**PI Full Name:**

### Protocol Full Title (must match full title in myIRB and OnCore):

**Please select the most applicable option from the list below**:

Interventional Industry Trial

Interventional Investigator-Initiated Trial

Survey, Interview, Questionnaire

Investigator-Initiated Multicenter Trials with Prior Approval from an NCI-designated cancer center

Cooperative Group Clinical Trial

Registry

Prospective Tissue / Specimen Collection

Retrospective Chart Review / Use of Existing Specimens (data / specimens from:      )

Compassionate Use (only safety data being collected)

Grant Applications in need of HRPO approval (\*contact PRMC Protocol Office for further information)

**1**. **Prior Scientific Review**

Has this protocol received scientific review and approval from: an NCI-designated cancer center or CTEP,

NIH funding, or external peer review?

Yes  No

* **If yes**, please upload the following letter(s) as applicable with the OnCore submission documents:
  + Documentation of peer review and approval of the study
  + Documentation of the NCI-designated cancer center’s PRMC in current good standing with the NCI

**2.** **Rare Disease**

Does your study population meet any of the following criteria?

A rare cancer defined by the NCI as < 6 / 100,000 cases

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

An uncommon clinical presentation (e.g., comorbidities, prior therapies)

No, this study population does not meet the rare disease criteria.

**3. For Washington University (WU) and Non-WU Institutional Studies Only:**

Is this a **Multi-Site study?**

Yes – complete questions below  No – skip to Question 4

(a) Is Siteman Cancer Center the Coordinating Center?  Yes  No**🡪** List name of Coordinating Center

(b) Semi-annual DSM reports will be prepared by:  WUSTL Study Team  External Site

(c) Will the study be **audited** by an External Site? (Check **NO** if Siteman is the coordinating center)

No  Yes **🡪** List name of External Site that will conduct audits:

**4.** **Accrual\* – must match information in OnCore, see** [**OnCore Work Instructions**](https://cbmiapps.wustl.edu/confluence/x/naCRAQ) **for further information**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Protocol Target Accrual  (total planned accrual-all sites) |  | Research Center (RC) Total Accrual Goal – Lower**\*** (max # pts **enrolled**) |  | RC Total Accrual Goal – Upper**\***  (max # pts approved to **consent**) |  |
| RC Annual Accrual Goal |  | Affiliate Accrual Goal  (non-WU sites) |  | Accrual Duration (Months) |  |
| Number of subjects meeting similar eligibility seen in the last 2 yrs at WUSTL | | | |  | |

**\**If your study does not include a consent process (e.g. chart review or use of specimens with waiver of consent), indicate the number of participants whose information/specimens you will use in your study.***

### 5. Is this project a clinical trial?

For purposes of this document, we define a *clinical trial* operationally as a prospective study involving human subjects designed to answer specific questions about the effects or impact of particular biomedical or behavioral interventions; these may include drugs, treatments, devices, or behavioral or nutritional strategies. Participants in these trials may be patients with cancer or people without a diagnosis of cancer but who are at risk for it.

Yes – Proceed to complete Questions 6 and 7.  No – Proceed to the Submission Information section below.

**Determine the Primary Focus Group and if CGCI review is required. A Focus Group Leader from the Primary Group must sign below. Focus Group Leader listing found** [**here**](https://siteman.wustl.edu/research/clinical-research-resources/research-focus-groups/)**.**

**6. For clinical trials, will WU be participating in all aspects of the study?**

Yes – skip to question 7  No – complete question below

1. Which parts of the study will WU participate in?  Escalation/Phase I  Expansion/Phase II

A particular cohort **🡪** List applicable cohort(s)

**7. Prioritization of Trials**

Complete the table below in order of priority with any **pending or actively accruing** clinical trial (s) that have overlapping eligibility with this trial. Focus Group assessment and sign off required before submission to PRMC.

Reference the Study Map <https://oncologyprotocols.wustl.edu/> as a resource. Add rows as needed.

There are no competing studies

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Priority Score | HRPO # | Study Title (**full**) | Date Open to Accrual | Accrual Goal | # Enrolled to date | Expected Closure |
| 1 |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |

Provide justification for opening this competing trial; especially emphasizing availability of potential subjects.

**Reviewed and Approved by Focus Group**

Print Name of Focus Group Leader:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Focus Group Leader Date

**Reviewed and Approved by Center for Gene and Cellular Immunotherapy (CGCI) Focus Group**

CGCI must review any treatment study using the following products: CAR-T; TCR T; Tumor Infiltrating Lymphocytes; NK cells; Viral CTLs (like EBV CTL, CMV CTL, etc.); Gene therapies using vectors

Print Name of CGCI Focus Group Leader:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Focus Group Leader Date

Reviewed by CGCI Focus Group and determined to not fall under their domain (no signature necessary): Yes N/A

SUBMISSION INFORMATION:

Create your PRMC submission in OnCore at <https://oncore.wustl.edu> and upload the required documents listed below for review. If you do not have access to OnCore yet, please refer to the **FAQs section** of the OnCore Support Services website for step-by-step information on how to train for and gain access to OnCore: <https://cbmiapps.wustl.edu/confluence/display/OSS/OnCore+Support+Services>

### Document Checklist (please mark all documents being submitted):

|  |
| --- |
| PRMC Request for Initial Review of a Protocol Form **with signature of Focus Group leader**, when applicable |
| myIRB Application (select “view printer friendly version” in myIRB and **convert to PDF**) |
| Informed Consent Form draft |
| Protocol, including Appendices |
| Investigator’s Brochure **and** Pharmacy Manual, if applicable |
| Data Collection Forms or Data Dictionary, **required** **for all** **WU *and* Non-WU Institutional trials** |
| Documentation of Prior Scientific Review, if applicable (see question 1) |
| Documentation of the NCI-designated cancer center’s PRMC approval at its last NCI site visit (see question 1) |
| Quality of Life/ Surveys/ Questionnaires, if applicable |

### Reminders:

* Once the study is approved, an approval email is sent to the PI, regulatory coordinator and HRPO.
* Questions should be directed to the PRMC Protocol Office at: protocoloffice@wustl.edu
* PRMC Policies & Procedures available at: <https://siteman.wustl.edu/research/clinical-research-resources/protocol-review-and-monitoring-committee/>