OHSRP Education Series: eIRB Demo & Change Considerations

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OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

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Agenda

Announcement! System name: ‘PROTECT’

System Selection

Partnerships and Stakeholders

Project Progress

Testing

Training

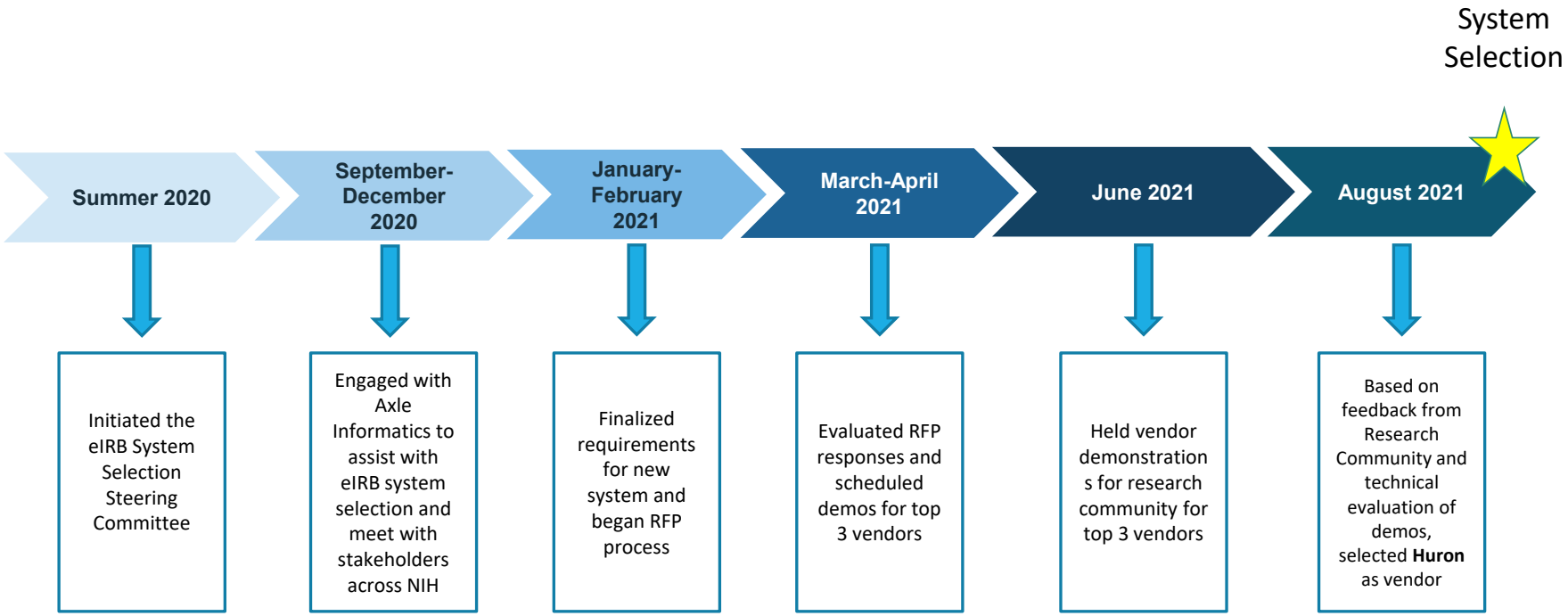
Migration Plan and Cutoffs

System Overview and Demo

Known Process Considerations

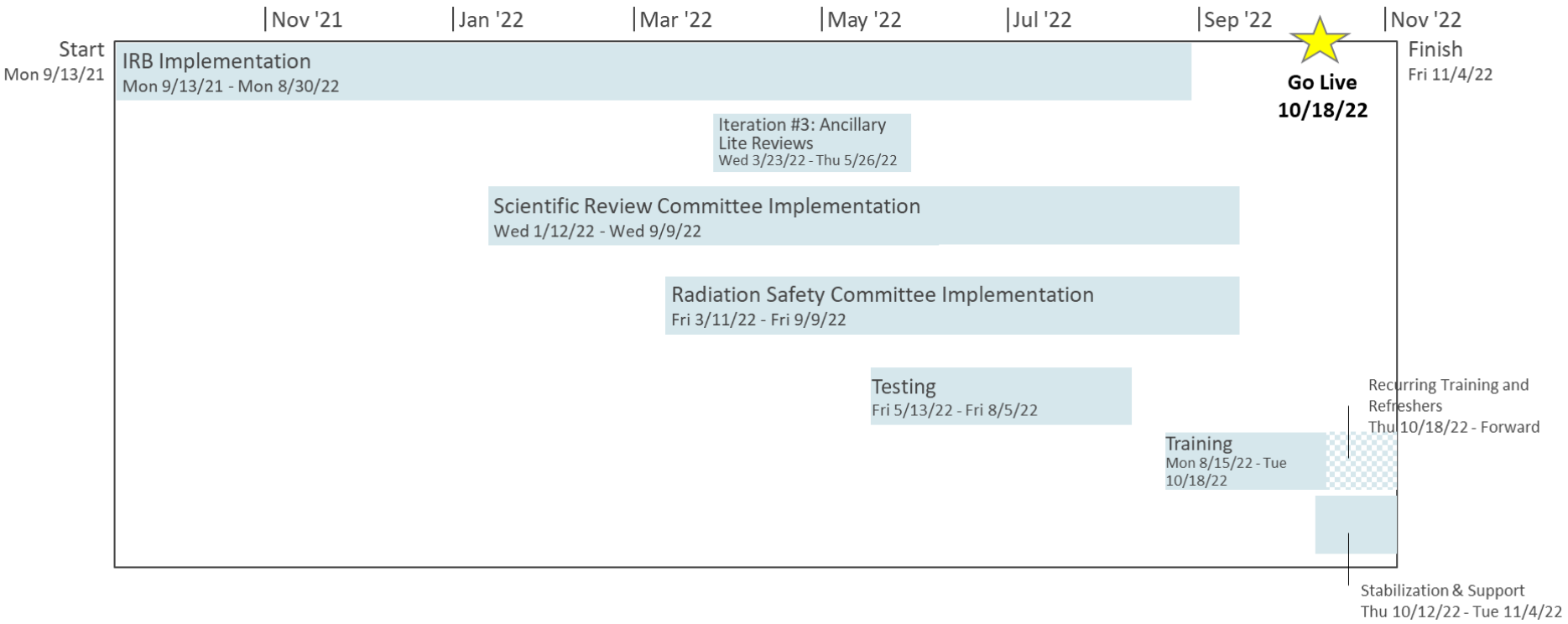
Resources

System Selection



NIH Partnerships and Stakeholders

Progress


Nov '21
Jan '22
Mar '22
May '22
Jul '22
Sep '22
Nov '22
Start
Mon 9/13/21
IRB Implementation
Mon 9/13/21 - Mon 8/30/22
Go Live
10/18/22
Finish
Fri 11/4/22
Iteration #3: Ancillary Lite Reviews
Wed 3/23/22 - Thu 5/26/22
Scientific Review Committee Implementation
Wed 1/12/22 - Wed 9/9/22
Radiation Safety Committee Implementation
Fri 3/11/22 - Fri 9/9/22
Testing
Fri 5/13/22 - Fri 8/5/22
Training
Mon 8/15/22 - Tue 10/18/22
Recurring Training and Refreshers
Thu 10/18/22 - Forward
Stabilization & Support
Thu 10/12/22 - Tue 11/4/22

Testing

Testing Group	Content	Timeframe
Huron	Test the individual system requirements that were requested by NIH.	*In Progress*
eIRB Exec Team	Test the individual system requirements that were requested by NIH.	*In Progress*
eIRB Core Team	End-to-end system testing to ensure it behaves as expected.	~ Early July
NIH End Users	End-to-end system testing to ensure it behaves as expected.	~ Late July

Trainings: Researcher

Training Course	Content	Timeframe
Getting Started with PROTECT	Overview of system log-in, workspaces, dashboards, navigation, and locating studies and documents	Aug - Oct
Submitting an Initial Study in PROTECT	End-to-end training of new studies, including ancillary reviews (RSC, SRC, DEC, PRIA, IBC)	Aug – Oct
Submitting Mods, CRs, and RNIs in PROTECT	End-to-end training of "follow-on submissions" (Continuing Reviews, Modifications, and Reportable New Information)	Aug - Oct
Multisite Studies Management in PROTECT	Review of multisite activities, including adding sites, site-specific amendments, site-specific CRs, etc.	Aug - Oct

Trainings: Reviewer/Leadership/Staff

Training Courses	Overview	Timeframe
• OHSRP Staff/IRB Member Training	Log-in, workspaces, dashboards, navigation, and locating studies and documents, and conducting activities for various roles in the IRB workflow.	Sept - Oct
• Scientific Review for Scientific Review Coordinators • Scientific Review for Reviewers • SRC Chairs/Designated Reviewer Training	Log-in, workspaces, dashboards, navigation, and locating studies and documents, and conducting activities for various roles in the SRC roles in the workflow.	Sept - Oct
• Radiation Safety Review for Analysts • RSC Members/Chairs/Designated Reviewer Training	Log-in, workspaces, dashboards, navigation, and locating studies and documents, and conducting activities for various roles in the RSC roles in the workflow.	Sept - Oct
• DEC/PRIA/IBC/Pharmacy for Reviewers	Log-in, workspaces, dashboards, navigation, locating studies and documents, and conducting these 'ancillary lite' reviewer activities.	Sept - Oct

Migration Plan

What will come over from iRIS to PROTECT?

- Studies: Active/Approved studies
- Documents: All currently approved consents and protocols
- Data: Data that the systems have in common (about 25-30 fields)
- Personnel: Study Team Members

Migration Plan (con't)

Two waves of migration:

Wave #1: Go Live (Oct 18)

- After PROTECT go live, in-process iRIS submissions may be completed, but no new submissions created
- In-Process submissions in iRIS may ONLY be completed until wave #2

Wave #2: ~30 days after go live (Will capture any recently approved iRIS submissions that were in-process during Wave #1)

- System will transition to a read-only state for ~ 1 year
- After ~1 year, the intent is to archive the system

IRB Submission Cut Offs

Submission Type	Details
Continuing Reviews	Continuing Reviews that expire between October 1, 2022, through November 15, 2022, must be submitted in iRIS before September 1, 2022. Continuing reviews that expire on or after November 15th, 2022, can be submitted in PROTECT once the system is live on October 18, 2022
Initial Reviews	No new Initial Reviews will be accepted in iRIS after September 1, 2022, until PROTECT is live October 18, 2022. New Initial Reviews must be submitted in PROTECT starting on October 18, 2022.
Modifications	No new Modifications will be accepted in iRIS after September 1, 2022, until PROTECT is live October 18, 2022. New Modifications must be submitted in PROTECT starting on October 18, 2022. Urgent safety modifications will be accepted on an as needed basis in iRIS during this time. Please consult with the IRB office via the irb@nih.gov mailbox if you are unsure whether something is urgent
Reportable New Events	Continue to submit in iRIS until October 14

Ancillary Submission Cut Offs

Submission Type	Details
Radiation Safety Submissions	No new actions (initial reviews, amendments, triennial reviews) will be accepted in iRIS after September 10, 2022. New Radiation Safety submissions must be submitted in PROTECT starting on October 18, 2022. Responses to stipulations in iRIS will not be accepted after October 10, 2022
Scientific Review Submissions	Final date to process submissions in iRIS October 14 Submission Deadline for each IC committee will be communicated to their IC by that committee.
PRIA	No new PRIA submissions will be accepted in iRIS after September 1, 2022. New PRIA submissions must be submitted in PROTECT starting on October 18, 2022.
DEC	Final date to process submissions in iRIS October 14 No new DEC submissions will be accepted in iRIS after September 1, 2022. New DEC submissions must be submitted in PROTECT starting on October 18, 2022.

Demo of PROTECT System

Known process considerations

Process	Impact
SRC/RSC	Will still conduct full committee reviews in system. All ICs will complete a common SR form, approved by Dr. Gallin. SOP has also been approved by Dr. Gallin. We will train all SR coordinators and reviewers.
DEC/PRIA/IBC	"Ancillary Lite" – Will be able to view submissions, attach any review materials, and record their approval. We will train all specialists (analysts) and reviewers.
Tracked change documents	We will no longer require/allow tracked change documents in IRB submissions as the PROTECT system executes tracked changes very nicely. Scientific Review has agreed that they may still require tracked changes.
KSP Changes	There will no longer be a study personnel page ("study team members") as an attachment. Instead, study personnel will be listed solely in PROTECT. Study team members can easily be modified in the system via an abbreviated modification form.
Single Patient Use/Not Human Subjects Research	These will no longer be a system form, but an attachment.
Planned Enrollment/Cumulative Enrollment Reports	These will no longer be collected in the IRB module but will be collected via the SRC module as an attachment.
OPS	Office of Protocol Services is building an interface for researchers to enter data that OPS collects for clinicaltrials.gov and other purposes. PROTECT will have a link a to this system. Support and questions related to the OPS interface will be handled by the Office of Protocol Services.
DRTS information	This will no longer be collected in the IRB module. The OPS interface will collect this information.

Resources

eIRB Refresh Project Page:
Visit us here for progress updates, testing and training info, etc.
eIRB Refresh Project - eIRB Refresh Project - Confluence (nih.gov)

Questions? eIRB Main Inbox
Email us here if you have any questions or considerations about the system you would like to bring to our attention.
OHSRPeIRBProject@nih.gov

Follow Up Survey
eIRB System - End User Testing Interest Poll

Slides
(will be sent after)