

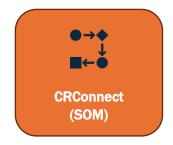
## School of Medicine (SOM) and Institutional Review Board (IRB) Research Systems at UVA

## **Study Start-Up**



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 nonengaged. 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 <u>IRB-HSR staff</u> or IRBHSR@virginia.edu



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



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 <u>IRB-HSR staff</u> or IRBHSR@virginia.edu

## **Study Management**



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.



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**.