JEFFERSON—Office of Human Research

**PROPOSAL TRANSMITTAL AND APPROVAL FORM**

**Version Date – FOR OHR USE: 8/24/2022**

**1. PROPOSAL DETAILS:**

**PRINCIPAL INVESTIGATOR:**

**Dept/Div:**

**Office Address:**

**Tel:**

**Email:**

**STUDY TITLE:**

**SINGLE IRB REVIEW:**

**Is this submission part of a cooperative single IRB submission to Jefferson IRB?** [ ]  Yes [ ]  No

If Yes, please attach documentation of approval by the Federal department or agency supporting or conducting the research or lead institution as part of your submission. IRB approval will NOT be issued until documentation has been received.

**COMMERCIAL IRB: Check the appropriate box if you are applying to a Commercial IRB.**

|  |  |
| --- | --- |
|  | Advarra IRB (Merger of Schulman IRB and Chesapeake IRB) |
|  | Quorum Review IRB |
|  | Western IRB (WIRB) (Includes Copernicus IRB and NEIRB) |
|  | Other IRB (Specify): |

**FUNDING (Please check all that apply)**

**For trials conducted or supported by a Federal department or agency**: Unless otherwise directed by the Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee on <https://ClinicalTrials.gov> after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject.

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|  | Departmental Funds Only  |  | Grant (provide name of granting entity, i.e., American Cancer Society, Damon Runyon Fund, etc.): |
|  | Departmental with Partial Funding from Commercial Entity (in the form of funding and/or drug or device)Name of Entity Providing Funds:  |  | NIH. Specify institute:  |
|  | Commercial Sponsor (please identify): |  | Commonwealth of PA |
|  | Other (please identify entity): |  | Department of Defense (contact OHR before submission) |

**ORA ACCOUNT NUMBER (if applicable):**

**DEPARTMENT CHARGE CODE:**

## GRANTEE (If subcontract to Jefferson):

**SPONSOR CONTACT PERSON (For-Profit):**

**Tel: Email:**

**STUDY CONTACT (INTERNAL):**

**Tel: Email:**

**Please be reminded that a sponsored study may not begin until the sponsored agreement is fully executed by the sponsor and Thomas Jefferson University. Contact the Office of Research Administration for more information.**

**2. HOW TO SUBMIT A NEW STUDY:**

* Consult the Guidance Documents for IRB Submission on the IRB Forms and Submission Materials web page to determine level of IRB review and forms & number of copies to submit for your study.
* You must create your study record in JeffTrial (for studies with consenting document) and upload your documents to the Portal for your study to be scheduled for IRB review. (For Commercial IRB submissions, upload OHR-1 only. If applicable, see the link for Submitting to Commercial IRBs on the OHR website).
* For instructions on how to use JeffTrial to create study records and notate transactions, access the [JeffTrial training manuals](https://www.jefferson.edu/university/human_research/training/jefftrial-training.html) for oncology and non-oncology research.
* For instructions on how to upload documents to the Portal, access the [Portal training manual](https://black.kcc.tju.edu/legacytrialapps/esubmission/docs/Coordinator%20Training%20Document%20-%20The%20Portal%20v.%201.1.pdf).
* If study is FDA-regulated, please submit a copy of the IND or IDE letter.

**3. AUTHORIZATIONS (As Applicable):**

**CREATION OF JEFFTRIAL RECORD**

[ ] If your study involves the use of a consent/assent form, please certify that you have contacted JCRI@jefferson.edu for review and creation of a JeffTrial record. This includes all OHR-8, 8B, 8C, etc., forms and any other consent/assent forms that require a signature for participation in a study.

**EMERGENCY DEPARTMENT APPROVAL**

[ ] If your study involves human subjects from the Emergency Department (ED), please certify that the ED has been notified, and attach a copy of the ED letter of acknowledgement. **YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER**. Contact the ED at 215-955-4696 or Anna.M.Chang@jefferson.edu for more information.

**ECHOCARDIOGRAPHY APPROVAL**

[ ] If your study involves echocardiography, please certify that the protocol has been reviewed by the ECHOCARDIOGRAPHY LAB and include the approval letter with your submission. **YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER**. Contact the Director of the Echocardiography Lab at 215-503-4940 for more information.

**RADIOLOGY APPROVAL**

[ ] If your study involves radiological imaging through the Department of Radiology for research purposes, or if your study will require data management services of the Radiology department for data extraction from archives, de-identification of patient imaging studies, additional post-processing of images and/or exporting of images from the radiology PACS, please certify that the protocol has been reviewed and approved by the Radiology Dept. and include the approval letter with your IRB submission. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS APPROVAL.  Submit your request using the Radiology Research Feasibility Assessment link on the forms page of the IRB website under Miscellaneous Forms. You may also contact the Radiology Research Team at RadRequest@jefferson.edu.

**ALL CANCER-RELATED RESEARCH**

Any study involving cancer (including pre-cancerous lesions) must be approved by the Sidney Kimmel Cancer Center’s Protocol Review Committee (PRC) prior to IRB submission. Additionally, most studies must be approved by a Multidisciplinary Disease Group (MDG) Committee prior to PRC submission.

For details and instructions on these requirements, please visit the [SKCC Clinical Trials Start-Up web page](https://ewebapp01pa.jefferson.edu/intranet/clinicaltrials/start-up.php).

1. Does the scope of your research involve the screening, diagnosis, staging, treatment, support, outcome, prevention, control or characterization of cancer (patients, tissue, data, blood, charts, etc.)?

 [  ] YES           [  ] NO

1. If you marked “YES” for question 1, please certify that your trial has been submitted to and approved by the Protocol Review Committee (PRC). Please include a copy of the PRC approval email in the IRB submission.

[  ] YES           [  ] NO

1. Is the CRO acting as the administrative support office for this study?

[  ] YES           [  ] NO

**YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE PRC APPROVAL. For questions, please contact the SKCC PRC Coordinator at 215-955-5426.**

**RADIATION SAFETY COMMITTEE APPROVAL**

[ ] If your study involves ionizing radiation exposure to research subjects, please submit form OHR-32 to the Radiation Safety Officer (RSO) at Catherine.Anderko@jefferson.edu (phone 215-955-1950 or 215-955-7813).

**INSTITUTIONAL BIOSAFETY COMMITTEE AND IRB REVIEW AND APPROVAL**

[ ] If your study is interventional and involves recombinant DNA technology (gene therapy or gene transfer) please contact Sue Gotta in Environmental Health and Safety at 3-7422 or Susan.Gotta@jefferson.edu AND the IRB prior to study submission.

**NURSING DEPARTMENT APPROVAL**

[ ] If your study involves Nursing Department personnel in any role or requires nurses to add to or alter their patient care and/or documentation practices, please certify that the project has been reviewed by the Department of Nursing's Office of Nursing Research and attach a letter of acknowledgment. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER. Contact the Office of Nursing Research at 215-503-9678 or Donna.Molyneaux@jefferson.edu for more information.

[ ] JHNJ Only - If your study involves JHNJ Nursing Department personnel in any role or requires nurses to add to or alter their patient care and/or documentation practices, please certify that the project has been reviewed by the Research and EBP Council  and attach a letter of preliminary approval. YOU MAY NOT SUBMIT TO THE IRB UNTIL YOU HAVE THIS LETTER.  Contact the Research Steering Committee at JH\_NJ\_Nursing Research@jefferson.edu for more information.

**EXPORT CONTROL APPROVAL**

[ ] If your study has an international component, such as international travel, international researchers, institutions or companies, or the international transfer or shipment of materials, samples, equipment, documents, data, proprietary information, etc., please certify that the Office of International Affairs/Export Control Office has been contacted. Contact: exportcontrol@jefferson.edu

**INVESTIGATOR-INITIATED TRIAL INVOLVING MULTIPLE SITES**

[ ] If your study is an investigator-initiated trial (IIT) involving multiple research sites, you must complete the Multi-Site Clinical Study Review Form. Please contact JCRI@jefferson.edu to obtain form.

**DIGITAL TECHNOLOGY**

[ ] If your study involves digital technology (e.g., telehealth, iPhone apps, wearable devices, etc.), you must obtain preliminary approval from the Enterprise Digital Health Governance Committee (EDHGC). Please contact DigitalHealthIntake@jefferson.edu.

**4. CERTIFICATION OF CONFLICTS OF INTEREST:**

This section is addressed to the Principal Investigator, and applies to the Principal Investigator, Co-Investigators and all Key Personnel. Generally, Key Personnel are individuals who are contributing to the conduct of the study. The PI should check the appropriate boxes and provide the required information as needed. Refer to University Policy 107.03, Attachment 2 for more detailed information.

1. Do you (the PI) or a family member maintain a relationship with the sponsor OR do you maintain an ownership interest in intellectual property that may be related to the research? [ ]YES [ ]NO

2. If yes, have you disclosed details about the relationship to the COI Committee via COI-Smart? [ ]YES [ ]NO

• If yes, please provide the date of disclosure or a copy of the disclosure confirmation received from Jefferson Conflicts of Interest Committee via COI Smart (from noreply@coi-smart.com).

• If no, please disclose via COI Smart using the link on the [Office of Legal Affairs Conflict of Interest Page](https://www.jefferson.edu/university/counsel/coi.html). If you have questions or need access, please contact the COI Office at JeffCOISmart@jefferson.edu .

Family member: includes spouse, dependent children, and all other persons living in the same household

3. Are you aware of any study personnel identified for this study who have relationships or interests as described above? [ ]YES [ ]NO

• If yes, please name the individual(s) and briefly describe the relationships/interests:

• These individuals must immediately report their relationships/interests in COI-Smart using the link on the [Office of Legal Affairs Conflict of Interest Page](https://www.jefferson.edu/university/counsel/coi.html), if they have not already done so.

If the COI Committee has issued a COI management plan for any research personnel identified on this study, please include the management plan(s) with this application.

**5. SIGNATURES:**

The OHR-1 must be signed by the **Principal Investigator**, and the **Chair** and **Business Administrator** of his/her department. The names of all other Investigators/Key Personnel must be listed below but their signatures are not required. However, if an individual is from a department other than that of the PI, the name and signature of the individual’s Departmental Chair and the Business Administrator are required.

* The **Principal Investigator** agrees to accept responsibility for the conduct of the project according to the tenets of Good Clinical Practice (OHR Policy GA 124, “Good Clinical Practice for Investigators”) and to provide the required progress reports if a grant/contract results from application/proposal.
* **Department Chairs** certify that the project meets Departmental standards with respect to scientific validity and that the project is consistent with Departmental goals.
* **Administrators** certify that the project meets applicable federal fiduciary requirements.

**Please note that CITI training must be up-to-date for all study personnel listed below.**

|  |  |  |
| --- | --- | --- |
| **Principal Investigator** | **Departmental Chair** | **Business Administrator** |
|  |  |  |
| Sign above and print name here | Sign above and print name here | Sign above and print name here |

|  |  |  |
| --- | --- | --- |
| **Co-Investigators/Key Personnel**(List names below – signatures not req’d) | **Departmental Chair**(Name and Signature required if department differs from that of PI) | **Business Administrator**(Name and Signature required if department differs from that of PI) |
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