

**PRMC PROTOCOL CHECKLIST**

**For PI/Transdisciplinary Team**

**This form is for the PI to complete and, if applicable, to guide the protocol review done by a Transdisciplinary Team (TDT). Studies that involve multiple departments are required to be vetted by a TDT using this form. It is recommended that the PI/designee of the proposed study complete through Section II prior to the TDT discussion. All sections must be completed prior to submission to the Protocol Review and Monitoring Committee (PRMC).**

|  |  |
| --- | --- |
| **Study ID and Title:** | |
| **PI for this study:** | **Date submitted to PRMC:** |
| **Sub-investigators or Faculty Sponsors for this study (if applicable):** | |
| **Transdisciplinary Team (TDT) Meeting Date (if applicable):** | **TDT Name (if applicable):** |
| **TDT Leader (if applicable):** |  |

|  |
| --- |
| **Brief Description of proposed study (please limit to 3 paragraphs, with phase of study, endpoints, eligibility summary, and special requirements if any):** |

|  |
| --- |
| **Please give all pages of this form to the responsible CRA *and* the PRMC Coordinator, Emily Harwood (**[**Emily.harwood@uvm.edu**](mailto:Emily.harwood@uvm.edu)**).** |

1. **Procedures/Clinical Assessments**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **YES** | **NO** | **NA** |
| 1. | Are the observations/procedures required appropriate? |  |  |  |
| 2. | Is the visit schedule appropriate? |  |  |  |
| 3. | Are follow-up visits appropriate? |  |  |  |
| 4. | Are study facilities and resources adequate for the safe conduct of this research? |  |  |  |
| 5. | Is additional staffing/specialist involvement needed? |  |  |  |
| 6. | Is the specified Standard of Care appropriate? |  |  |  |
| 7. | Are there non-standard of care tests/procedures required as part of this protocol? If yes, please list those test/procedures: |  |  |  |
| 8. | Is there a Data and Safety Monitoring Plan described in the protocol? |  |  |  |
| 9. | Has funding been identified to cover the costs associated with the non-standard of care protocol requirements? |  |  |  |
| 10. | Is this protocol funded by an NIH grant?  If yes, please identify the type of grant: |  |  |  |
|  | Comments to above answers: |  |  |  |

1. **Resource Utilization**
2. Does the protocol utilize UVM Cancer Center resources (mark those that apply with an X)?

Please note that before the proposed protocol is submitted, investigators can contact Emily Harwood at the UVMCC to obtain help with any of the following categories.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Research Coordinator |  | Tumor bank (please describe in comments) |
|  | DNA analysis (please describe in comments) |  | Other Core facilities (please describe in comments) |
|  | Statistical Input (please describe in comments) |  | Other (please describe in comments) |
|  | Translational Laboratory (Specimen collection, PKs, etc.) |  |  |
| Comments: | | | |

1. Does the protocol utilize institutional resources (mark those that apply with an X)?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Pathology (blocks, slides, etc.) |  | Radiology (attach completed radiology research support form) |
|  | Pharmacy |  | Other (please describe in comments) |
| Comments: | | | |

1. **Review Topics Considered by the Transdisciplinary Team (or PI, if appropriate)**

**If the proposed study does not require TDT review, the PI/designee should complete this last section prior to submission to the PRMC.**

**Review to determine scientific validity:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | YES | NO | NA |
| 1. | Does this research incorporate the least risky procedures that are scientifically  sound and appropriate to the purpose of this research? |  |  |  |
| 2. | Does this study compete with another active study?  If yes, please explain why this study should be opened: |  |  |  |
| 3. | Please list other competing studies: |  |  |  |
| 4. | Is the consent form adequate?  If no, why do you want to open the study and how will you proceed: |  |  |  |

**Review of site-specific enrollment goals**

|  |  |  |
| --- | --- | --- |
|  |  | Number |
|  | Number of anticipated eligible patients per year at the site(s) |  |
|  | Number of anticipated patients to be enrolled onto study per year |  |
|  | Anticipated duration of enrollment period | \_\_\_\_\_ months  Or \_\_\_\_\_ years |

**PI Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**This study was presented and vetted by the Transdisciplinary Team on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.**

(if applicable) (date)

**TDT Leader Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(if applicable)

**Modalities needed to conduct the study (if applicable):**

*(Please check all that apply and obtain signatures for all modalities engaged in this research)*

**Radiation Oncology: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Medical Oncology: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Surgical Oncology: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**



**Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**