**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://washu.atlassian.net/wiki/spaces/OSS/overview) **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 remaining questions.  No – Proceed to question 8.

**Determine the Primary Focus Group and if TWG co-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/resources-for-researchers/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.

**8. Does the proposed project include collaboration with any community partners in the catchment area?**

Examples include members of the BJC Collaborative, the Siteman Cancer Network, or any other community partner.

No  Yes **🡪** List name of organization:

**Reviewed and Approved by Focus Group**

Print Name of Focus Group Leader:

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

Signature of Focus Group Leader Date

**Reviewed and Approved Theranostics Working Group (TWG)**

TWG must review any treatment study using the following products: theranostics, radionuclide therapy, radionuclide targeted therapy, radiopharmaceutical therapy (RPT), peptide receptor radionuclide therapy (PRRT), radioligand therapy, Lutathera, Pluvicto, Xofigo, AZEDRA, Lutetium 177 (177Lu), Radium 223 (223Ra), Actinium 225 (225AC), Pb 212 (212Pb), Cu67 (67Cu), Tb161 (161Tb), radioimmunotherapy

Print Name of Theranostics Working Group Leader:

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

Signature of Theranostics Working Group Leader Date

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

SUBMISSION INFORMATION:

Create your PRMC submission in OnCore at <https://wustl-oncore.forteresearchapps.com/forte-platform-web/login> and upload the required documents listed below for review. If you do not have access to OnCore yet, please refer to 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](https://washu.atlassian.net/wiki/spaces/OSS/pages/185827746/Access+to+OnCore)

### 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@wudosis.wustl.edu](mailto:protocoloffice@wudosis.wustl.edu)
* PRMC Policies & Procedures are available at: <https://siteman.wustl.edu/research/resources-for-researchers/protocol-review-and-monitoring-committee/>