OHSRP Town Hall

11/17/2022

Team members

Jonathan Green, Director OHSRP

Nicole Grant, Associate Director OHSRP and Exec. Chair NIH IRB

Tiffany Gommel, Director, IRBO

Melissa Bryant, Deputy Director, IRBO

Meredith Mullan, Program Manager OHSRP

Ramesh Karuppiah, IT Team lead

Armen Martirosov, IT specialist

Marcelo Fontinha, IT specialist

Sue Tindall, change management and training

Kelly Pauly, training

Kevin Rasmussen, training

Mollie Fraser, scheduling

Jason Levine, NCI

Jon McKeeby, CC

Phil Lightfoot, CC

Kim Mitchell, CC

Steering Committee Members

Other Review Committees (RSC, IBC, PRIA, DEC)

Huron Team

Agenda

Go live update

Data migration

What to expect and do on your first action in PROTECT

Q and A

PROTECT – Go Live

Go-Live was planned for 12/6/2022

However: 2 problems
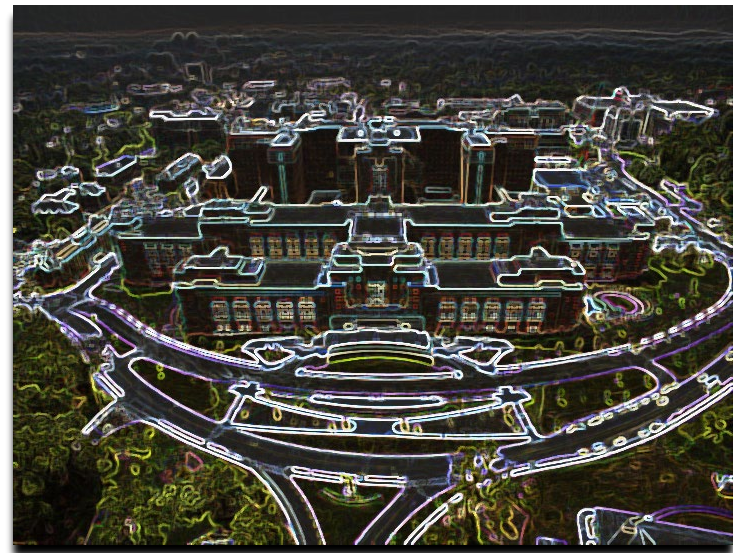- Security Vulnerability scans
- API

Green's general principles for Go Live

1. Based on a state of readiness, not a date

2. We have a working system

3. Perfection on day 1 is not a reasonable expectation

4. We have to pull the trigger at some point

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5. Don't short out the lights in the Clinical Center

Security Vulnerabilities

NIH scans detected a number of high and medium priority vulnerabilities

These prevent software from being outside the NIH firewall until remediated

- ◦ No high vulnerabilities allowed

Some fixes in place this week.

Major items require "portal upgrade" which will take until mid/end of January

- ◦ Will still have to be rescanned and any new issues addressed

Can operate inside firewall pending fixes

Application Programming Interface (aka API)

IRB system feeds information to Protrak, CRIS and NCI
- ◦ Mission critical functionality

Not yet working as needed
- ◦ Downstream consumers of data need 6 weeks to integrate and test.

Going live w/o this working properly violates principle 5

Options for go live

BEFORE PORTAL UPGRADE

Inside firewall
- Unaffiliated IRB members cannot access system
  - IRB sends packets to members
- pSites outside NIH cannot access system
  - Study teams enter data into system for pSites

Possible dates
- Depends on API being functional
  - December not feasible
  - Early-mid January possible

AFTER PORTAL UPGRADE

Delays go-live until March or later
- No guarantee that portal upgrade will solve all security issues

Pre-portal upgrade

PROS

Can keep closer to schedule

Training memory not lost

NIH users get benefit of system sooner

Less staff burnout

CONS

Extra work for OHSRP
◦ Materials to unaffiliated members

NIH multisite study teams when NIH is sIRB will need to submit materials for pSites

Need to keep submissions to iRIS limited for a longer period
◦ Would allow CRs and urgent amendments

Post-portal upgrade

PROS

Can go live outside firewall

More time to address API and any other issues

CONS

4+ month delay

Have to reopen submissions fully then go through entire shut-down process again to allow for data migration

Loss of training memory
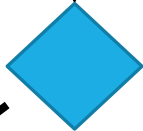◦ Need to rerun classes

Staff burnout

October in the IRBO

New submissions to IRB

October 2021 = 547
October 2022 = 933

API/Security fixes in process

Assess readiness week of 12/5-9

Yes

No

Plan for go-live inside firewall ~1/13
- Keep submissions limited until go live
- Inside firewall until security fixed

Security fixed

Open to outside firewall

Delay go live until spring 2023
- Re-open to submissions 12/6
- Go live after all fixes in place
  - System retested
  - outside firewall
  - Re-shut down submissions
  - Redo data migration

Summary

We will not be going live 12/6
- Submissions to the IRB in iRIS remain closed for now

We will assess all factors that would impact go-live the week of 12/5
- API
- All system functionalities
- System security status
- Investigator input (through steering committee and CDs)

If go live in mid January
- Submissions remain limited until then
- We will provide information as to how to let us know of high priority submissions

If go live after mid-January
- Will re-open iRIS to all submissions (date will be announced)

Requests to submit actions in iRIS should go to Tiffany Gommel (tiffany.gommel@nih.gov and Melissa Bryant (melissa.Bryant@nih.gov)

Week of PROTECT Go Live

- Prior to go live, ensure you've attended or watched PROTECT training sessions
  - Guides and videos available in the PROTECT system
- Know who your PROTECT experts are in your IC
  - Resource for questions
  - Listed on website
- Know how to log into PROTECT
- Be understanding
  - Core Team has been working on the system since October 2021
  - System has been thoroughly tested
  - Issues may come up, but we will work to resolve

Migration Plan

As a reminder… below is what will come over from iRIS to PROTECT:

- <u>Studies</u>: Active/Approved studies
  - ◦ In the first wave only active studies that do not have a modification or continuing review outstanding or still in progress in iRIS will migrate. These studies will migrate at the second wave if the action(s) are completed. Otherwise, they will have to start over in PROTECT.

- <u>Documents</u>: All currently approved consents and protocols
  - ◦ Only the latest version of each document is migrated (i.e. historic/archived versions will not be migrated)

- <u>Data</u>: Data that the systems have in common (about 25-30 fields)
  - ◦ The same fields will be migrated for each record

- <u>Personnel</u>: Study Team Members

Migration Plan

Two waves of migration:

Wave #1: Go Live (Date TBD)

- After PROTECT go live, ALL new submissions must be in PROTECT

- In-Process submissions in iRIS can ONLY be completed until wave #2

Wave #2: ~30 days after go live (Protocols that did not migrate in wave # 1 will migrate in wave #2)

- iRIS will transition to a read-only state for ~ 1 year

- After ~1 year, the intent is to archive iRIS

Migration Plan

Important to note:

- Only protocols that are in a "end state" (no actions pending) in iRIS will be migrated
    - ◦ Approved studies
    - ◦ Lapsed studies

- Before Wave 1, the IRB office will work to approve as many submissions as they possibly can, to move them to the "approved" state
    - ◦ These studies will then migrate in Wave 1

- Studies that are not in end state for Wave 1, will migrate in Wave 2
    - ◦ **If your study does not migrate in Wave 1, when system goes live, your study will not be in PROTECT until Wave 2**
    - ◦ Wave 2 will take place within ~30 days of Wave 1, and your study will then be available in PROTECT
    - ◦ Only studies in an "end state" will migrate in Wave 2

Migrated Protocols

- NOTE – Exempt & NHSR protocols will not be migrated into PROTECT
  - If you need to amend a study that is exempt, you will need to submit it as a new study in PROTECT.

- We will be sending out a document to help you review & update your study information with your first submission in PROTECT prior to go-live

Logging into PROTECT for the First Time

- Link to PROTECT production will be shared the day we go live

End User Support

- Go Live Command Center
  - Will serve as the central point of contact in actively managing the go-live execution, intake, documentation, and resolution of issues encountered

Command Center

What It Is

- Serves as a single point of contact for managing execution of go-live activities
- Identifies and ensures rapid response and resolution of go-live issues
- Manages regular Command Center meetings and produces a dashboard / reports

What It Is Not

- Information technology help desk
- Substitute for PROTECT Experts

End User Support

Follow steps below if you need help/run into issue in PROTECT:

1. Contact your IC PROTECT expert

2. Log ticket in JIRA
   i. Member of core team will reach out to assist you

3. Attend daily "office hours" with OHSRP trainers
   i. Dates and times will be listed on our website with outlook invitations

End User Support

- When submitting PROTECT support tickets in JIRA, please follow the priority definitions listed to below to prioritize your ticket:

Priority Definitions

Priority	Description	Expected Action	Impact	Example
Critical	Critical functionality not working with no work around; major operational impact	Resolve immediately with the highest urgency	Show-stopper for end user	PROTECT unavailable / internet outage
High	Critical functionality not working but a work around exists; operational impact	Issue resolved within first week of go-live or resolution plan in place	Major workarounds or manual processes for a short timeframe	System latency or slowness causing disruptions
Medium	Non-critical functionality not working but a work around exists; no major operational impacts	Issue is to be resolved based on normal prioritization	Minor workarounds or minimal manual processes	User cannot complete an action in PROTECT due to limitations in system access
Low	Cosmetic or non-end user impacting issue (i.e., spelling or screen display)	Resolve as time / resources permit	Nice to have but does not impact successful go-live	Formatting of applicable letters or spelling