IRB-HSR Announcements

**July 1, 2022**

**\*\*\*\*\*\*\*\*\*\*\*\*NEW\*\*\*\*\*\*\*\*\*\*\*\*\*\***

**PERSONNEL CHANGE PORTAL in IRB PRO**

**Effective July 1, 2022**, the IRB HSR will go live with the **NEW Personnel Change Portal in IRB PRO.**

<https://hrpp.irb.virginia.edu/irbpro/index.cfm>

This NEW feature will permit specific member roles within a study to add or delete personnel within IRB PRO. This process will **replace** the Personnel Change form which will NO LONGER be accepted for submission to the IRB HSR. **All deletions and additions will be done within IRB PRO by the study team.**

**Key Points:**

1. The following positions are permitted in this Pro feature to modify user roles:
2. Principal Investigator
3. IRB Coordinator
4. Study Coordinator I or II
5. Additional Study Coordinators
6. Sub investigators
7. This feature may only be used for adding or deleting AFFILIATED UVA personnel.
8. **IMPORTANT:** If you are adding an unaffiliated investigator to a study OR changing the UVA PI, you will be required to submit a modification to the IRB HSR via PRO (Submit Documents). Detailed instructions for submission can be found on the Modification Request Form.
9. **Note:** To ADD personnel, the BASIC IRB- HSR training MUST be up to date. You will not be allowed to add or change user roles if training has expired. \*ALSO SEE NEW GCP requirements for Full Board Studies (p.2)\*
10. Each user can only be assigned to one position.



**INSTRUCTIONS**

1. Click on Personnel Changes tab
2. A list of studies will appear
3. Far right tab, under Personnel, click hyperlink **View/Edit**



1. From this page, you will be able to ADD NEW PERSON, or REMOVE an existing person from the study.





1. An event of a personnel change will NO LONGER be added in IRB online or IRB PRO.
2. The HISTORY tab will allow you to view when a person was removed, added and by whom. The history feature can serve as a running report to share with your sponsors as well.

**\*\*\*\*\*\*\*\*\*\*\*\*NEW\*\*\*\*\*\*\*\*\*\*\*\*\***

**GCP Training Requirements for Full Board Studies\*\***

**Effective July 1, 2022,** **GCP training is required for ALL FULL BOARD STUDIES.**

GCP training **describes the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials**. GCP training aims to ensure that: the rights, safety, and well-being of human subjects are protected. clinical trials are conducted in accordance with approved plans with rigor and integrity.

GCP training can have either FDA or ICH focus. **This determination is study specific.**

ICH focus-conduct of clinical trials of drugs and biologics in the U.S. and internationally

FDA focus-conduct of clinical trials of drugs, biologics, and devices primarily in the U.S.



GCP training for full board studies is in addition to the standard IRB BASIC RESEARCHER Training via CITI.

Access to GCP training in CITI must be done behind Netbadge. Information can also be found on the [IRB HSR website](https://research.virginia.edu/human-research-protection-program/hrpp-citi-training)

**New full board studies created in Protocol Builder after July 1,2022** will indicate in protocol builder under the *Auxiliary Info tab*, the TYPE Of GCP training (ICH or FDA). This information will also populate on the Protocol Coversheet.



**For currently active full board studies, the GCP requirement will default to EITHER.** To change from EITHER to ICH focus for an already active study, contact the IRB HSR.

**Study team members have 6 months to complete the required GCP training.**  After 6 months, the IRB HSR will run a report to identify those individuals that have not completed training and who may be removed from the study at that point.

**\*\*\*\*REMINDER\*\*\*\*\***

**Submission of Study Documents to IRB HSR via IRB PRO \*\*NEW ROUTE FOR SUBMISSION\*\***

You are REQUIRED to use the NEW route for submission of study documents to the IRB via IRB PRO effective May 20,2022.

<https://hrpp.irb.virginia.edu/irbpro/index.cfm>

**NOTE: This NEW route DOES NOT apply to NEW Expedited or NEW Full Board studies whose applications MUST still be submitted through CRCONNECT.**



Once logged into IRB PRO, the study team view shows both “My STUDIES” and the

**NEW** feature “SUBMIT DOCUMENTS”. Click on SUBMIT DOCUMENTS to open the following:







The drop-down menus will provide ALL event options available to submit to the IRB-HSR via IRB PRO along with the study numbers that the sender is listed on.

You will be prompted with the following instructions:



This new feature will also provide an email confirmation to the sender that indicates the study title, PI, type of submission and the list of documents submitted.



As always, we welcome any feedback.

Sincerely,

**Eileen Sembrowich CCRP, CIP**

Interim Director

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**Upcoming Out of Office: July 1st-July 5th**