POLICY

The NIH IRB allows for administrative changes in key study personnel for a protocol. “Key Study Personnel” is a term used in iRIS, the IRB management system, for research staff including investigators, referral contact(s), and collaborators. Changes in personnel (aside from the Principal Investigator, which must be processed as an amendment) can be submitted to the IRB on the Key Study Personnel Change form in iRIS.

PURPOSE

Describe the steps to notify the IRB of administrative changes in key study personnel for a protocol using the Key Study Personnel Change form in iRIS.

RESOURCES

Intramural NIH Human Research Protection Program (HRPP) Policy and Procedures

SOP 19: Investigator Responsibilities
SOP 21: Conflict of Interest Requirements for Research and Research Staff

PROCEDURES

**Step 1: Create a protocol study personnel page**

Using the template in appendix A, include a listing of all personnel involved at the NIH site in the conduct of the protocol. Include identification of the roles of each investigator. To initially create this document for an existing protocol, an amendment submission will be required to remove the personnel from the title page of the protocol and onto the study personnel page.

**Step 2: Submit Study Personnel to the Deputy Ethics Counselor (DEC)**

Submit the Personal Financial Holdings form (DEC clearance form) to the IC DEC via iRIS if applicable.

**Step 3: Submit the study personnel page to the IRB for a new protocol**

Submit the study personnel page to the IRB as a separate document (not attached to the protocol document) attached to the initial review submission form in iRIS.
Step 4: Move the personnel off the current protocol title page onto the study personnel page

- If you are not changing any of the personnel in the amendment, just moving people administratively:
  Note in the cover memo to the IRB that personnel are being removed from the protocol title page for administrative purposes only, and there are no changes to the personnel with this amendment. Submit the amendment to the IRB in iRIS on the amendment submission form, and attach a separate clean study personnel form to the amendment submission form in iRIS.

- If you are changing study personnel as part of the amendment:
  Note in the cover memo who the staff are that are being added/deleted. Make all changes to the personnel in the amendment submission form in iRIS, and attach the DEC clearance to the amendment submission form. Prepare a tracked and clean version of the protocol study personnel page. Include the version date of the study personnel page. Attach the tracked and clean versions of the study personnel page to the amendment submission form in iRIS.
  Route the amendment submission form to any new personnel as applicable.

Step 5: Submitting the KSP Change form in iRIS

Once all personnel are on a separate study personnel page, you can use the KSP changes form in iRIS to inform the IRB of any ongoing changes to the study personnel (aside from the PI). Create a tracked and clean study personnel page, and attach to the KSP changes submission form in iRIS. Attach the DEC clearance if applicable.

Step 6: Assign signatures in iRIS

Route the submission form to any new NIH employee personnel in iRIS. Personnel who are not NIH employees are not required to sign off on iRIS. Route form to the Principal Investigator and Clinical Director(s) (if applicable).
APPENDIX A – TEMPLATE FOR STUDY PERSONNEL PAGE

Abbreviated Title: 

CC Protocol #: 

Study Personnel Version Date: 

Title: 

Investigators: 

Note: for definitions of roles, refer to OSHRP SOP 19.

List the affiliation, address, and contact information to include telephone, fax and email for the PI and Study Coordinator

NIH Principal Investigator:

XXX Branch
National Cancer Institute
Building 10, Rm XXXX
9000 Rockville Pike
Bethesda, MD 20892
Phone: XXXX
E-mail: XXXX

NIH Associate Investigators: Limit to contributing investigators (i.e., do not include persons participating in routine patient care).

List the branch and institute affiliation for each AI.

Referral Contact:

Study Coordinator: include study coordinator contact information: telephone, fax, email

Page 3 of 4
Non-NIH Associate Investigators:  *Include institutional affiliation of each investigator*

Collaborators:  *Include collaborators information (name, institutional affiliation) in this section only if they are not otherwise listed in the body of the protocol document.*

For each person listed above, identify their roles with the appropriate letter:

A. *Obtain information by intervening or interacting with living individuals for research purposes*

B. *Obtaining identifiable private information about living individuals*

C. *Obtaining the voluntary informed consent of individuals to be subjects*

D. *Makes decisions about subject eligibility*

E. *Studying, interpreting, or analyzing identifiable private information or data/specimens for research purposes*

F. *Studying, interpreting, or analyzing de-identified data or specimens for research purposes*

G. *Some/all research activities performed outside NIH*