The IRB at UVA

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University of Virginia

Goals

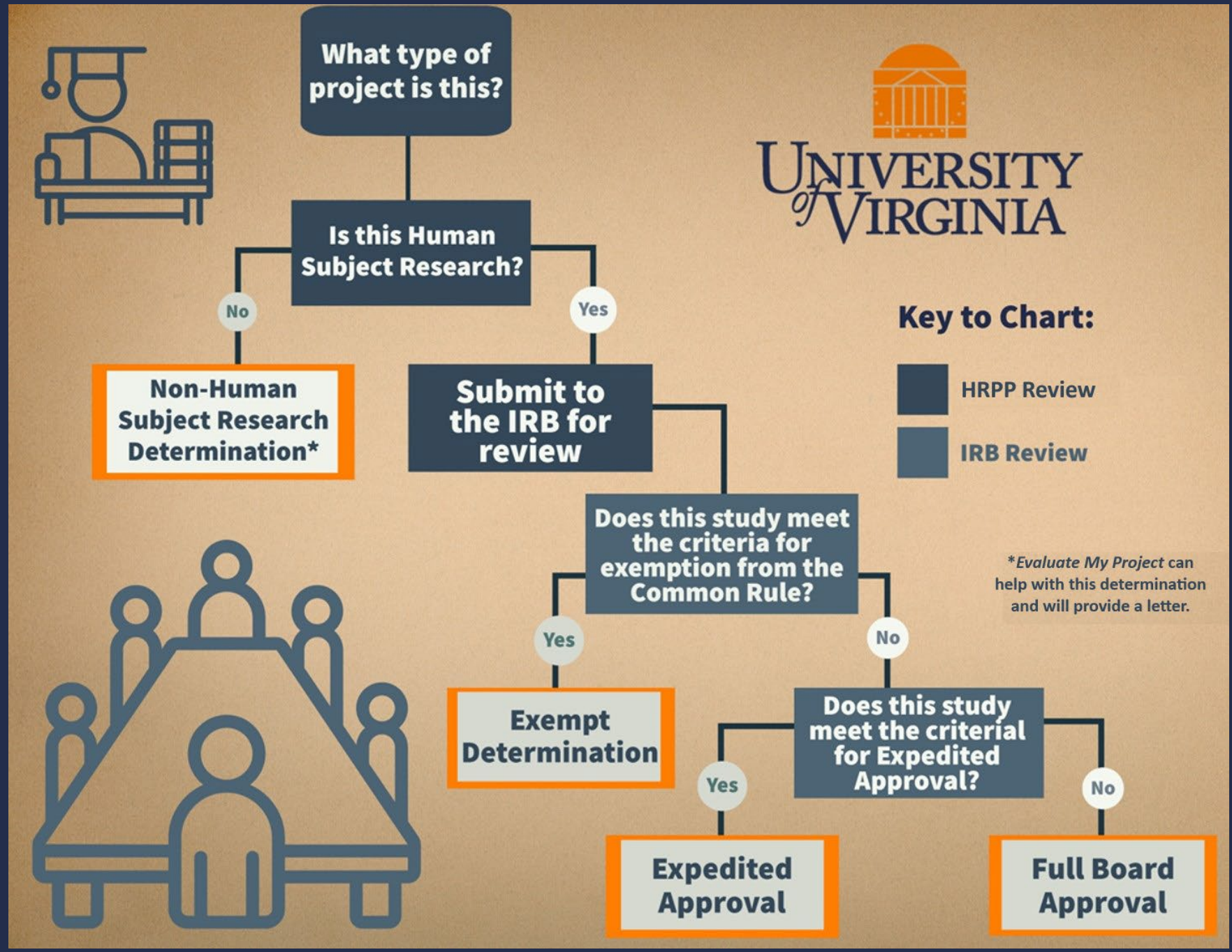
UVA | Office of the Vice President for Research
Human Research Protection Program

- Understand how the IRB is structured at UVA
- Explore the IRB process to approval
- Review protocol approval and management topics
  - IRB submission types
  - IRB systems
  - Protocol development
- Identify available IRB resources
- Learn to like the IRB ☺

The IRB at UVA

Why IRB approval?

- To protect human subject research participants
- Federal guidelines - Initial and ongoing review of research
- Evaluate My Project -Non-Human Subject Research Determination Tool


What type of project is this?
Is this Human Subject Research?
No
Yes
Non-Human Subject Research Determination*
Submit to the IRB for review
Does this study meet the criteria for exemption from the Common Rule?
Yes
No
Exempt Determination
Does this study meet the criterial for Expedited Approval?
Yes
No
Expedited Approval
Full Board Approval
UNIVERSITY of VIRGINIA
Key to Chart:
HRPP Review
IRB Review
*Evaluate My Project can help with this determination and will provide a letter.

Which UVA IRB do I submit to for review?

IRB-HSR (HIPAA)

- Medically invasive procedure
- FDA regulated product
- Use of UVA Health records
- Specimens
- Exercise intervention/testing
- Physiological/biomechanical measures
- Direct recruitment of patients

IRB-SBS (Non-HIPAA)

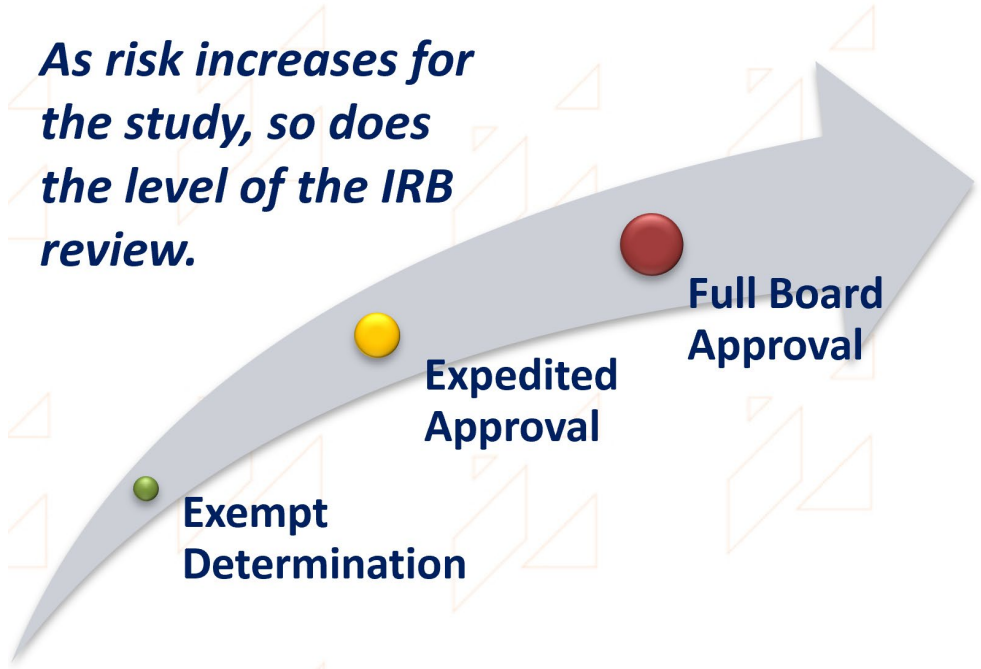
- Educational initiative
- *Self-disclosed* health information
- Human behavior
- Ethnographic research
- Surveys, interviews, and/or focus groups

If you are not sure which IRB to submit, please reach out to IRBSBSHelp@virginia.edu or IRBHSR@virginia.edu

Tips for Protocol Development

Considerations when developing a protocol

- Start early
- Review resources as you develop your study protocol
  - IRB-HSR Researcher Guide
  - IRB-SBS Researcher Guide
- Consider the risk in your proposed research
  - Defining risk in your protocol
- Understand the permissions and approvals required



School of Medicine (SOM) and Institutional Review Board (IRB) Research Systems at UVA

Study Start-Up

Protocol Builder (IRB)

Protocol Builder must be used by investigators who wish to submit a new study to the IRB-HSR that meets the criteria for review by any of the following review types: full board, expedited, exempt or non-engaged. Protocol Builder will ask a series of questions which it uses to build the templates for the protocol, consent form, and IRB application that are specific to the study. If a Sponsor has provided a protocol document, the Investigators don't need to utilize the protocol template.

For support, please contact IRB-HSR staff or IRBHSR@virginia.edu

CRConnect (SOM)

For School of Medicine Expedited and Full Board studies, study teams are required to process an application through CRConnect and provide initial information for study start-up. Researchers must upload documents into CRConnect and follow the instructions for submission to IRB-HSR for pre-review.

For support, contact CRConnectSupport@uvahealth.org or 434.297.5757, Option 2

Study Management

IRB Pro & IRB Online (IRB)

IRB Pro is an electronic storage system for IRB-HSR regulatory documents. Finalized documents with the determination are uploaded manually to IRB Pro by IRB staff. Researchers can view approved documents, submit personnel changes and additional documents related to study events (modifications, continuations, deviations, adverse events) throughout the study life cycle.

Study teams can use IRB Online to track submissions and access links to documents available in IRB Pro.

For support, please contact IRB-HSR staff or IRBHSR@virginia.edu

OnCore (SOM)

Online Collaborative Research Environment (OnCore) is a web based, comprehensive clinical trial management system (CTMS). OnCore serves as a centralized place to manage all study protocols and subjects.

For support, contact oncoresupport@uvahealth.org or 434.297.5757, Option 1

For additional information about CRConnect, OnCore and Florence, click HERE.

Florence (SOM)

An electronic regulatory system that is used for clinical research studies conducted within the UVA School of Medicine. Florence eBinders is designed to replace physical binders and paper forms, giving clinical research teams an efficient and compliant way to electronically sign, manage, store, and collaborate on all study related documents.

For support, contact Florencesupport@uvahealth.org or 434.297.5757, Option 3

Not Sure Which IRB To Submit To? Click HERE

LabArchives - UVA's Electronic Lab Notebook (ELN) platform, which can be used to store data, observations, notes and other digital materials generated during the research process. Beginning July 1, 2025, UVA will require that all sponsored funded projects with federal funding will be required to use LabArchives. At this time, clinical trials are exempt from the requirement, though this could change in the future. For additional information, click HERE. For support, contact **LabArchives@virginia.edu.**

Updated | July 17, 2024

IRB-HSR Submission Types
Unsure of the correct submission type? See Staff Directory for assistance for each submission type
A conversation TODAY eliminates issues TOMORROW

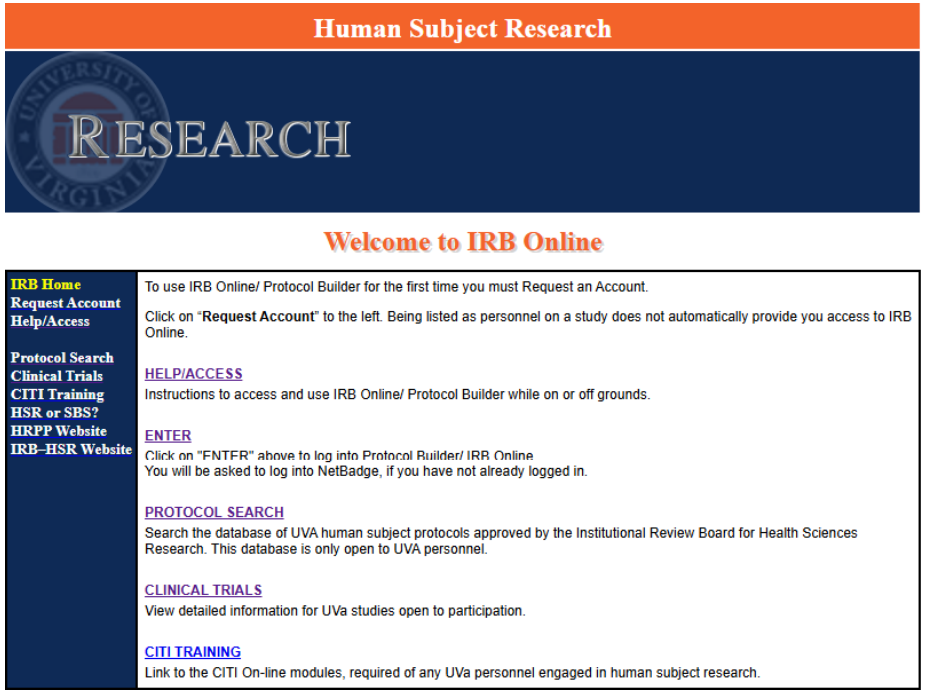
Single Patient Emergency or Non-Emergency Use of an Unapproved Drug or Device	**Humanitarian Device Exemptions (HDE) Non-Emergency requires Full Board Review**	**Non-Human Subject Research Determination**	**Non-UVA Agent Determination**	**Exempt Determination**	**Non-Engaged Determination** *Not applicable if FDA regulated*	**Expedited Approval** ***IRB Approval by IRB Chair/Member (sIRB review permitted)***	**Full Board Approval** ***IRB Approval by IRB at a convened meeting*** **(sIRB review permitted)**
Single patient reported to the UVA within 5 working days *(Includes Emergency HUD_*	*Exemption for use of a Humanitarian Use Device (HUD).*	*Project does not meet the definition of human subject research or a clinical investigation of a test article.*	*Involved in Human Subject Research but research is not being done on behalf of UVA.*	*Must be minimal risk and meet an Exempt Criteria (see below).*	*Research that does not meet previous Determination types and does not "engage" UVA in human subject research.*	*Must not meet previous review types, be minimal risk and meet an Expedited Criteria (see below).*	*Any protocol that does not qualify for another review type.*
Examples: • Patient who is in an immediate life threatening situation and does not meet the inclusion/exclusion criteria of a research protocol or the research protocol is not being conducted at UVA. No other acceptable alternative treatment available.	**Examples:** • Applies to a condition treated/diagnosed that affects fewer than 4,000 in US per year	**Examples:** • Preparatory to research and no HIPAA identifiers collected. • Use of specimens from deceased individuals • Case study (up to 3 patients) • Only using commercial cell lines • Specimens purchased from commercial supplier • Data from Public Data Set • Health Care Delivery Improvement Projects • Only using de-identified or coded data/specimens and not FDA Regulated. • Sharing data/specimens with other researchers • Medical record review and all subjects are deceased.	**Examples:** • UVA personnel asked to assist with a research study after arriving at the non-UVA institution. • Graduate students conducting their research outside of UVA. • Person completing research at previous institution after transferring to UVA • UVA Faculty member has an appointment or clinical privileges at another institution. Research will only be conducted at outside institution.	**Examples:** • Surveys/interviews with adults that do not involve sensitive topics • Surveys/ interviews with adults that do collect sensitive information but do not record identifying information (e.g. HIPAA identifiers) • Review of medical records. Either not recording identifying information or recording identifiable information and study is regulated by HIPAA. • Research with data previously collected as part of an Improvement Project in which there was no interaction or intervention with an individual and the project only involved the use of information from UVA medical records. Data will be de-identified before sharing outside of UVA. *NOT ALLOWED: Collection of new specimens for this study*	**Examples:** • Provide commercial or other services for researchers. • Perform clinical related procedures (e.g. x-ray or blood draw) for subject enrolled in research at another institution • Administer study drug for subject who in town on vacation. • Inform prospective subjects about research but do not obtain consent • Permit non- UVA researchers to use UVA space to conduct their research • Perform analysis on coded data/specimens from collaborators at other sites conducting the same study.	**Examples:** • One blood draw by finger stick, heel stick, ear stick, or venipuncture. *Minimal blood volumes/frequency must be met- see Expedited Criteria.* • Nasal swab that does not go beyond the nares • MRI without contrast/ ultrasound • Surveys/interviews with minors • Banking identifiable data/specimens for future unspecified research • Research with data previously collected as part of an Improvement Project in which there was no interaction or intervention with an individual & the project only involved the use of information from UVA medical records. Data will remain identifiable after sharing outside of UVA.	**Examples:** • Blood draw from existing IV, central or arterial line. • All greater than minimal risk research • Clinical trials • Any research use of radiation • Any research involving use of anesthesia • Any research use of invasive procedures • Use of viable embryos or embryonic stem cells • Planned Emergency Research including Exemption from Informed Consent (EFIC)

IRB-HSR Submission Types Guide

IRB-HSR Systems

IRB Online & Protocol Builder

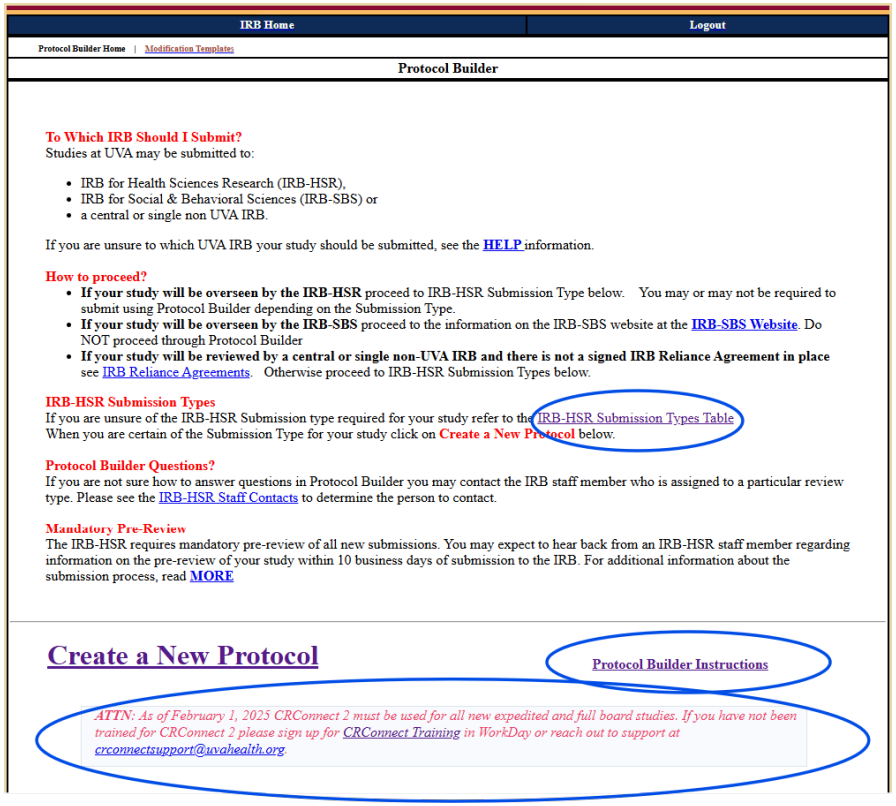
- Intertwined systems- Access via the same link
  - Accessible off grounds via a UVA Anywhere VPN (this is different from a VPN from UVA Health).
- **Protocol Builder** is used for creating study documents for submission to IRB-HSR
- **IRB Online** is the database for IRB-HSR administrative tracking
- Syncs with **CRConnect**



IRB-HSR Systems

IRB Online & Protocol Builder

- Answer questions related to your study
  - Protocol Builder Instructions
- Generates documents that are specific to your study
  - Protocol, consent form, IRB application
- Upload completed documents to
  - **CRConnect** if *Expedited or Full Board submission*
  - **IRBPro** if *Exempt submission*

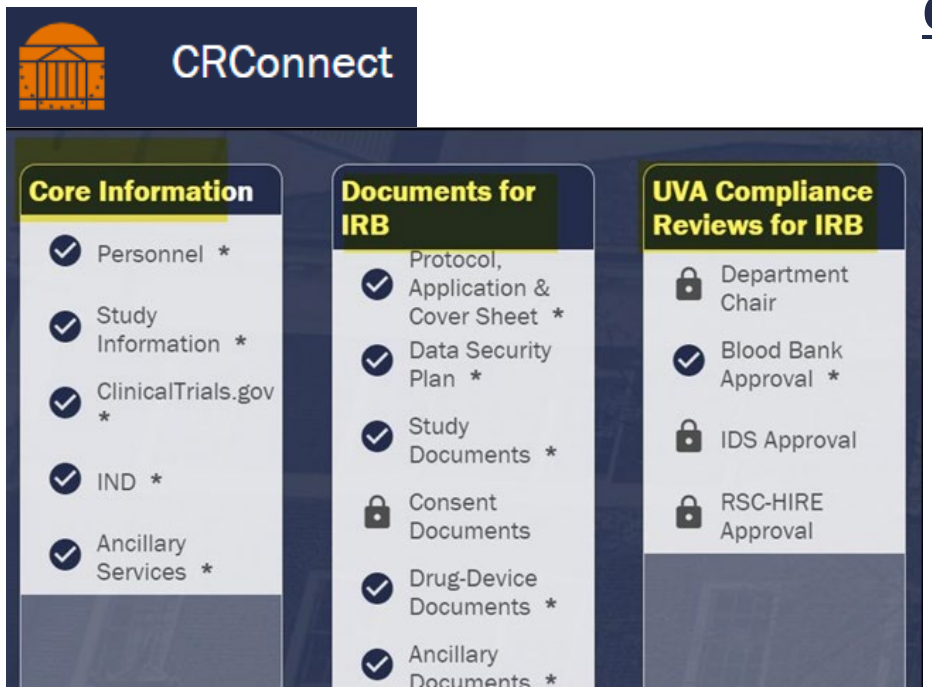


IRB-HSR Protocols

Protocol Elements:

- Table of Contents
- Introduction/Abstract
- Hypothesis
- Objectives and Rationale
- Methods and Procedures
- Subject Population Selection and Inclusion/Exclusion Criteria
- Risks and Benefits
- Provisions for Treatment of Adverse Events
- Subject Recruitment
- Review Preparatory to Research and Recruitment
- Subject Compensation/Reimbursement
- Study Management and Personnel
- Confidentiality and Data Storage
- Data Analysis and Evaluation Techniques
- Bibliography
- Appendices

IRB-HSR Systems



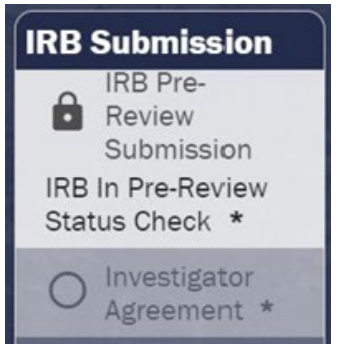
CRConnect

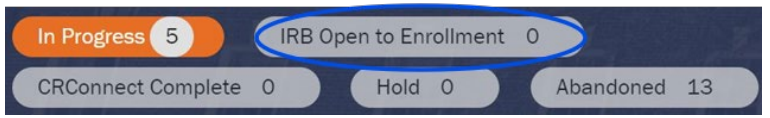
- School of Medicine Clinical Research Office
- Streamlines multiple approvals e.g., Department Chair, IDS, RSC, HIRE
- **Expedited and Full Board** submissions
- Follow steps in CRConnect to submit documents to IRB
- Emails sent from IRB staff regarding revisions and timeline for Full Board review
- Final documents posted in **IRBPro**
- CRConnect 2 guidance document

IRB-HSR Systems

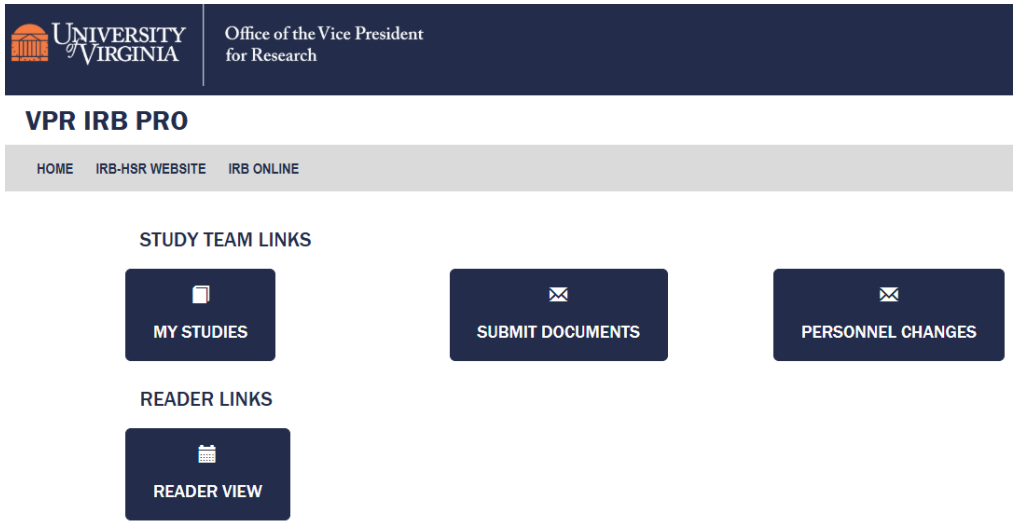
CRConnect

- Once check boxes in all sections, the IRB submission option will open
- Click on the IRB Submission tab and complete actions
- A zip file will be sent to the IRB
- IRB staff will send emails regarding revisions and timeline for Full Board review
- When pre-review is complete by IRB, the Investigator Agreement button will go live for signature- See SOP- 19: Investigator Responsibilities
- Once approved, your study will move to the “IRB Open to Enrollment” section
- Final documents posted in **IRBPro**





IRB-HSR Systems



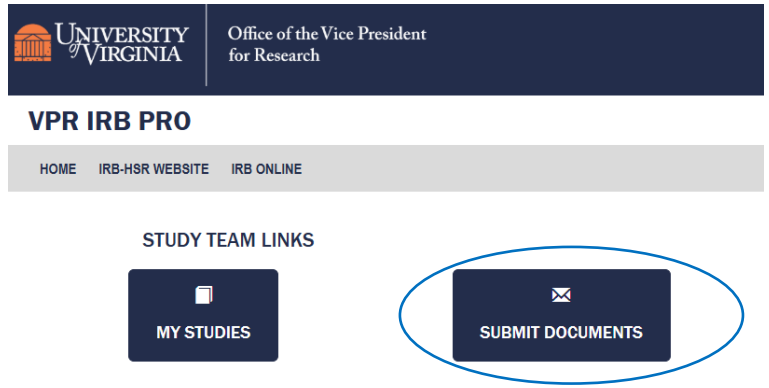
IRBPro

- **Exempt and Non-Engaged** submissions
- Document repository
- Shows status of documents under IRB review
- Documents needing revision will be posted to IRBPro with requested changes tracked
- Final IRB-approved documents post to IRBPRo
- Study team is notified by email when documents are posted
- Personnel changes

IRB-HSR Systems

IRBPro

- Submit documents for **Exempt or Non-Engaged** submissions to IRBPro
- Upload the documents you completed using Protocol Builder
  - Protocol Cover Sheet
  - Exempt, or Non-Engaged Application
  - Protocol (if applicable)
  - HIPAA Authorization (if applicable)
  - Outside IRB approvals (if applicable)
  - Proposed study-specific research tools (e.g., interview questions, questionnaires) (if applicable)
  - Recruitment tools



IRB-HSR Systems

IRBPro

Document Status Descriptions

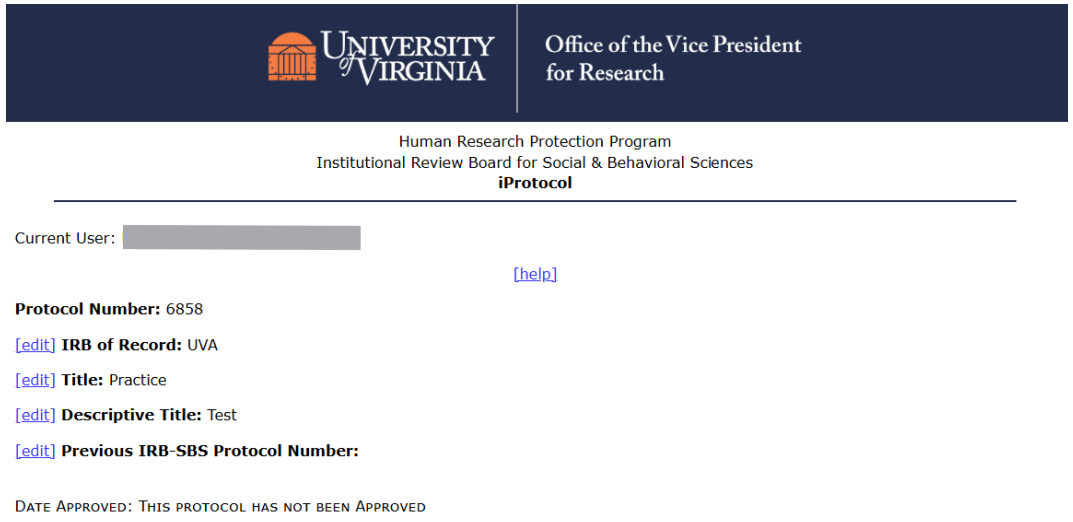
Status	Description
Active	Most current version of an approved document (example: application, protocol, consents).
Archived	Documents that are no longer needed (example: previous version of protocol that will never be made active again).
Deferred	Documents for a study that has been reviewed by the Full Board, but the IRB requires changes to the study prior to re-review by the Full Board.
Disapproved	Documents for a study that has been reviewed by the Full Board, but the IRB disapproved the study. New study documents must be submitted.
Inactive	Documents for a study that are currently not active (example: consent forms for a study that is closed to enrollment are inactive but may be made active if study is re-opened to enrollment).
On File	Documents that are on file but not approved by the IRB (example: documentation from the FDA, HIRE approval letter, case report forms, subject diaries, etc.) or documents related to Non-Engaged Determinations.
Pending	Documents that have not yet been reviewed by the IRB.
Withdrawn	Documents for a study which the study team withdrew before IRB review.

IRB-SBS System

iProtocol

- Questions with text boxes
  - Describe study procedures
  - iProtocol Question Guide

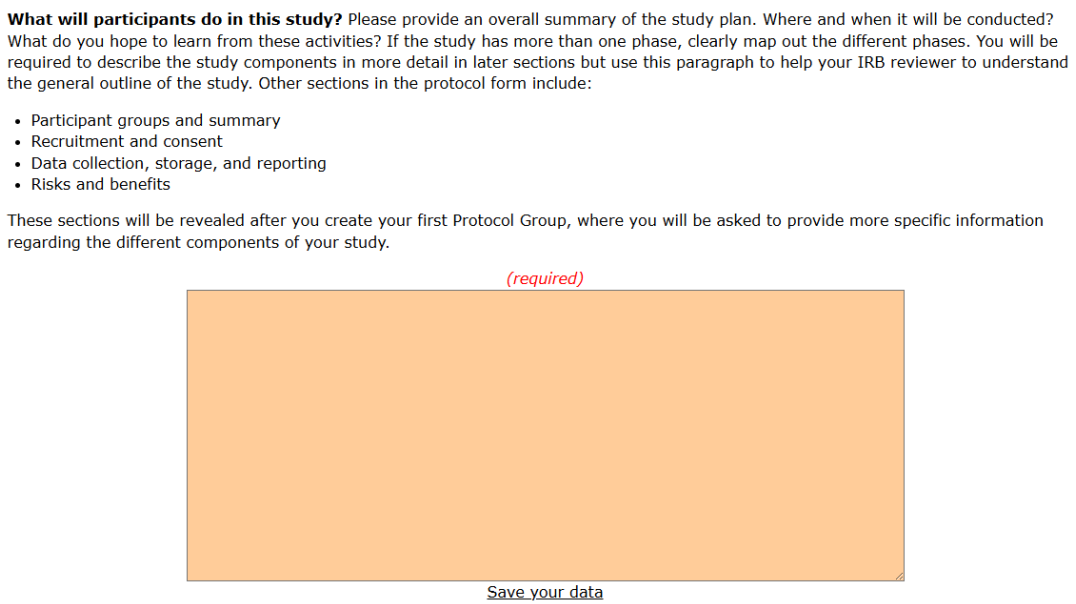
- Upload study documents such as
  - Consent form
  - Recruitment tools
  - Outside IRB approvals (if applicable)
  - Proposed study-specific research tools (e.g., questionnaires, interview questions)



IRB-SBS System

iProtocol

- Question box example



Submitting a Study to the UVA IRB

Identify if proposed research is human subject research

Use Evaluate My Project

If NO, your study does not need further IRB review

If YES, determine which IRB to submit to

See HRPP Website

If IRB-SBS:

Review Researcher Guide

Use iProtocol

Submit study documents for IRB-SBS Review

If IRB-HSR:

Review Researcher Guide and determine Submission Type

If IRB-HSR *Exempt*

Use Protocol Builder to generate study documents

Submit to IRBPro for IRB-HSR review

If IRB-HSR *Expedited or Full Board*

Use Protocol Builder to generate study documents

Submit to CRConnect for IRB-HSR and ancillary reviews

Final approved study documents available in IRBPro

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Human Research Protection Program

Protocol Submission Support

- IRB-HSR
  - Email: IRBHSR@virginia.edu
  - IRB-HSR Office Hours
- IRB-SBS
  - Email: IRBSBSHelp@virginia.edu
  - IRB-SBS Team Directory

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Human Research Protection Program

After IRB Approval

Modifications

- It is possible to make changes to your planned research after IRB approval.
- Any deviation from the original approved protocol must be submitted, reviewed by the IRB, and approved **before** implementation.
- Examples of common modifications
  - Change in recruitment methods
  - Incentive amounts
  - Data collection methods
  - Some personnel changes
- IRB-HSR: Use **IRBPro** to submit modification
- IRB-SBS: Use **iProtocol** to submit modification

Reportable Events

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IRB recognizes there are different types of undesirable research events

- Protocol deviations (Minor deviations, major deviations, unanticipated problems)
- Non-compliance (Serious non-compliance, continuing non-compliance)

- All major protocol deviations and issues of noncompliance must be reported to the IRB-HSR immediately upon discovering them, and no later than seven (7) calendar days from the time the study team receives knowledge of the event

- Events must be reported within the protocol DSMP required timeframe

- Unsure? Please communicate with the IRB so we can guide you in the next steps

Post Approval Monitoring

- The purpose is to ensure research participants are safe and verify research is being conducted as approved by the IRB
- Study selection for a PAM review
  - Random selection
  - Follow-up of previous audit findings or IRB request
  - Requested assistance with FDA or sponsor audit preparation
  - New CRC or PI assessment
  - Focus on non-UVA IRB of record or UVA sIRB of multi-site study
  - Study team request
- Multi-step review process remote or in-person

Goals of the PAM Review Process

The PAM & Ed Team will use findings to make recommendations to study teams and to develop educational resources that support the UVA research community.

Discussion

Additional Resources

- Evaluate My Project
- IRB-HSR Website & Researcher Guide
- IRB-HSR Submission Types Guide
- IRB-SBS Website and Researcher Guide
- Microlearning videos
- UVA Human Research Protection Program (HRPP)

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IRB Systems

- IRB-HSR:
  - IRB Online & Protocol Builder
  - IRB Pro
  - CRConnect2 (SOM)
- IRB-SBS:
  - iProtocol

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IRB Contacts

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Thank you!

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