

# Clinical Research Improvement In Systems and Processes

## Steering Committee

### May 24



**Non-IRB Regulatory**

- ISPRO
- RSC / HIRE
- PRC
- Scientific Pre-Review
- IBC
- Medical Device
- Gene Transfer
- Cert. of Confidentiality
- Conflict of Interest
- ESCRO
- FERPA / SBS
- CIRB

**Ancillary Services**

- Investigational Drug Services
- Biorepository and Tissue Research Facility (BTRF)
- Radiology and Medical Imaging
- Clinical Laboratories
- Ambulatory Clinic/Hospital Nursing Unit/Cancer Center Infusion
- New Medical Device/Supply Chain Management
- Clinical Research Unit
- Continuum Home Health
- Therapy Services (Physical Therapy, Occupational Therapy)

Health Sciences Research  
Human Study Start-Up

- Personnel, Common Study
- Feasibility Assessment
- Non-IRB Regulatory
- IRB
- Budget
- Billing Coverage Analysis
- Contract
- PTAO (request)
- PTAO (notification)
- Ancillary Services

✓ Ready for Enrollment

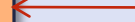
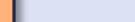
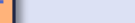
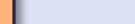
IRB Protocol Builder

IRB Online

ResearchUVa

OnCore

When proposal submitted for funding in ResearchUVa first



# Health Sciences Research Start-Up Workflow

## Health Sciences Research Start-Up

Process Phase	Step	Current Status	Last Action Taken
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	Personnel, <u>Common Study</u>  <u><b>Feasibility Assessment, Feasibility Assessment Committee</b></u>  Certification		
Parallel processing with smart validations	<u><b>Non-IRB Regulatory</b></u>  IRB  Contract  <u><b>Ancillary Services, IDS</b></u>  <u><b>Epic Order Set</b></u>  Budget/Cost Analysis  <u><b>Billing Coverage Analysis</b></u>  PTAO  Billing Set-up	Some options available: <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>	
	Ready for Enrollment Notification		Date & Timestamp is provided

# Next 90 days view

2016

90 days

2017

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



Common Study



Contract

Specification

Interface with ResearchUvA



Feasibility Assessment



Certification



PTAO

Specification



Ancillary Services - IDS

Ancillary Services - Other

Epic Order Set



Billing Coverage Analysis



Budget/Cost Analysis..

New application



Non-IRB Regulatory

Specification

Interfaces with IRB systems

IRB



Initiation & Security,  
Change within Start-up and transition to "Conduct"

## Legend & Resources:

Workflow Configuration  
(Configurator, Workgroup)

Programming, Interfaces  
(IT)

Specification  
(Workgroup and IT)



On track



More attention



Issue,  
team managing



Issue, need help