SKCC Protocol Review and Monitoring Committee
New Study Application

Instructions: Submit the following documents with this application to **prmc@jefferson.edu.** All sections of this Application are required to be completed, if applicable.

- Protocol Feasibility Committee form and Approval Letter (if applicable)
- MDG Priority Score form (if applicable)
- Current MDG disease map diagram that includes this study *(if applicable)*

MDG Committee and Protocol Feasibility Committee Approval

All cancer related studies (including pre-cancerous lesions) are required to obtain MDG and PFC Committee approvals with the following exceptions:

- Study has an IRB approved waiver of written and verbal consent
- Retrospective chart reviews
- Correlative lab trials that will utilize banked blood and/or tissue that do not require informed consent

Does the study require MDG Committee and Protocol Feasibility Committee approval? If yes, approvals must be obtained prior to PRMC submission.

◯ Yes ◯ No

General Information

JeffTrial Number

If the study does not require MDG Committee review and therefore has not been registered in JeffTrial,enter N/A.

Sponsor's Protocol ID (if applicable)

Principal Investigator

Protocol Title

Please list all Jefferson and Affiliate or Network site Co-Investigators involved in this study.

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If this is an investigator-initiated study, is it:

◯ Quantitative ◯ Qualitative ◯ Mixed Methods

[Note: Quantitative studies are designed to collect numbers; data is structured and statistical in nature. Qualitative studies are designed to describe a topic more than measure it; data is often in words and phrases. Mixed methods studies employ both strategies to complement one another.]

For investigator initiated **quantitative or mixed methods studies**, provide the name of the statistician:

Study Type: ◯ Retrospective ◯ Prospective ◯ Both Retrospective and Prospective

Please indicate the appropriate category using the following definitions:

◯ **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 cancer 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 study participants may receive diagnostic, therapeutic, or other interventions, but the observational study investigator is not responsible for assigning specific interventions to the study participants.

◯ **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 clinical research study.

◯ **Correlative**: Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, responseto therapies, etc.

◯ **None of the Above:** Retrospective research such as institutional chart review studies; institutional registries, databases, serum and tissue banking research with no research objective; and single subject compassionate or emergency use protocols where there is no research objective.

Please indicate the primary purpose of this study using the following definitions.

◯ **Basic Science**: Protocol designed to examine the basic mechanisms of action (e.g., physiology,biomechanics) of an intervention.

◯ **Diagnostic:** Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.

◯ **Health Services Research:** Protocol designed to evaluate the delivery, processes, management,organization, or financing of health care.

◯ **Prevention**: Protocol designed to assess one or more interventions aimed at preventing the development ofa specific disease or health condition.

◯ **Screening**: 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**: 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.

◯ **Treatment**: Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition.

◯ **Other:** Not in other categories

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Please indicate what line of therapy is being used in the study. *Skip if this study does not involve treatment.*

- ☐ First line
- ☐ Second line
- ☐ Third line or greater
- ☐ Consolidation
- ☐ Adjuvant
- ☐ Neoadjuvant
- ☐ Other, please specify:
- ☐ Maintenance
- ☐ Induction

Is this a Pilot study?

◯ Yes ◯ No

Please indicate the study phase(s).

- ☐ Early Phase I
- ☐ I
- ☐ II
- ☐ III
- ☐ IV
- ☐ Not Applicable (i.e. epidemiological, cancer control/behavioral, observational, ancillary, correlative, or other biological)

If the study involves more than one phase, please indicate which phase(s) SKCCC will participate in:

☐ Phase I ☐ Phase II ☐ Phase III

If there are any portions of the study in which SKCCC is not participating (specific cohorts or arms, correlative studies), please explain.

Describe the primary endpoint.

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Please select the primary disease sites that apply to this study.

- ☐ Lip, Oral Cavity and Pharynx
- ☐ Stomach
- ☐ Anus
- ☐ Pancreas
- ☐ Larynx
- ☐ Other Respiratory and Intrathoracic Organs
- ☐ Soft Tissue
- ☐ Kaposi's Sarcoma
- ☐ Other Skin
- ☐ Cervix Uteri
- ☐ Ovary
- ☐ Prostate
- ☐ Bladder
- ☐ Other Urinary
- ☐ Brain And Nervous System
- ☐ Hodgkin Lymphoma
- ☐ Lymphoid Leukemia
- ☐ Leukemia, Other
- ☐ Unknown Sites
- ☐ Esophagus
- ☐ Small Intestine
- ☐ Rectum
- ☐ Liver
- ☐ Other Digestive Organ
- ☐ Lung
- ☐ Bones And Joints
- ☐ Melanoma, Skin
- ☐ Mycosis Fungoides
- ☐ Breast
- ☐ Corpus Uteri
- ☐ Other Female Genital
- ☐ Other Male Genital
- ☐ Kidney
- ☐ Eye And Orbit
- ☐ Thyroid
- ☐ Non-Hodgkin Lymphoma
- ☐ Multiple Myeloma
- ☐ Other Hematopoietic
- ☐ Ill-Defined Sites

- ☐ Other, please describe:

Patient Population

Indicate the population being studied:

- ◯ Subjects without a known cancer diagnosis (e.g. healthy subjects)
- ◯ Subjects with cancer
- ◯ Both subjects with cancer and subjects without cancer

Provide the number of participants traditionally accrued to trials in this patient population at the participating site(s) in the past:

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Sponsor's national or total protocol accrual goal:

SKCCC specific total accrual goal (inclusive of TJU enterprise sites):

		RRC Review Pending	RRC Approved	Not participating
Please indicate which SKCCC Regional Research Sites will be participating in this study, and the status of Regional Research Committee (RRC) reviews:	**Center City:**	◯	◯	◯
	Abington:	◯	◯	◯
	Northeast:	◯	◯	◯
	New Jersey:	◯	◯	◯
	Einstein:	◯	◯	◯

SKCCC specific duration of accrual (months):

As of 1 June 2022, trials will be assigned a minimum accrual expectation category at the time of PRMC approval. Accrual goals should reflect these minimums as appropriate. **Justification should be provided below if projections are lower than minimum**.

Does the study compete or overlap with any active or pending studies?

◯ Yes* ◯ No ◯ Early Phase^

* If **yes**, provide your justification for opening a competing study, list the JeffTrial number of the competing studies, and describe how you will assign a priority to each study.
^ If **Early Phase**, please certify that at the time of Early Phase MDG approval, the study was considered within the context of the Early Phase portfolio and while there may be competing studies the leadership of the MDG agrees that this trial is of sufficient priority within the portfolio to conduct this trial at the SKCCC.

Rare population. PRMC evaluates all studies for scientific progress and accrual. PRMC may give leniency to the accrual expectations for studies that target rare participant populations. Please indicate whether your study population meets any of the following criteria:

◯ A rare cancer defined as incidence of ≤ 6/100,000 per year

◯ A narrow molecular subtype (e.g. rare mutations, targeted therapies)

◯ None Apply

If this study targets a rare population, please provide a justification and rationale for opening this trial at SKCCC.

Please describe your site specific plan for the inclusion of women and minorities in the study. Please address incidence rates of the cancer in males vs. females, ethnic minority populations vs. Caucasians, and any other relevant vulnerable populations that should be considered for accrual, how you will monitor this ratio, recruitment plans for each participating site, etc.

Recruitment Enhancement Service Involvement

For assistance completing this section, please contact Recruitment Enhancement Services at ONCTrialNow@jefferson.edu

Will this study be offered to our network affiliate partners or other academic centers?

◯ Yes ◯ No

If yes, please list other participating sites outside of SKCCC:

Funding and Resources

Principal Sponsor:

How is the study funded? (Check all that apply)

☐ Departmentally funded (internal)
☐ Industry support
☐ National Cancer Trials Network (NCTN) group
☐ Grant funding (specify):
☐ Other, please describe:

Did an SKCCC investigator significantly contribute to the authorship of the protocol?

◯ Yes ◯ No

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Who will provide the study drug or study device? (Write "N/A" if not applicable)

Is the protocol part of an existing IND or IDE?

- ◯ Yes*
- ◯ *IND or
- ◯ *IDE
- ◯ IND or IDE application is currently pending with FDA
- ◯ N/A

*If yes, provide the following information:

IND or IDE number

IND or IDE holder

What group will monitor the data and safety of this study?

- ◯ SKCCC Data and Safety Monitoring Committee (DSMC)
- ◯ Other, please describe:

Principal Investigator Approval

Principal Investigator Signature Date