

# Institutional Review Board: New System Updates

Human Research Application Portal (HRAP) Improvements

### **Human Research Application Portal Features**

# Improved Design

- User friendly, modern interface, cloud based application
- Protocol based, as opposed to submission based
- Integrated help and guidance within the application
- Within system comment sections

# Integrations to Reduce Administrative Burden

- Phase 1: Integrations with PennERA, RIA, Workday, and IBC
- Phase 2: Integration with Velos CTMS

### Transparency Improvements

Improved transparency and tracking around items holding up approval

Status	Requirement	Completion State	Revision	Completed by
Draft Submission Pending	Submit Protocol	<b>✓</b> Completed	#1.1	Yoos, Jessa Researcher
PI Certification Pending	Certify Protocol (PI)	<b>✓</b> Completed	#1.1	Yoos, Jessica L
Pre-Submission Requirements	Department Approve Protocol	✔Not required	#1.1	Yoos, Jessica L
Pre-Approval Requirements	Ancillary OCR Sponsor Support Unit review	<b>✓</b> Completed	#1.2	Yoos, Jessica Ancillary
	Ancillary IBC review	Ready to Start		
	Ancillary Human Stem Cell Research Advisory Committee review	Ready to Start		
	Complete Human Subjects training on Citi: Jakub Svoboda	<b>✓</b> Completed	#1.1	Yoos, Jessica L
	Complete Human Subjects training on Citi: Jessa Researcher Yoos	<b>✓</b> Completed	#1.1	Yoos, Jessica L
	Complete Human Subjects training on Citi: David A Heagerty	<b>✓</b> Completed	#1.1	Yoos, Jessica L
	Complete COI Disclosure: Jessa Researcher Yoos	✓ Completed	#1.1	Yoos, Jessica L

#### **Human Research Application Portal Efficiency Improvements**

Smart e-forms for QI, NHSR, Compassionate Use, Just-in-Time, & Ongoing Reviews (e.g., CR, modifications, reportable event, deviation, etc.)

Facilitation of multicenter single IRB submissions with external site access

Automatic assigning and deadlines to IRB staff to improve prioritization and decrease time to review

Facilitation of personnel modifications, including **ability to add external personnel** and **auto-approvals**, if training and FCOI clearance are complete

Ability to submit a concurrent modification and continuing review in one submission

Researcher portfolio ad hoc reporting

System generated document lists for IRB letters

Immediate generation of protocol number in an intuitive format (e.g., 24-250)

### **Transparency Improvements**

► Table for tracking Penn Medicine Ancillary Committees' letters/correspondence, including the ability for these committees to communicate via the application.

Ancillary Reviews					
Ancillary Committee	Review Status	Status Submission Date	Letters/Correspondence		
	Pending				
☐ IRB CCHSRC Reviewer	Modifications Needed	03/21/2024 6:01 PM	gerd.be.eacicf_tracked_march2024.docx		
■ IRB CHPS Reviewer	Approved	03/21/2024 6:02 PM	gcar_7213_masterprotocolv8.0_clean_28oct2022_signed_updated.pdf consentform_irb.pdf		
IRB Contracts Offices Reviewer	Modifications Needed	09/04/2024 10:35 AM	ib_dnl593_ed_03_20240524.pdf		
	Approved	03/21/2024 6:02 PM	gerd.be.eacicf_tracked_march2024.docx		

### **Additional Efficiency Improvements**

Drag and drop file upload

Auto-generation of select IRB letters

Application version control and comparison

Enhanced workflow and automatic routing capabilities

