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— EST. 1818 —

# ARCH-IRB Overview Faculty Senate-March 2025





# Background & Context

- A 2022 Huron Consulting Engagement recommended replacement of antiquated legacy eIRB system, which was inefficient and lacked adherence with updated Common Rule (HHS)
- Product Selection- An RFP and selection process was undertaken to select its replacement, resulting in the selection of the Huron IRB platform
- Huron IRB is the leading product in the market nationally and used by more R1 Universities and academic medical centers than any other product
- Designed with both software and IRB toolkit/SOPs that is fully compliant with 2018 Common Rule and AAHRPP Accreditation requirements



# ARCH IRB Facts

- ARCH stands for Administration & Research Collaborative Hub and is also a reference to the St. Louis Arch
- Scalable to additional modules in the future (e.g. Conflicts of Interest)
- Features single sign-on for easy access
- Currently working on migration of all existing studies from eIRB into the ARCH platform
- Link to the system is available on the SLU MyApps page



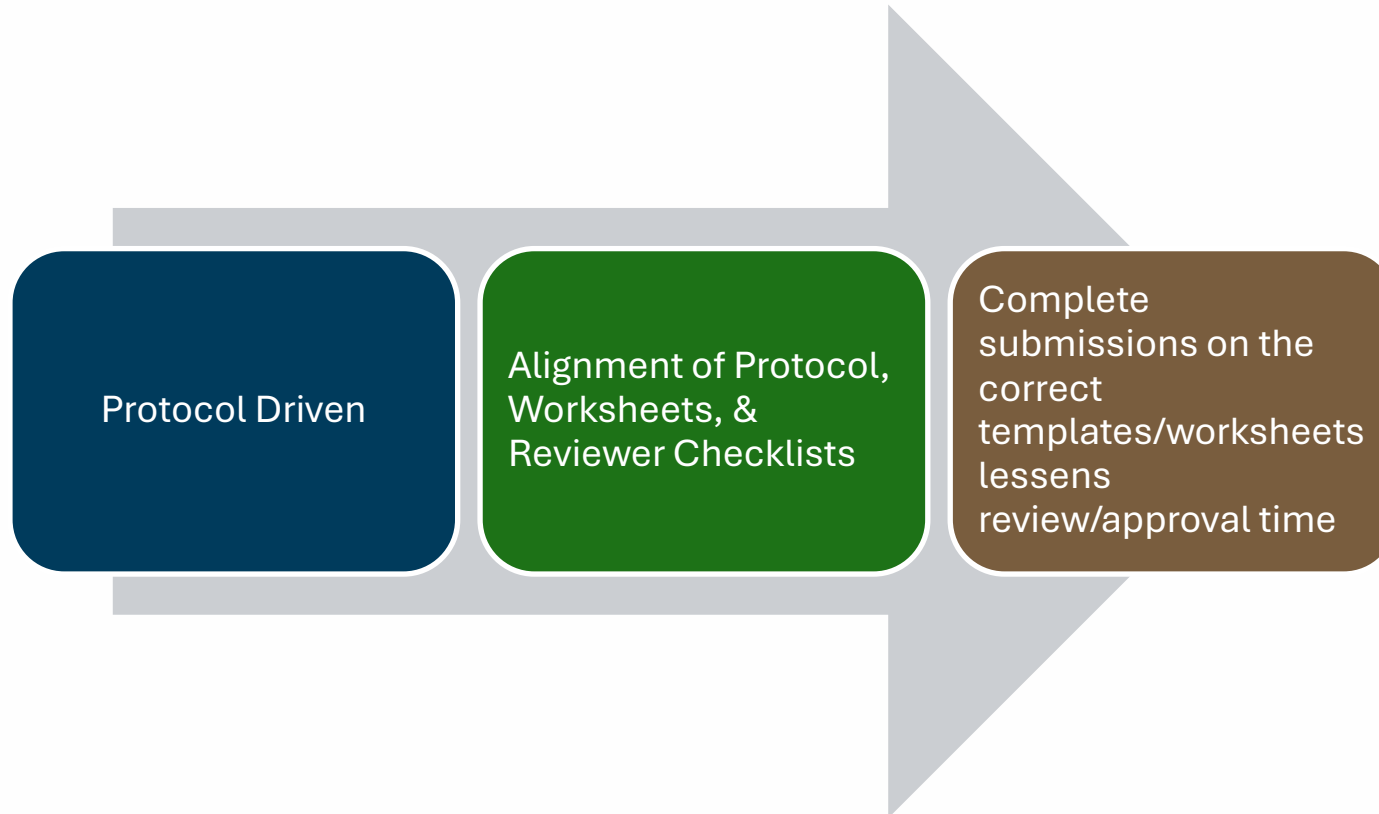
# ARCH-IRB Features/Capabilities

- Library of SOPs, Templates, Worksheets, & Checklists for reference and use by researchers, IRB staff, and IRB reviewers
- Direct feeds from CITI to manage user compliance training status
- Training resources like slides and recorded videos available at any time. In-person training also ongoing and available.
- User dashboard interface with existing active studies, current submissions, enhanced transparency & review status with prompt emails if something is awaiting your action
- Used for both SLU IRB and IRB reliance management
- Single interface for all aspects of the IRB process
- System and processes designed to align templates, checklists, and review processes with regulatory and approvability requirements





# ARCH-IRB Process



- Protocol templates contain guidance to point you to the correct corresponding worksheet(s)
- IRB staff will provide link to appropriate templates/worksheets in their comments/stipulation



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# ARCH IRB System Preview


The dashboard displays a grid of application tiles. A green arrow points to the 'ARCH-IRB' tile in the bottom right corner of the grid.

Application	Icon
Incident Report Form	MAXIENT
CourseLeaf CIM-Courses	CourseLeaf
Glint Manager Access	Star
Historical HR / Finance	Historical HR / Finance
Banner Self Service - Student	Banner
Payment Suite	Payment Suite
911 INFORM	911 INFORM
REDCap Survey	REDCap
SLU Course Materials Ordering	Textbook Brokers
Billiken Bookstore	THE BILLIKEN SHOP
Wellness Portal - App	SAINT LOUIS UNIVERSITY Student Health Center
Percipio	skillssoft percipio
International Student Portal	SAINT LOUIS UNIVERSITY INTERNATIONAL SERVICES
myCPHSJ	myCPHSJ college intranet page
Human Resources SharePoint	SAINT LOUIS UNIVERSITY
Transact SLU Cards	TRANSACT
Charter - Spectrum U	Spectrum U
ARCH-IRB	ARCH-IRB
Zoom (Telemedicine)	Zoom

⊕ Add section



# ARCH IRB Dashboard



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[Dashboard](#) | [Admin](#) | [IRB](#) | [Settings](#)

Page for Lee Seabrooke

[Create](#)

### Recently Viewed

Recent	Pinned
STUDY00000022: The Influen...n in the JHS	
STUDY00000013: Shifts in Ma...il Relations	
STUDY00000015: Intertrochan...ure Outcomes	
STUDY00000014: Outcomes of ...t Treatments	
IRB Central Actions: IRB Central Actions	
STUDY00000005: RPP Testing Outcomes	
STUDY00000000:	

My Inbox | My Reviews

### My Inbox

Filter by ID  [+ Add Filter](#) [X Clear All](#)

ID	Name	Date Created	Date Modified	State	Coordinator
No data to display.					

◀ page 1 of no results ▶





# ARCH IRB Library

IRB > Library

**Library**

Standard Operating Procedures | General | Worksheets | Checklists | Templates

Name	Document
HRP-306 - WORKSHEET - Drugs and Biologics	HRP-306 - WORKSHEET - Drugs and Biologics
HRP-307 - WORKSHEET - Devices	HRP-307 - WORKSHEET - Devices
HRP-310 - Worksheet - Human Research Determination	HRP-310 - Worksheet - Human Research Determination
HRP-311 - Worksheet - Engagement Determination	HRP-311 - Worksheet - Engagement Determination
HRP-312 - Worksheet - Exemption Determination	HRP-312 - Worksheet - Exemption Determination
HRP-313 - Worksheet - Expedited Review	HRP-313 - Worksheet - Expedited Review
HRP-314 - Worksheet - Criteria for Approval	HRP-314 - Worksheet - Criteria for Approval
HRP-319 - Worksheet - Limited IRB Review and Broad Consent	HRP-319 - Worksheet - Limited IRB Review and Broad Consent
HRP-830 - WORKSHEET - Communication and Responsibilities	HRP-830 - WORKSHEET - Communication and Responsibilities

9 items | page 1 of 1

- For Investigator-Initiated Studies, please use our protocol templates to ensure complete submissions and lessen turnaround times





# ARCH IRB System Preview

Dashboard IRB

Page for Rebecca Simms (pi) Help

Create ▾

My Inbox My Reviews

### My Inbox

Sort by  Enter text to search

	Name	Date Created	Date Modified	State	Coordinator
<input type="button" value="Create New Study"/>	STUDY00000007 Onboarding Demo 7	11/6/2023 12:05 PM	12/4/2023 3:46 PM	Clarification Requested (Pre-Review)	Orlando Max (irbc)
<input type="button" value="Report New Information"/>	STUDY00000015 test	11/14/2023 11:36 AM	12/1/2023 9:56 AM	Pre-Submission	
	STUDY00000009 Test 1_SLU	11/7/2023 2:17 PM	11/30/2023 12:17 PM	Pre-Submission	
	RNI00000009 Onboarding Demo 11/15	11/15/2023 12:07 PM	11/20/2023 1:14 PM	Pre-Submission	
	CR00000003 Continuing Review for Study Onboarding MSS- Internal 11/16/2023	11/16/2023 2:31 PM	11/16/2023 2:31 PM	Pre-Submission	Orlando Max (irbc)
	STUDY00000013 20231108KB	11/8/2023 3:22 PM	11/9/2023 12:59 PM	Clarification Requested (Pre-Review)	Orlando Max (irbc)
	MOD00000004 Modification / Update #2 for Study Onboarding Study 2	11/1/2023 12:43 PM	11/6/2023 12:00 PM	Deferred	Orlando Max (irbc)

7 items page 1 of 1 25 / page

- STUDY00000002: Onboarding Study 2
- STUDY00000015: test
- RNI00000009: Onboarding Demo 11/15
- STUDY00000025: LS\_1
- CR00000005: Continuing R...y 20231115KB



# ARCH IRB System Preview

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You Are Here: >> \_IRBSubmission

## Creating New: IRB Submission

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Basic Study Information

### Basic Study Information ?

- 1. \* Title of study:**
- 2. \* Short title: ?**
- 3. \* Brief description: ?**
- 4. \* What kind of study is this? ?**

Multi-site or Collaborative study  
 Single-site study  
[Clear](#)
- 5. \* Will an external IRB act as the IRB of record for this study? ?**

Yes  No [Clear](#)
- 6. \* Local principal investigator: ?**

Rebecca Simms (pi) ... +
- 7. \* Does the local principal investigator have a financial interest related to this research? ?**

Yes  No [Clear](#)
- 8. \* Attach the protocol: ?**

+ Add

Document	Category	Date Modified	Document History
<span style="font-size: x-small;">Update</span> <span style="font-size: x-small;">Best Protocol Document(1.0)</span>	IRB Protocol	1/3/2024	History <span style="float: right;">?</span>





# ARCH IRB System Preview

## Study Funding Sources [?](#)

## Local Study Team Members

## Study Scope [?](#)

## Drugs [?](#)

## Devices [?](#)

## Local Site Documents [?](#)

### 1. Consent forms: (include an HHS-approved sample consent document, if applicable) [?](#)

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

### 2. Recruitment materials: (add all material to be seen or heard by subjects, including ads) [?](#)

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

### 3. Other attachments:

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			



# ARCH IRB System Preview

Dashboard
IRB

Submissions
Meetings
Reports
Library
Help Center

IRB > Best Trial

Pre-Submission

Last updated: 1/3/2024 9:26 AM

**Next Steps**

Edit Study

Printer Version

- [Submit](#)
- [Assign Primary Contact](#)
- [Assign PI Proxy](#)
- [Manage Ancillary Reviews](#)
- [Manage Guest List](#)
- [Add Related Grant](#)
- [Add Comment](#)
- [Copy Submission](#)
- [Discard](#)

## STUDY00000026: Best Trial

**Principal investigator:** Rebecca Simms (pi)  
**Submission type:** Initial Study  
**Primary contact:** Rebecca Simms (pi)  
**PI proxies:**

**IRB office:** IRB 1

**IRB coordinator:**

```

graph LR
    A[Pre-Submission] --> B[Pre-Review]
    B --> C[IRB Review]
    C --> D[Post-Review]
    D --> E[Review Complete]
    B --> B1[Clarification Requested]
    B1 --> B
    C --> C1[Clarification Requested]
    C1 --> C
    D --> D1[Modifications Required]
    D1 --> D
          
```

History
Funding
Contacts
Documents
Reviews
Snapshots

**Filter by** Activity  🔍 + Add Filter ✕ Clear All

Activity	Author
Study Created	Simms (pi), Rebecca





# ARCH IRB System Preview

## Pre-Review

Entered IRB: 1/3/2024 9:43 AM  
Last updated: 1/3/2024 9:43 AM

### Next Steps

View Study

Printer Version

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

Add Comment

Copy Submission

Withdraw

Discard

## STUDY00000026: Best Trial

Principal investigator: Rebecca Simms (pi)  
Submission type: Initial Study  
Primary contact: Rebecca Simms (pi)  
PI proxies:

IRB office:  
IRB coordinator:



History	Funding	Contacts	Documents	Reviews	Snapshots
Filter by <span>Activity</span> <input type="text" value="Enter text to search"/> <span>+ Add Filter</span> <span>✕ Clear All</span>					
Activity	Author				
Submitted	Simms (pi), Rebecca				
Study Created	Simms (pi), Rebecca				



## ARCH IRB System Takeaways

- SLU IRB system and processes now fully aligned with industry standards, best practices, and regulatory requirements
- Please use our protocol templates for investigator-initiated studies – additional attention on the submission on the front end will save time in the review/approval timeframe
- There will be a learning curve to adapt from the legacy eIRB system
- Don't get or stay frustrated...training is ongoing and available to you. Just contact the SLU IRB at [irb@slu.edu](mailto:irb@slu.edu)
- We are open to discussions and conversations if you experience challenges. We can't help if we don't know.





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# Questions?

