JEFFERSON—Office of Human Research

Adding Study Personnel

**Version Date – FOR OHR USE: 9/29/21**

**PLEASE NOTE:** Use this form to add a Principal Investigator, Co-Investigator, or Key Personnel. To remove study personnel, use the OHR-12C. In addition, all study personnel additions and removals must be reported on the OHR-9 at the time of continuing review. Once approved, this form will be signed by an IRB Official and sent to the contact person identified below. The signed form constitutes your approval letter.

**Use this form to add study investigators and key personnel to a study.**

**For adding Affiliated Personnel**: For Jefferson, Hand Center, Rothman, and Wills Eye personnel, provide signatures for personnel, Department Chair(s), and Administrator(s) on attached signature page, and complete COI section for each added personnel.

**For JKCCN:** Include signed “Addendum to IRB Authorization Agreement” (IAA). Provide signatures for added personnel only, and complete COI section for each added personnel.

**For adding Unaffiliated Personnel**: Signatures not required for unaffiliated personnel. Include Unaffiliated Investigator agreement for each added personnel or IRB Authorization Agreement (IAA) if a site is being added. Also, submit COI disclosure Attachment D form for each non-affiliated personnel to the Legal Office. These forms are on the IRB forms page.

**Also**, please email a copy of this OHR-12B to the COI Office within Corporate Compliance at [JeffCOISmart@jefferson.edu](mailto:JeffCOISmart@jefferson.edu) (phone at 215-503-6300), for COI review.

**IRB Control #:** **Department:**       **PI:**

**Study Title:**

**Sponsor:**       **Contact Person:**        **Phone/Fax/Email:**

**Indicate if study is overseen by: Quorum**       **Advarra**       **WIRB**       **Other (Specify):**

**Current IRB Expiration Date:**

**Directions: Please complete table for each study personnel being added. Duplicate table as necessary. To activate drop-down menu, click on “Choose an item.” (If you cannot access drop-down menus, go to Word toolbar, click on File > Convert button>OK in dialogue box. This should enable the drop-down menus. If you still cannot use them, type responses.)**

|  |  |  |  |
| --- | --- | --- | --- |
| NAME | STUDY ROLE | AFFILIATION\* | CAMPUS KEY |
|  | Choose an item. | Choose an item. |  |
| \*If Affiliation is “Other” or “Unaffiliated/Private Practice”, please explain: | | | |
| DEPARTMENT | DIVISION | ONCOLOGY | EMAIL |
| Choose an item. | Choose an item. | Choose an item. |  |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Principal Investigator Date**

Do not fill out the section below – For IRB Use

**The signature below indicates that this amendment has been approved by the Jefferson IRB.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

IRB Official Date of Approval

Walter Kraft, M.D. Kyle Conner, M.A., CIP Patricia Oden Kathleen Avender

Director, OHR Associate Director, OHR Admin. Coord., OHR IRB Administrative Assistant

**CERTIFICATION OF CONFLICTS OF INTEREST**

This section 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. Please check the appropriate boxes and provide the required information as needed.

Yes  No Do the Principal Investigator, Co-Investigator(s), or any Key Personnel have any conflicts of interest with this research?

**If Yes, please list the individual(s) with the conflict of interest**:

**Signatures**

If a new PI is added, the name and signature of the new PI and his/her Departmental Chair and Business Administrator are required.

The names of Co-Investigators/Key Personnel being added must be listed below but their signatures are not required. However, if an individual being added is from a department other than that of the PI, the name and signature of the individual’s Departmental Chair and Business Administrator are required.

* The new **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.

|  |  |  |
| --- | --- | --- |
| **Principal Investigator**  (Only required if a new PI is added) | **Departmental Chair** | **Business Administrator** |
| Name:  Signature: | Name:  Signature: | Name:  Signature: |

|  |  |  |
| --- | --- | --- |
| **Co-Investigators/Key Personnel**  (List all names below – signatures not required) | **Departmental Chair**  (Name and Signature required if individual being added is from a department other than that of the PI) | **Business Administrator**  (Name and Signature required if individual being added is from a department other than that of the PI) |
| Name: | Name:  Signature: | Name:  Signature: |
| Name: | Name:  Signature: | Name:  Signature: |