**IRB-HSR UPDATE**

January 2023

**Electronic Informed Consent (E-Consent)**

**Effective December 9, 2022**, the IRB HSR updated the IRB application and website surrounding electronic consenting. Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent. When implementing an electronic informed consent, a variety of approaches may be used to fulfill HHS and FDA regulatory requirements for informed consent and IRB review (45 CFR part 46 and 21 CFR parts 50 and 56) and FDA regulations for electronic records and electronic signatures (21 CFR part 11).

The IRB encourages study teams to review the [Use of Electronic Informed Consent Questions and Answers Guidance for Institutional Review Boards, Investigators, and Sponsors](https://www.fda.gov/media/116850/download)

**IRB HSR Website**: [Use of Electronic Informed Consent](https://research.virginia.edu/irb-hsr/informed-consent)

The consenting process should include:
• platform used: how the consent form is presented/reviewed
• how signatures of the subject and/or LAR will be obtained,
• how the study team is verifying identity
• how are copies provided to subjects

**IN PERSON E CONSENT:**

* Researcher and subject are in the same physical location
* Consent discussion occurs in person
* Signature is obtained electronically
* Platform: REDCap, DocuSign

**REMOTE E-Consent**

* Researcher and subject are NOT in the same location
* Consent discussion is conducted via video teleconference
* Verify identification of the subject
* Signature is obtained electronically
* Platform: REDCap, DocuSign

Please review the [IRB Learning Shot: Electronic Informed Consent](https://hrpp.irb.virginia.edu/learningshots/Use-of-Electronic-Informed-Consent/presentation_html5.html)

* Use of Electronic Informed Consent Questions and Answers: Guidance for IRBs,
Investigators, and Sponsors, joint FDA/OHRP, Dec. 2016:
* <https://www.fda.gov/media/116850/download>
Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21
CFR Part 11, Questions and Answers, Guidance for Industry (Draft), FDA, June 2017:
<https://www.fda.gov/media/105557/download>
* Guidance for Industry: Part 11, electronic Records; Electronic Signatures – Scope and
Application, FDA, August 2003:
<https://www.fda.gov/media/75414/download>

**UVA Non-Human Subject Research Online Tool**

**Effective September 1,2022 the IRB launched the** [**Non-Human Subject Research online tool**](https://redcapsurvey.healthsystem.virginia.edu/surveys/?s=EAFEDMEEFD)**.** This feature replaces the Determination of Human Subject Research Document.

The Project Leader is responsible for the accuracy and reliability of the information submitted through the **UVA Non-Human Subject Research Online Tool**, for following all applicable Federal, State, and local laws and/or regulations, and is also responsible for submitting research studies to the IRB-HSR when required. This is NOT an IRB determination.  Activities that meet the definition of [Human Subject Research](https://grants.nih.gov/policy/humansubjects/research.htm)/ [Clinical Investigation](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=50.3) WILL REQUIRE SUBMISSION of an application to the IRB-HSR.



**Preferred Email Address**

**Effective December 15,2022,** the IRB HSR via IRB PRO, individuals can choose which email address should be used for IRB-HSR communication.

Through [IRB PRO](https://research.virginia.edu/irb-hsr/irb-pro), click Investigator, scroll down to CONTACT INFORMATION, and click EDIT. You have three email address options to choose from. Please update your contact information at any time.



**IRB HSR Office Contact**

For individual staff email addresses see [Staff Directory](https://research.virginia.edu/irb-hsr/staff-directory-0)

General Office Phone: (434)-924-2620

General Questions: I[RBHSR@virginia.edu](https://research.virginia.edu/irb-hsr/IRBHSR%40virginia.edu)

**Note:** irbhsradmin@virginia.edu has been disabled

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

**GCP training is required for any individual listed on a FULL BOARD STUDY and must be complete by January 15,2023**

**\*Email reminders have been sent to those individuals who have not completed their required training.**

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 FDA to ICH focus for an already active study, contact the IRB HSR.

**The deadline for completion is now January 15,2023**. At that time, 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\*\*\*\*\***

**Effective May 20,2022,** you are REQUIRED to use the NEW route for submission of study documents to the IRB via IRB PRO. <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.



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

**Effective July 1, 2022**, the IRB HSR went 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.