

**SOP#: RPS-16**

**Key Study Personnel Changes**

**Version #: 3.1**

**Next Review Date: 07/2022**

**Approved Date: 12/2020**

**Review Interval Period: Biennial**

**NCI Clinical Director Signature:**



William L. Dahut, MD 12/30/2020

## **POLICY**

The NIH Institutional Review Board (IRB) allows for administrative changes in Key Study Personnel (KSP) for a protocol. “Key Study Personnel” is a term used in iRIS, the IRB management system, for research staff including investigators, research nurse coordinators, referral contact(s), and collaborators. Changes in personnel (aside from the Principal Investigator, which must be processed as a full protocol amendment) can be submitted to the IRB using the Amendment form in iRIS.

The Principal Investigator is responsible for ensuring that all research staff required to be on the KSP Page are listed and assigned the appropriate roles.

## **PURPOSE**

Describe the steps to notify the IRB of administrative changes in key study personnel for a protocol using the KSP Page. These steps are performed by the Protocol Support Office (PSO) manager assigned to the protocol.

## **RESOURCES**

- NIH Office of Intramural Research Policies & Guidance [website](#)
  - Policy 300 - Investigator Responsibilities
  - SOP 21 - *Conflict of Interest Requirements for Researchers and Research Staff*
- CCR Policies/Standard Operating Procedures [website](#)
  - RPS-14 - *Submission of the Personal Financial Holdings Form to the Institute/Center Deputy Ethics Counselor*

## **PROCEDURES**

### **STEP 1: Create a Protocol Key Study Personnel (KSP) Page**

- **For new studies:** Using the KSP Page template from the PSO Share Drive, include a listing of all personnel (including collaborators) involved in the conduct of the protocol. Include identification of the roles of each investigator. Send to PI to confirm accuracy.
- **For existing studies:** To initially create a KSP Page for an existing protocol, an amendment submission will be required to move the personnel from the title page of the protocol onto a clean KSP Page. Send to PI to confirm accuracy.

Note: The NIH Principal Investigator (PI) will be listed on both the protocol title page and the KSP Page.

- If personnel are NOT changed: Mention in the IRB cover memo that personnel are being moved from the protocol title page for administrative purposes to create a KSP Page and that changes to staff are not being made.
- If personnel are added and/or deleted: Personnel changes will be shown as tracked in the MS Word version of the KSP Page. Mention in the IRB cover memo that personnel are being moved from the protocol title page for administrative purposes to create a KSP Page and that staff are being added/deleted.

### **STEP 2: Amend an Existing Protocol KSP Page**

Using the MS Word version of the most recently approved KSP Page, track all changes for staff being added/deleted and update the document version date. Verify accuracy of all information on the KSP Page and revise, as needed. Send to PI to confirm accuracy.

### **STEP 3: Verification of Required Training**

For all KSP Page submissions: Ensure that all investigators are in compliance with required training. If investigators are not in compliance, please contact the CCR Director of Office of Education and Compliance. KSP Page cannot be submitted to the IRB until verification of training has been confirmed.

### **STEP 4: Submit KSP Page to the Deputy Ethics Counselor (DEC), if applicable**

Attach the clean KSP Page to the DEC request form and submit to the IC DEC via iRIS. See CCR SOP RPS-14 for more information.

### **STEP 5: Submit the Protocol KSP Page in iRIS**

- **For initial studies:** KSP Page is submitted to the IRB as a clean document attached to the Initial Review Submission Form. DEC clearance must be attached, if applicable.

Note: Ensure that all study personnel (PI, AI and other research staff) are listed on the Study Application at the time of Initial Review submission.

- **For existing studies:** The KSP Page is submitted to the IRB using the Amendment Form in iRIS. List all key study personnel changes in the Amendment form, except for collaborators as they are not listed in iRIS.
  - KSP changes may be submitted as a stand-alone action or along with other actions.
  - If newly added personnel do not have an iRIS account, one will be requested by the PSO manager via iRIS Help Desk Support web page (<https://iris.helpdesk.nih.gov/jira/servicedesk/customer/portal/3/group/4>)
  - Complete the Amendment form and attach the following:
    - Clean KSP Page
    - Tracked KSP Page (if applicable)
    - DEC Outcome Letter-approval (if applicable)
    - Study Application

**STEP 6: Assign Signatures in iRIS**

- KSP at time of Initial Review: Route with the Initial Review form to the IRB
- KSP changes at time of Amendment: Route the Amendment form to the study PI for signature.