

# Clinical Research Improvement In Systems and Processes

## Steering Committee

### June 28



# Agenda

## 1. Short demo of the HSR Workflow:

1. new components and features as referenced in slide 3

## 2. High level description of the Interfaces:

1. Between the workflow and IRB systems (slide 4)
2. Between the workflow and OnCore systems (slide 5)

## 3. Project status (slide 6)

## 4. Coming soon / July-Sept (slide 7)

## 5. Oct-Dec (slide 7)

# Health Sciences Research Start-Up Workflow

## Health Sciences Research Start-Up







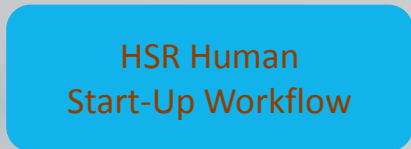
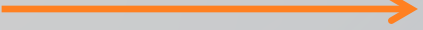
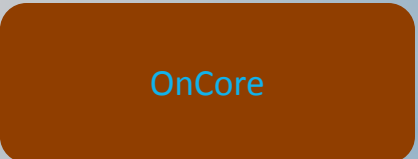
Process Phase	Step	Current Status	Last Action Taken
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	<p><u>Common Study (Study Type, Documents, Reports)</u></p> <p>Feasibility Assessment, Feasibility Assessment Committee</p> <p>Certification</p>		
<div style="background-color: #f4a460; padding: 5px; writing-mode: vertical-rl; transform: rotate(180deg);">                     Parallel processing with smart validations                 </div>	<p><u>Non-IRB Regulatory, HIRE</u></p> <p>IRB</p> <p>Contract</p> <p><u>Ancillary Services, IDS</u></p> <p>Epic Order Set</p> <p><u>Budget/Cost Analysis</u></p> <p>Billing Coverage Analysis</p> <p>PTAO</p> <p>Billing Set-up</p>		<p>Some options available:</p> <ul style="list-style-type: none"> <li>Open</li> <li>In Progress/Save</li> <li>Pending Approval</li> <li>Complete/Finalize</li> <li>Informational</li> </ul> <p>Date &amp; Timestamp is provided</p>
	<p>Ready for Enrollment Notification</p>		

# HSR Workflow and IRB Interfaces

	Purpose	From and When	What	To and How
1	<p>Single Point of Data Entry; Leveraging Workflow and IRB systems; Flexibility when to proceed in IRB Protocol Builder</p>	<p><b>HSR Human Start-Up Workflow</b></p> <p>(Step= TBD, Status= TBD)</p>	<p>→</p> <ul style="list-style-type: none"> <li>• UVA Study Tracking #</li> <li>• Study Name</li> <li>• PI Name</li> <li>• PI Org</li> <li>• Responsible Org</li> </ul>	<p><b>IRB Protocol Builder</b></p> <p>Creating an entry in IRB PB with UVA Study Tracking # (connecting two systems with primary key)</p>
2	<p>Visibility over Required vs. Not Applicable in the workflow; Electronic submission to non-IRB Regulatory</p>	<p><b>IRB Protocol Builder</b></p> <p>(IRB PB Non-IRB Regulatory=Submit)</p> <p>Repeated if IRB corrects</p>	<p>→</p> <ul style="list-style-type: none"> <li>• Non-IRB Regulatory</li> </ul>	<p><b>HSR Human Start-Up Workflow</b></p> <p>Opening non-IRB Regulatory steps as applicable for submission</p>
3	<p>Electronic submission to IRB via workflow</p>	<p><b>HSR Human Start-Up Workflow</b></p> <p>(Step=IRB, Status=Submit)</p> <p>Repeated if IRB rejected</p>	<p>→</p> <ul style="list-style-type: none"> <li>• Common Study</li> <li>• Personnel</li> <li>• Non-IRB Regulatory Statuses</li> <li>• Documents</li> </ul>	<p><b>IRB Protocol Builder</b></p> <p>Ready to start pre-review and access submitted information</p>
4	<p>Visibility over personnel and IRB status: (a) Prior to IRB Approval (b) After IRB Approval and prior to Opening Study for Enrollment in the workflow</p>	<p><b>IRB Protocol Builder</b></p> <p>(IRB Review Coordinator updated)</p> <p><b>IRB Online</b></p> <p>(Status update, Event change)</p>	<p>→</p> <ul style="list-style-type: none"> <li>• IRB Review Type</li> <li>• IRB Agenda Date</li> <li>• IRB Event Statuses</li> <li>• Personnel</li> <li>• Documents</li> </ul>	<p><b>HSR Human Start-Up Workflow</b></p> <p>Step=IRB, Status = Approve/Reject Update IRB information Update Personnel information</p>

# HSR Workflow and OnCore Interfaces

Purpose	From and When	What	To and How
Submission to Protocol Review Committee (PRC); Single data entry	 <p>Step =PRC, Status = "Submit"</p>	 <ul style="list-style-type: none"> <li>• UVA Study Tracking #</li> <li>• &lt;PRC required information&gt;</li> </ul>	
View PRC status; Transparency	 <p>PRC Approved                      PRC Rejected</p>	 <ul style="list-style-type: none"> <li>• UVA Study Tracking #</li> <li>• Status</li> <li>• Notes</li> </ul>	
Transition from "start-up" to "conduct"	 <p>Study approved for enrollment</p>	 <ul style="list-style-type: none"> <li>• UVA Study Tracking #</li> <li>• Executed Contract</li> <li>• Executed IRB Approval Assurance</li> <li>• PTAO information</li> <li>• Executed BCA</li> <li>• TBC</li> </ul>	

# Next 90 days view

2016

June

Next 90 days

2017

Feb	Mar	April	May	June	July	August	Sept	Oct	Nov	Dec	Jan



Common Study

Expected to continue

Contract

Not started

Specification

Interface with ResearchUvA

Feasibility Assessment

Certification

PTAO

Not started

Specification



Ancillary Services - IDS

Ancillary Services - Other



Epic Order Set



Billing Coverage Analysis



Budget/Cost Analysis..

New application



Non-IRB Regulatory

Expected to continue

Specification

Interfaces with IRB systems



IRB

Expected to continue



Interface with OnCore

## Legend & Resources:

Workflow Configuration  
(Configurator, SME)

Programming,  
System Interfaces (IT)

Specification  
(SME and IT)



On track



More attention



Issue,  
team managing



Issue, need help



Initiation & Security,

Change within Start-up and transition to "Conduct"

Expected to continue

# July – Sept and Oct – Dec, 2016

## 1. Coming soon / July-Sept:

- Project update (entire project team) on July 20
- Partnership and system interfaces with ResearchUvA
- Engaging with other schools
- Forte, OnCore vendor: review and procurement
- Specification and planning completed

## 2. Oct - Dec:

- Educational components
- Portfolio and prioritization
- Metrics and analysis
- Change management
- Final estimations
- Rollout decisions