

☐ **Industrial:** Design and implementation of the study is controlled by the pharmaceutical company.

4. Primary Purpose (leave blank if project is only comprised of a retrospective chart review):

☐	**Diagnostic (DIA)**: Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition
☐	**Health Services Research (HSR)**: Protocol designed to evaluate the delivery, process, management, organization or financing of health care
☐	**Other (OTH)**: Not in other categories
☐	**Prevention (PRE)**: Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or condition
☐	**Screening (SCR)**: Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).
☐	**Supportive Care (SUP)**: Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease
☐	**Basic Science (BAS)**: Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention
☐	**Treatment (TRE)**: Protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition. Note: This equates to therapeutic trials in the previous versions of the guidelines

5. Clinical Trial Type (choose one of the following):

☐ Phase I ☐ Phase I/II ☐ Phase II ☐ Phase II/III ☐ Phase III ☐ Phase IV ☐ NA

6. Study Complexity:

Yes	No	
☐	☐	Is this a multi-center trial?
☐	☐	Does the study require PKs?
☐	☐	Does the study require EKGs?
☐	☐	Does the study require / permit biospecimen collection?
☐	☐	Does the study involve gene therapy?
☐	☐	Does the study involve medical imaging that requires pre-qualification or certification?
☐	☐	Does the study involve a quality of life question?
☐	☐	Does the study involve a rare tumor?

7. Main Inclusion Criteria (Top 3 - such as primary treatment and recurrence):

_____

_____

_____

_____

_____

Main Exclusion Criteria

_____

_____

_____

8. Appropriate Clinical Research Disease Site Group (choose one):

☐ Breast Cancer	☐ Hepatocellular Carcincoma
☐ Dermatologic Cancers	☐ Lung Cancer
☐ G. I. and Colorectal Cancers	☐ Neurologic Cancers
☐ Gynecologic Cancers	☐ Orthopedic Oncology
☐ Head and Neck Cancers	☐ Pediatric Cancers
☐ Hematologic Cancers	☐ Urologic Cancers
☐ Phase I Cancers	

9. Patient Population and Study Prioritization:

SCC Projected Total Accrual: _____ National Planned Total Accrual: _____

SCC Projected Annual Accrual: _____ Expected Duration of the Accrual Period (months): _____

Does the study have competing protocols currently active? Yes ☐ No ☐

If yes, the PI must attach a written justification for opening this protocol. Prioritization of competing protocols should be discussed and adjudicated in the appropriate Clinical Research Disease Site Group.

10. Primary Disease Site (choose one):

☐ Anus	☐ Mycosis Fungoides
☐ Bones & Joints	☐ Myeloid and Monocytic Leukemia
☐ Brain & Nervous System	☐ Non-Hodgkins Lymphoma
☐ Breast-Female	☐ Other Digestive Organ
☐ Breast-Male	☐ Other Endocrine System
☐ Cervix	☐ Other Female Genital
☐ Colon	☐ Other Hematopoietic
☐ Corpus Uteri	☐ Other Male Genital
☐ Esophagus	☐ Other Respiratory and Intrathoracic Organs
☐ Eye and Orbit	☐ Other Skin
☐ Hodgkins Lymphoma	☐ Other Urinary
☐ Ill-Defined Sites (Multiple Sites)	☐ Ovary
☐ Kaposi's sarcoma	☐ Pancreas
☐ Kidney	☐ Prostate
☐ Larynx	☐ Rectum
☐ Leukemia, Other	☐ Small Intestine
☐ Leukemia, not otherwise specified	☐ Soft Tissue
☐ Lip, Oral Cavity and Pharynx	☐ Stomach
☐ Liver	☐ Thyroid
☐ Lung	☐ Uknown Sites
☐ Lymphoid Leukemia	☐ Urinary Bladder
☐ Melanoma, skin	☐ NA
☐ Multiple Myeloma	

11. Study Contact Information (to include in campus protocol book and web protocol listing):

Name: _____

Campus phone and extension: _____

Email Address: _____

12. Enrollment and Study Status will need to tracked and entered into Velos. **If this study will not be handled by CTO regulatory please checkmark the option that will best describe how the data will be tracked and entered.**

☐ Study PI will submit data to CTO informatics staff. Arrangements can be made for that by contacting the SRC coordinator at SCC-PRMC@ouhsc.edu.

☐ Study PI and/or PI department staff will enter into Velos.

IMPORTANT! Please sign and return <u>before</u> the next SRC meeting deadline: _____

Required Signature: Principal Investigator

_____ _____

Principal Investigator **Date**

Required Signature: Clinical Research Disease Site Group Chair

_____ _____

CRDSG Chair **Date**