**Protocol Facilitation Committee Review Form**

**Abbreviated MULTI-SITE Oncology Version**

All cancer protocols that require consent (written and/or verbal) must be submitted to the Protocol Facilitation Committee after MDG approval and before PRC submission.

TJU’s Facilitation Committee meetings are held every Monday at 1pm in the Clinical Research Organization’s (CRO) 7th floor Conference Room at 1015 Chestnut Street in Philadelphia.

Abington’s Facilitation Committee meetings are held every 4th Wednesday of each month at 7 am in the Gribbel Conference Room at Abington Hospital.

Protocols to be reviewed by this committee must follow the Protocol Facilitation Committee Policies and Procedures document and the instructions below:

1. The protocol has been MDG approved
2. Please complete this form pages 1-4, and email it and the MDG approved protocol to [facilitation.committee@jefferson.edu](mailto:facilitation.committee@jefferson.edu) (add Site Location to the subject line), the deadline for submission is end of business on the **previous** Monday
3. Ensure to bring a copy of this review form to the meeting

A representative from the clinical group coordinating this protocol must be present in person or via phone for the meeting. Note, if no representation is present for the meeting, the trial will be tabled and placed on the next available meeting agenda.

If you have questions, please email: [facilitation.committee@jefferson.edu](mailto:facilitation.committee@jefferson.edu)

|  |  |  |
| --- | --- | --- |
| ***To be completed by FC Coordinator***   * **Protocol Submission Date:** * **Facilitation Committee Meeting date:**  |  |  | | --- | --- | | **Is this a SWAT trial:** | 🞏 Yes 🞏No | |

|  |  |
| --- | --- |
| **Submitter to complete** | |
| Protocol JT Number |  |
| MDG Priority Score Number (enter the number)  (confirmed by the MDG leader) | Score:\_\_\_\_\_\_\_   |  |  | | --- | --- | | **MDG Priority Level:**  Low  Intermediate  High | **Ranges:**  0-5  6-10  >10 | |
| What is the sponsor’s timeline for recruitment (start ***and***end date)? | Start date:  End date: |
| Date for study completion |  |
| Does this trial require ancillary departments (e.g. Cardiology  Willis Eye)? |  |

|  |  |
| --- | --- |
| 1. **CHOOSE THE TYPE OF TRIAL** | |
| **NON- Interventional Trials**: | |
| Study Procedures | 🞏Interviews 🞏Focus Groups 🞏Survey 🞏 Blood/Saliva  🞏Other\_\_\_\_\_\_\_\_\_ |
| Person(s) responsible for conducting study procedures mentioned above |  |
| Please specify any specialized **study equipment** or other device required by protocol?  (audio recorders, ipads, etc.) |  |
| Complete **Data Analysis** section if this is an investigator initiated trial only:   * Identify staff/faculty member who will be analyzing data: * Type of analysis:    Qualitative   Quantitative -provide the name of the statistician:   Mixed Methods   * All software to be used :  Redcap JeffTrial  Other:\_\_\_\_\_\_\_\_\_ | |

|  |  |
| --- | --- |
| **Interventional Trials**: | |
| Is this a treatment trial? | 🞏 Yes 🞏 No  If Yes, complete the remaining questions in this section.  If No, Skip to section **B** Recruitment and Retention Plan |
| Treatment schema (include for drug/device/RT studies items such as length of infusion, observation window post procedure, etc.) | Protocol Treatment: |
| Schedule of Treatment: |
| Treatment Observation period: |
| Other (e.g. Procedure, device, etc.) |
| Pharmacokinetics (frequency, cycles, ⃞ inpt or ⃞ outpt) | 🞏 Yes 🞏 No  How Frequent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Side Effects / Adverse Reactions | Please reference the protocol section and page:\_\_\_\_\_\_ |
| Please indicate labs being used? | TJU clinic local labs: 🞏 YES 🞏 NO 🞏 NA  Can all labs done here: 🞏 YES 🞏 NO 🞏 NA  If not, where will these labs have to be sent and please describe details below: |
| Will a TJU – SKCC CORE Lab be used?:  🞏 YES (if yes, name below) 🞏 NO 🞏 NA  Lab name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Will a Central Sponsor Lab be used?:  🞏 YES (if yes, name below) 🞏 NO 🞏 NA  Lab name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| What lab results and parameters should be monitored/reviewed? |  |
| Is a radiology measurement required for this trial: | 🞏 YES 🞏 NO 🞏 NA  If Yes, which criteria is being used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Any special instructions for the nursing or other involved study staff? Note parameters in the protocol for consideration. |  |
| Complete **Data Analysis** section if this is an investigator initiated trial only:   * Identify staff/faculty member who will be analyzing data: * All software to be used :  Redcap JeffTrial  Other:\_\_\_\_\_\_\_\_\_ | |

|  |  |
| --- | --- |
| 1. **Recruitment and Retention Plan** | |
| Recruitment Plan: 🞏 Public event 🞏Flyers 🞏 Paper Letters 🞏Social Media 🞏Traditional Media 🞏 Radio/TV ads 🞏Physician Referral 🞏 Word of mouth 🞏 Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Description of Retention Strategy if applicable: | |
| Participant Support plan | *(For example: parking passes ,meal tickets, rides, etc)* |
| Type of consent required | 🞏Written  🞏 Verbal – please write rationale if using verbal consent |

|  |  |
| --- | --- |
| 1. **Jefferson Locations:**   Complete the below questions, if this trial will be opened at one of the controlled affiliate sites. Note, that a protocol specific site management plan is required, and the template is located on the document library. | |
| Which site is the lead study site? | ☐ Jefferson - Abington ☐ Jefferson - NE ☐ Jefferson - NJ ☐ Jefferson – Center City |
| What additional Jefferson locations will also participate? | ☐ Jefferson - Abington ☐ Jefferson - NE ☐ Jefferson - NJ ☐ Jefferson – Center City |
| If study is being opened at TJU and a controlled affiliate as separate sites with separate PIs (two separate PIs), has an effort been made to avoid this scenario? Please describe rationale for duplication of effort. | |

**Committee to complete:**

The following sections are to be completed by the department committee members **only**.

Instructions: Are there any special instructions or reasons that would limit your department in conducting the trial mentioned above?

Please:

* Check off “ **YES”** : if there aren’t any concerns/ reasons and therefore **you can** conduct this trial appropriately as written in the protocol
* Check off “**NO**” : if your department **cant c**onduct the trial and delineate in the comment box your concerns or reasoning
* Check off “**N/A**” : if the protocol doesn’t use your department or services

|  |
| --- |
| **CRO: 🞏 YES 🞏 NO 🞏 NA** |
| **PSU:**  **Clinical:**  **CRO Research Labs:**  **QA:** |

|  |
| --- |
| **Statistics: 🞏 YES 🞏 NO 🞏 NA** |
| **Biostatistics:** |
| **Check if applicable: 🞏 Qualitative 🞏 Quantitative 🞏 Mixed Methods**  For investigator initiated quantitative studies, provide the name of the statistician: \_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| **Nursing : 🞏 YES 🞏 NO 🞏 NA** |
| |  |  |  | | --- | --- | --- | | Location/Rationale  (To be completed by nursing) | **🞏In- Patient**  🞏 OR  ⃞ Other | **Out-Patient :** |   **Comments:** |

|  |
| --- |
| **Radiation Oncology : 🞏 YES 🞏 NO 🞏 NA** |
|  |

|  |
| --- |
| **Laboratory: 🞏 YES 🞏 NO 🞏 NA** |
| Would the clinical laboratory testing be done at Jefferson be done with in the protocol specifications **🞏 YES 🞏 NO 🞏 NA**  **If NO, identify test and location for completion.** |
| **Can the TJU – SKCC CORE execute the protocol?:** 🞏 **YES** 🞏 **NO 🞏 NA** |
| **Cell Therapy Laboratory : 🞏 YES 🞏 NO 🞏 NA** |

|  |
| --- |
| **Pharmacy:** |
| **IDS: 🞏 YES 🞏 NO 🞏 NA** |
| **Oncology: 🞏 YES 🞏 NO 🞏 NA** |
| **BMT/ Cell Therapy: 🞏 YES 🞏 NO 🞏 NA** |

|  |
| --- |
| **Pathology, Anatomy and Cell Biology (including Surgical Pathology) 🞏 YES 🞏 NO 🞏 NA** |
|  |

|  |
| --- |
| **Interventional Radiology 🞏 YES 🞏 NO 🞏 NA** |
|  |

|  |
| --- |
| **Radiology: 🞏 YES 🞏 NO 🞏 NA** |
|  |

|  |
| --- |
| **FC Coordinator TO COMPLETE COMMITTEE INFORMATION:** |
| Radiation Safety Committee **🞏 YES 🞏 NO 🞏 NA** |
| Institutional Biosafety Committee: **🞏 YES 🞏 NO 🞏 NA** |
| Value Analysis Committee: **🞏 YES 🞏 NO 🞏 NA** |

**Facilitation Committee Review Outcome:**

🞏 Approved

* + The study is approved for eventual activation at TJU or controlled affiliate as submitted and with no additional comments. The PI will receive an approval letter.

🞏 Contingent Approval

* + The study review results in concerns that require a PI response. PI will receive a letter requesting a written response to the concerns with in two weeks of receipt of the letter. Upon receipt of a successful response (as determined by the FC Coordinator, FC Chair, or the original reviewers affected, if necessary), the PI will receive a final approval letter.
  + If the PI does not respond to the concerns within 30 days, the study may be sent back to the MDG at the discretion of the FC Chair. The FC Chair will inform the CRLC.

🞏 Deferred

* + Significant revisions to the study are necessary. PI will receive a letter requesting a written response to the concerns for re-submission and re-review at a full committee meeting. Relevant MDG Committee Leaders (if applicable) will be copied on the notification.
  + If the PI does not respond to the concerns within 30 days, the study may be sent back to the MDG at the discretion of the FC Chair. The FC Chair will inform the CRLC.

🞏 Disapproved

* + TJU or controlled affiliates do not have the facilities or the resources to conduct the trial satisfactorily to the high quality expectations of the SKCC. PI will receive a letter with actions identified. Relevant MDG Committee Leaders (if applicable) will be copied on the notification.

🞏 Tabled

* + There was no representation present during the review of the trial to answer questions/concerns or there was significant number of department committee members who did not provide input. The trial will be placed on the next available meeting agenda and will be re-reviewed.

**Comments:**