

**Protocol Facilitation Committee Review Form (Resubmission)**

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

Center City Facilitation Committee meeting is held **online via Zoom every Monday at 1pm**.

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 and we have been selected as a participating site.
2. Please complete this form **pages 1-6 only**, and email it and the MDG approved protocol to [facilitation.committee@jefferson.edu](mailto:facilitation.committee@jefferson.edu) for Center City or the PM at an Advanced Care Hub. If there is a lab manual or pharmacy manual available, please submit those as well.
3. The deadline for submission to the committees is one week prior to the meeting (i.e. Center City deadline is end of business on the **Tuesday @3pm** before the meeting).
4. Questions marked with an asterisk must be answered to assist with trial prioritization
5. A representative from the clinical group coordinating this protocol must be present 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.
6. Trials opening at non-Jefferson owned institutions: complete “The Multi-site Clinical Study Review Form” under TJU Policy 127.51 <https://tjuh3.jeffersonhospital.org/policy/index.cfm/universitypnp/view/id/258717> and the abbreviated PFC form found in the SKCC intranet start-up section at <https://ewebapp01pa.jefferson.edu/intranet/clinicaltrials/pfc.php>

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

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| ***(To be completed by FC Coordinator)***   * **Protocol Submission Date:** * **Facilitation Committee Meeting date:**  |  |  | | --- | --- | | **Is this a SWAT trial:** | Yes No | |
| **Resubmission Purpose/ Study updates:** |

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| **Submitter to complete** | |
| MDG |  |
| MDG approval date |  |
| Protocol JT Number |  |
| Location (check all that apply) | Jefferson - Abington  Jefferson - NE  Jefferson - NJ  Jefferson – Center City  Jefferson – Methodist  Jefferson – Einstein  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Protocol Title |  |
| Phase of Study |  |
| Principal Investigator (PI) |  |
| Project Manager |  |
| Clinical Research Coordinator |  |
| Data Manager |  |
| Lead Regulatory Coordination | SKCC Protocol Support Unit  Other department name: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Sponsor  (Regulatory Sponsor, not funding Sponsor) | TJU IIT  External IIT Institution Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Industry/Device Sponsor Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NCTN group name: \_\_\_\_\_\_\_\_\_\_\_\_\_  ETCTN Lead Institution Name: \_\_\_\_\_\_\_\_\_\_\_\_\_  OTHER group name (Consortiums etc): \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Participant Population (healthy, disease, newly dx’d, relapsed, etc) |  |
| Total **(overall)** accrual at Jefferson |  |
| Number of Participants to be enrolled **per year** at each location | Jefferson – Center City: \_\_\_\_\_\_\_\_\_\_  Jefferson – Methodist: \_\_\_\_\_\_\_\_\_\_\_  Jefferson – Abington: \_\_\_\_\_\_\_\_\_\_  Jefferson – NE: \_\_\_\_\_\_\_\_\_\_  Jefferson – Einstein: \_\_\_\_\_\_\_\_\_\_\_\_  Jefferson – NJ: \_\_\_\_\_\_\_\_\_\_  SKCC Network Sites: \_\_\_\_\_\_\_\_\_\_  Community members/Non-Jefferson patients:\_\_\_\_\_\_\_\_\_  Other Non-Jefferson Sites:\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| \* What is the sponsor’s estimated timeline for recruitment | Start Date:  End Date: |
| \* Current National Accrual Status | Has the study been activated by the sponsor? Yes No  Total (overall) accrual in the study: \_\_\_\_\_ of \_\_\_\_\_ |
| \* Date for study completion |  |
| What is the anticipated Jefferson activation date? |  |
| Jefferson Led IIT Multisite  (This does not include TJU controlled affiliates and SKCC network sites) | Yes  No  If yes, STOP and complete the Multi-site Clinical Study Review Form under TJU Policy 127.51.  https://tjuh3.jeffersonhospital.org/policy/index.cfm/universitypnp/view/id/256607  AND complete the Abbreviated Version of this form found in the SKCC Document Library |

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| 1. **CHOOSE THE TYPE OF TRIAL** | |
| **NON- Interventional Trials**:  Defined by the NCI:  **Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.**  The non-interventional category includes observational and ancillary/correlative studies:   * Observational. Studies among cancer patients and healthy populations that involve no interventions or alteration of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study. * Ancillary-Correlative. A trial that is secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition. * 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. Report only those studies that can be linked to individual patient or participant data. * Correlative. Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Report only those studies that can be linked to individual patient or participant data. | |
| Is this a Non-Interventional trial? | Yes  No (if no, skip to interventional below)  If yes, indicate what type of Non-interventional study:  Observational  Ancillary  Correlative |
| 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:\_\_\_\_\_\_\_\_\_ | |

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| **Interventional Trials**:  Defined by the NCI:  **Studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.**  Examples include, but are not limited, to: drugs/small molecules/compounds, biologics, devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); and, treatment, prevention, and diagnostic strategies | |
| 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, etc.) | Protocol Treatment: |
| Schedule of Treatment: |
| Treatment Observation period: |
| Pharmacokinetics (frequency, cycles, input or  output) | Yes  No  How Frequent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Please specify any **specialized** **study equipment** or other device required by protocol? |  |
| Please specify any **specialized** **labs** required by protocol? |  |
| Does this trial require ancillary departments (e.g. Cardiology, Willis Eye)? |  |
| Please indicate labs being used? | Jefferson outpatient labs:  YES  NO |
| Will a TJU – SKCC CORE Lab be used?  YES (if yes, name below)  NO  Lab name (eg. Bluemle, College, etc):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Will CRO – PK/PD lab be used:  Yes  No |
| Will a Central Sponsor Lab be used?  YES (if yes, name below)  NO  Lab name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Are there biospecimens required for this protocol? | Yes:  standard of care  research  Biospecimens: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  No |
| Is a radiology measurement required for this trial: | YES  NO  If Yes, which criteria is being used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| 1. **Recruitment and Retention Plan** | |
| Recruitment Plan:  Physician Referral  Public Event  Flyers  Letters  Social Media  Traditional Media  Participant Referral  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Description of Retention Strategy if applicable: | |
| Participant support plan | *(For example: parking passes, meal tickets, transportation, etc)* |
| Type of consent required | On-site Written consent  Remote consent– *please write rationale if using remote consent*  Verbal consent– *please write rationale if using verbal consent*  e-consent– *please write rationale if using e-consent & specify platform to be used* |
| Complete **Data Analysis** section if this is an Jefferson investigator initiated trial:   * Identify staff/faculty member who will be analyzing data: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * All software to be used :  Redcap  JeffTrial   Other:\_\_\_\_\_\_\_\_\_ (if other: Is this software IS/IT approved: Yes No)  Please Detail usage of the software: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

**Facilitation 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 **cannot c**onduct the trial and delineate in the comment box your concerns or reasoning
* Check off “**N/A**” : if the protocol does not use your department or services

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

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| **Statistics:  YES  NO  NA** |
| **Biostatistics:** |
| **Check if applicable:  Qualitative  Quantitative  Mixed Methods** |

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| **Radiation Oncology :  YES  NO  NA** |
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| **Nursing:  YES  NO  NA** |
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| **Laboratory:** |
| 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. |
| **BMT/Cell Therapy Laboratory :  YES  NO  NA** |
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| **Pharmacy:** |
| **IDS:  YES  NO  NA** |
| **Oncology:  YES  NO  NA** |

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| **Pathology, Anatomy and Cell Biology (including Surgical Path):  YES  NO  NA** |
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| **Interventional Radiology:  YES  NO  NA** |
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| **Radiology:  YES  NO  NA** |
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| **PFC Coordinator to complete committee information for Center City Committees:** |
| 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:**