Tufts CTSI
Common Metrics Implementation

Learning Session 1

August 30, 2016

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Common Metrics Implementation

Agenda

- Welcome and Introductions
- Opportunities to Advance Translational Science via the Common Metrics Initiative
- Indiana CTSI IRB Process Improvement Project

Opportunities to Advance Translational Science via the Common Metrics Initiative

Redonna Chandler, PhD

Deputy Director, Division of Clinical Innovation

NCATS

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Common Metrics Initiative

August Collaborative Learning Session

Indiana CTSI IRB Process Improvement Project

Brenda Hudson, MA CCRP LSSBB
Director of Operations, Indiana CTSI
Joe Hunt, MPH, LSSBB
Director, Tracking and Evaluation, Indiana CTSI

Learning Objectives: At the end of the session participants will be able to:

- Describe the uses of a process map.
- Describe how to create a process map.
- Explain how a process map can be used to depict the IRB approval process.
- Describe some common types of IRB approval process delays.

Background to Indiana CTSI IRB Process Improvement Project

- Problem: How do we reduce approval times from date of submission to IRB until final approval letter is sent to the investigator?
- Prior to RBA training, we used Lean Six Sigma Methods
  - Project start up
  - Voice of the customer (getting process owners engaged early)
  - DMAIC (define, measure, analyze, improve, control)
  - Process mapping

Step 1: Engage Process Owners and Stakeholders

It is critical to engage the individuals who “own the process” early in the project and invite them to be part of the discussion

These individuals have:

- Detailed knowledge of the process
- Documentation of variation in process
- Source of improvement ideas
- Implementation of solutions

Indiana CTSI IRB Process Improvement Project

Project Start-up and Charter

Issues to be Addressed:

- Ideal process map for new, full-board submissions to move through the IRB post-meeting system to final approval
- Variability in the IRB and HSO processes and outputs
- Variability in the experiences of researchers (customers)
- Analysis of current post-meeting processes to final approval

Project Goal/Expected Results:

- Streamlined IRB meeting review, dissemination of communications/documents and approval processes
- Evaluate other AAHRPP-accredited HRPP organizational approaches
- Determine appropriate HSO organizational approach to maximize process improvements
- Maintain high quality review processes and protections for human subject research projects
- Track key metrics of HSO processes and benchmark them against best national standards

Team Responsibilities & Boundaries:

- Develop a process map of the current state best practices.
- Identify the inter-dependencies between sub-processes
- Produce a process map which meets the customer expectations
- Identify areas for improvement
- Implement improvements
- Analyze improvements

Support/Resource People:

- 5-10% of team member's effort.
- Access to stakeholders
- Access to data/metrics of existing processes

Stakeholders and Customers Impacted by this Project:

- Stakeholders: Dean, IU-SOM; Vice President for Research IU-SOM; IU-Research Compliance; Director, Indiana CTSI
- Customers: Researchers, Human Subjects, IRB members

Indiana CTSI IRB Process Improvement Project

Define the focus of the project and why it is important

1. **Project Charter:** used as
   a. a "contract" between the Six Sigma Team, CTSI and HSO leadership to ensure support for the project.
   b. for discussion and to create a problem statement, the issue(s) to be addressed, the goals of the project and rules and responsibilities of the team and the members.
   c. a "living" document
2. **Value Stream Map:** way to understand the "voice of the process", through a customer's voice, expectations, preferences, comments, of a product or service.

Measure the current process (steps in process and times)

3. **Current State Process Map:** used to understand some of the complexities and value/non-value added steps in the process.
4. **Data Collection:** collection of information related to process such as time for each step.
5. **GEMBA walk:** "walk the process" – observing the process and documenting it (i.e. "time-motion study"

Indiana CTSI IRB Process Improvement Project

Types of Waste in Processes

Turn-the-Curve Thinking

Work backwards to the Means

"Turn the Curve"?

Start with the End

Change the trend?

STRATEGY

Where are we headed?

Value stream and process mapping used to document processes

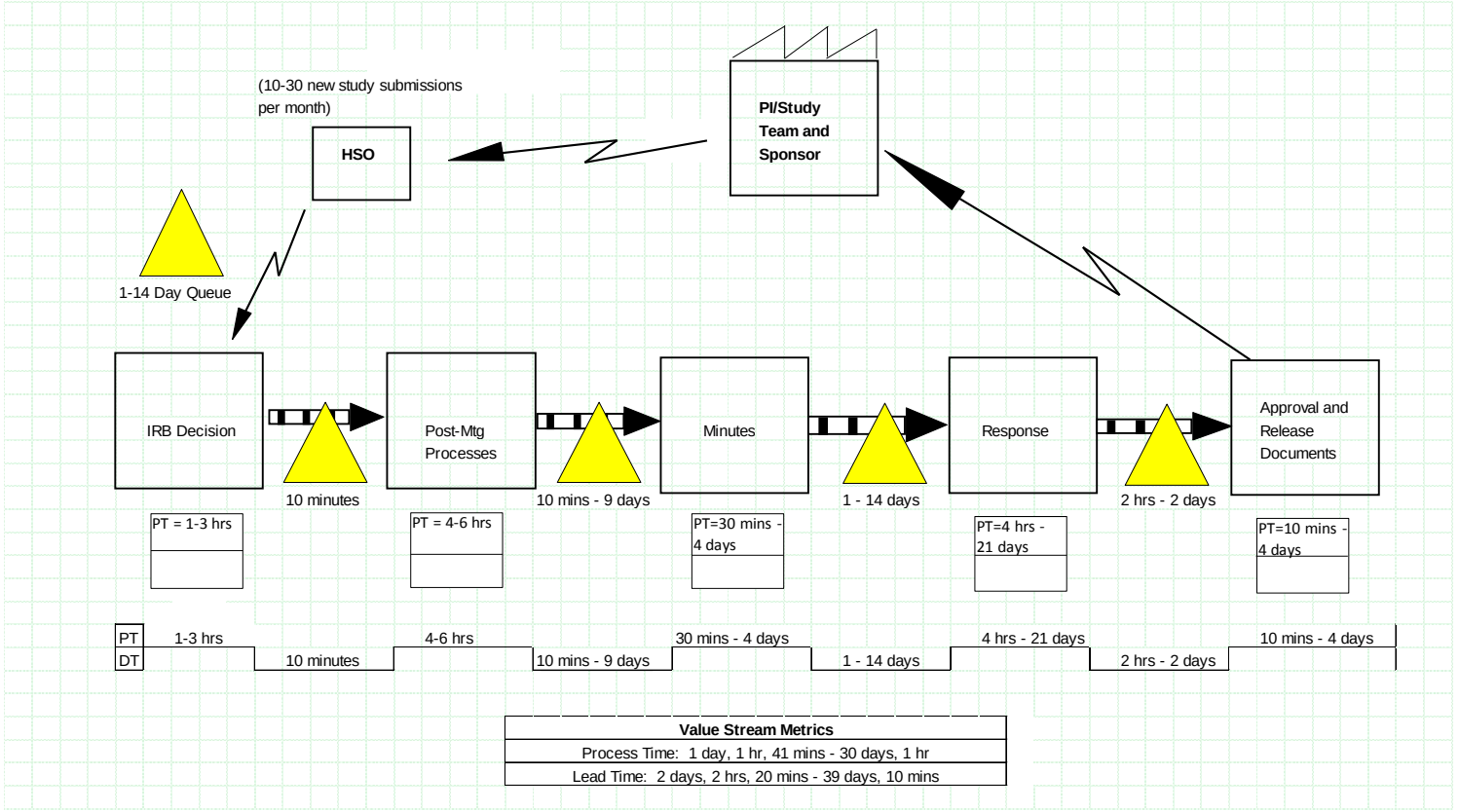
What are we going to do?

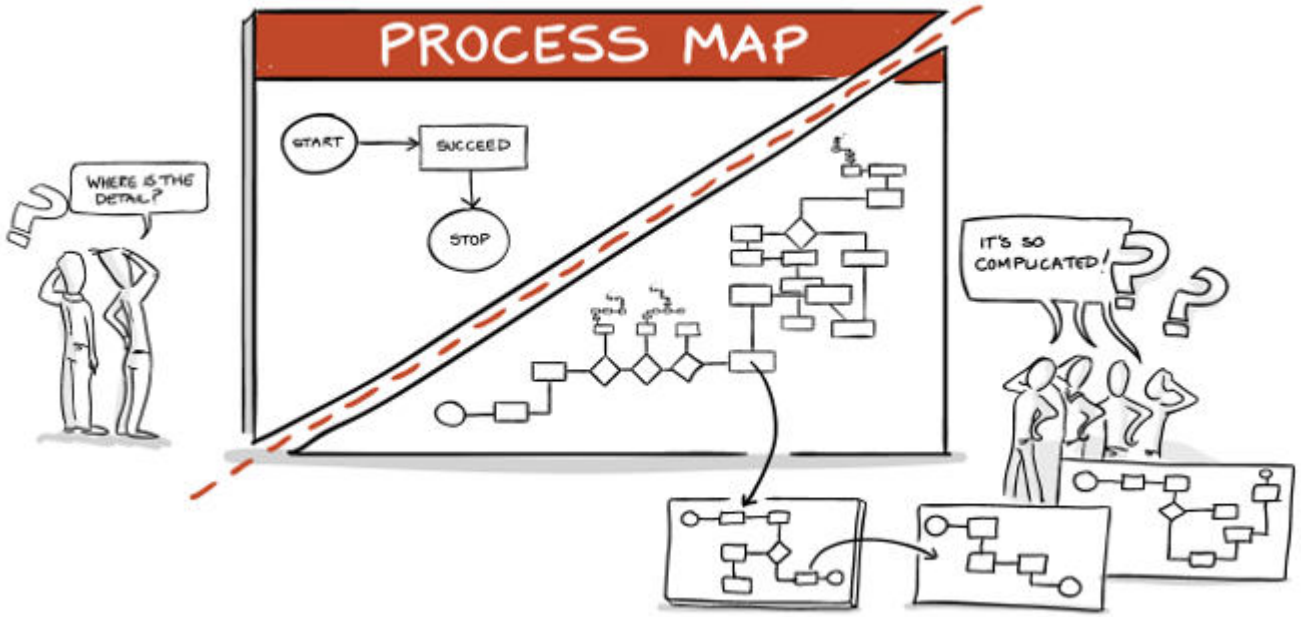
Why?

Who can help? Options?

Indiana CTSI IRB Process Improvement Project

Value Stream Map:





Process Mapping Symbols

Action/Process

End
Start

Start or End

Document

System Activity

No

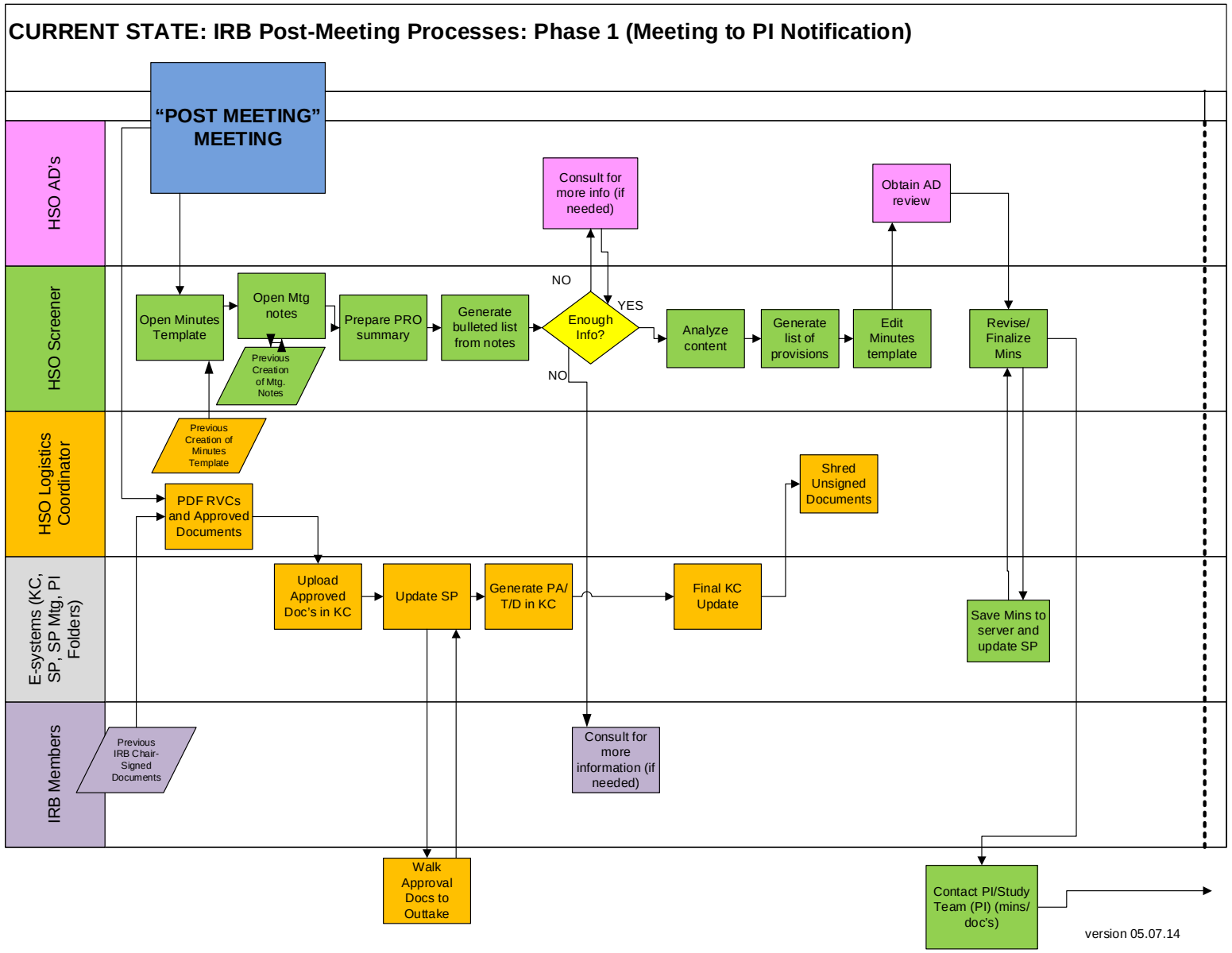
On Page Connector

Direction of Flow

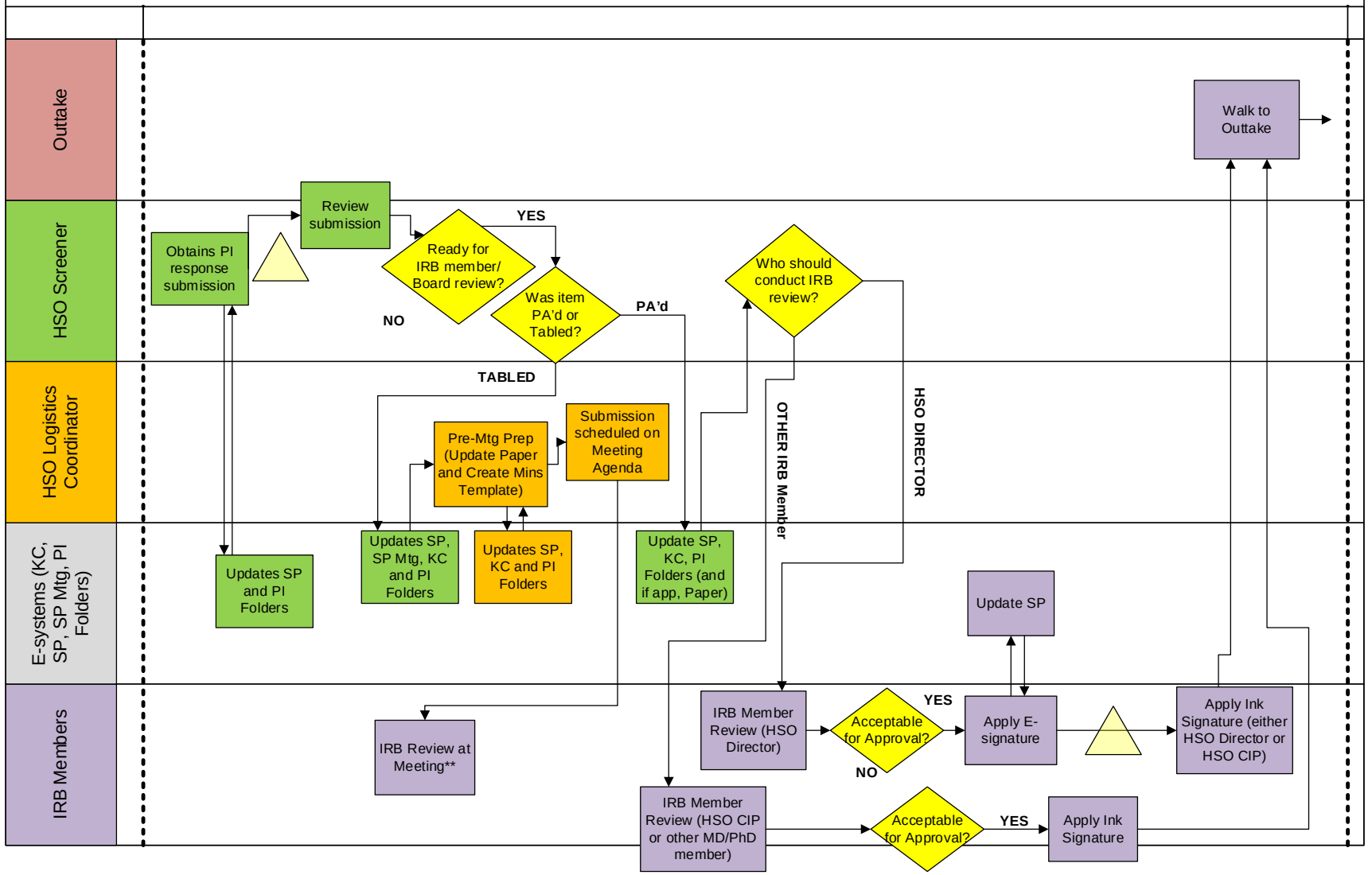
Decision

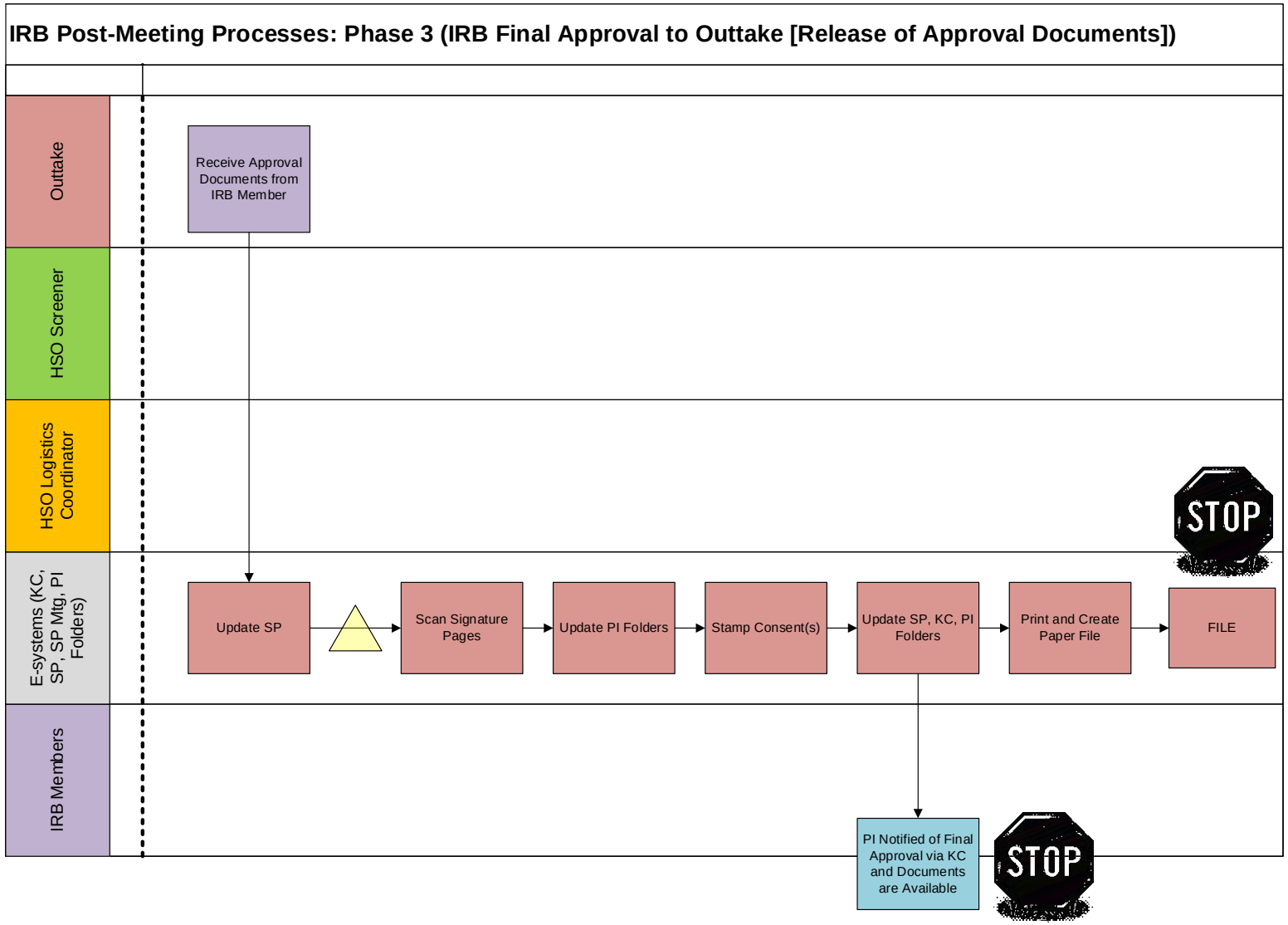
Yes

Off Page Connector


CURRENT STATE: IRB Post-Meeting Processes: Phase 1 (Meeting to PI Notification)
"POST MEETING" MEETING
HSO AD's
HSO Screener
HSO Logistics Coordinator
E-systems (KC, SP, SP Mtg, PI Folders)
IRB Members
Consult for more info (if needed)
Obtain AD review
Open Minutes Template
Open Mtg notes
Prepare PRO summary
Generate bulleted list from notes
Enough Info?
NO
YES
NO
Analyze content
Generate list of provisions
Edit Minutes template
Revise/ Finalize Mins
Previous Creation of Mtg. Notes
Previous Creation of Minutes Template
PDF RVCs and Approved Documents
Shred Unsigned Documents
Upload Approved Doc's in KC
Update SP
Generate PA/ T/D in KC
Final KC Update
Save Mins to server and update SP
Previous IRB Chair-Signed Documents
Consult for more information (if needed)
Walk Approval Docs to Outtake
Contact PI/Study Team (PI) (mins/ doc's)
version 05.07.14

IRB Post-Meeting Processes: Phase 2 (Response to IRB Final Approval)




IRB Post-Meeting Processes: Phase 3 (IRB Final Approval to Outtake [Release of Approval Documents])
Outtake
HSO Screener
HSO Logistics Coordinator
E-systems (KC, SP, SP Mtg, PI Folders)
IRB Members
Receive Approval Documents from IRB Member
Update SP
Scan Signature Pages
Update PI Folders
Stamp Consent(s)
Update SP, KC, PI Folders
Print and Create Paper File
FILE
STOP
PI Notified of Final Approval via KC and Documents are Available
STOP

Indiana CTSI IRB Process Improvement Project

WASTE	Examples of Waste Identified in IRB Project
 Defects	• Staff inspects Reviewer Checklists from IRB members to look for missing information.
 Waiting	• Batching minutes (writing for review by AD; AD review) • Staff wait until entire meeting (and internal Post-Meeting Meeting) is complete before processing/minutes writing begins • Investigator submits response to IRB review and must wait for processing/approval
 Motion	• Staff have to physically walk to printers down the hall to pick up printed items • Must physically deliver wet-ink signature pages during post-meeting processing
 Overprocessing	• Review by Asst/Assoc Director prior to minutes being sent out to investigator. • Staff must inspect Reviewer Checklists from IRB members to look for missing information/regulatory determinations. • Any re-work per items not being approved – editing minutes, agendas, provisions, etc. • Scanning documents in early post-meeting phase when not really needed to be scanned until final phase (e.g., excess 'inventory' of documents prior to when they are needed)

Analyze: identify, organize and validate critical outputs

Improve: develop and test solutions to process variation

Implementation Plan: This is where you implement solutions

Looking for "Ideal State": An ideal state was discussed so that the team could envision the process with reduced variation and waste. Characteristics of the ideal state included a reduction of "hand offs" from team member to team member, allowing a smaller number of people to "walk" a project through approval; completion of approval and minutes as close to the end of the IRB meeting as possible; reduction (if not elimination) of inspection of minutes

Control: monitor performance change

Calculate new average for time from IRB review to final approval notification

Statistical analysis

Things to remember:

- Engage process owners early
  - Documenting process
  - Developing strategies to improve
- Thoroughly document process steps
- Collect data on each step
- Develop quick victories
- Sustain effort
- Monitor performance

Possible delays:

- Clarification of decisions by IRB chair
- An approver is OoO or busy
- PI and/or team is non-responsive or slow to respond
- PI/team has to talk with sponsor first
- Backlogged due to number of studies processed and/or number and complexities of provisions

Questions

Next Learning Session

Tuesday Sep 27, 2016 3pm – 4pm Eastern

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