Making iRIS Work for YOU

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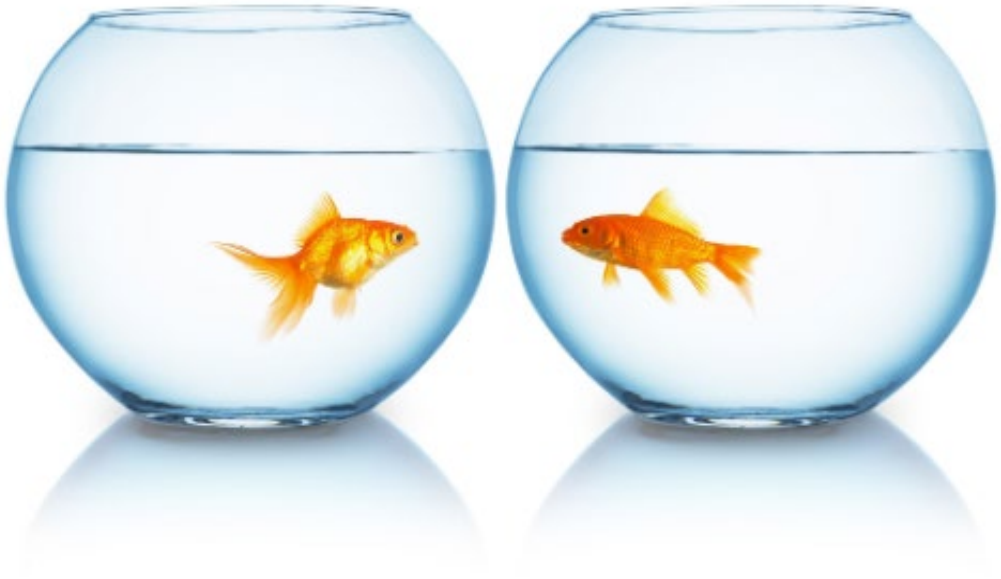
IRIS TEAM LEAD

OHSRP / IRBO

OHSRP EDUCATION SERIES – MAY 5, 2020

Together, apart…



Source: Getty Images

Objectives

Impact of recent & upcoming iRIS improvements

iRIS user guides & resources

Questions & Answers

Recent
iRIS Improvements

December

IRB took over stamping consents

Provides consents immediately at IRB approval

Launched Scientific Review Pilot (3 ICs)

Achieves leadership reporting data

v11.02 iRIS Upgrade

Offers nicer look & feel/streamlined workspaces

January

Created one single “Progress Report Form” for:
- Continuing Reviews
- Study Closures

Allows for simultaneous CR & SC

Progress Reports (min risk/no CR)

Brings us into compliance with Revised Common Rule

March

Created one single “Amendment Form” for:

- Investigator Brochure Submission Form
- KSP Changes Form
- Participant Recruitment Materials Form
- Miscellaneous Documents Submission Form
- Short Consent Approval Form
- DSMB or SMC Outcome Letter Submission
- Outside IRB documents for multi-institutional trials

One-stop shopping for further study actions

April

NEW NHSR Submission Form

No more hitting back to escape IR form

Streamlined KSP section

Prep for removing Section 4/Pulling CITI data in Section 3

Revised Study Application

Flag COVID research
Accommodate Radiation Safety changes
Accommodate PRIA in iRIS
Prep for ALL ancillary reviews in iRIS

Coming
Soon

Upcoming Improvements

Scientific Review (all ICs) (May)
Radiation Safety (all ICs) (May)

All ICs submitting electronically in one system

Multisite research application (June)

All ICs submitting electronically in one system

Automatic study numbering (June)
Separate IRB/OPS Applications (July/Aug)

Collect only IRB data in IRB app
No more waiting post IRB approval for #, approved docs, etc.

Ancillary reviews reorganization (July/Aug)

All ancillaries in iRIS (transparency)
Validate for approval automatically (not by a person)

HOT TOPICS

New Amendment form behavior

New workflow “bubble” graphics

Managing KSPs

Stacking/versioning documents

Cleaning up iRIS documents

New Amendment form

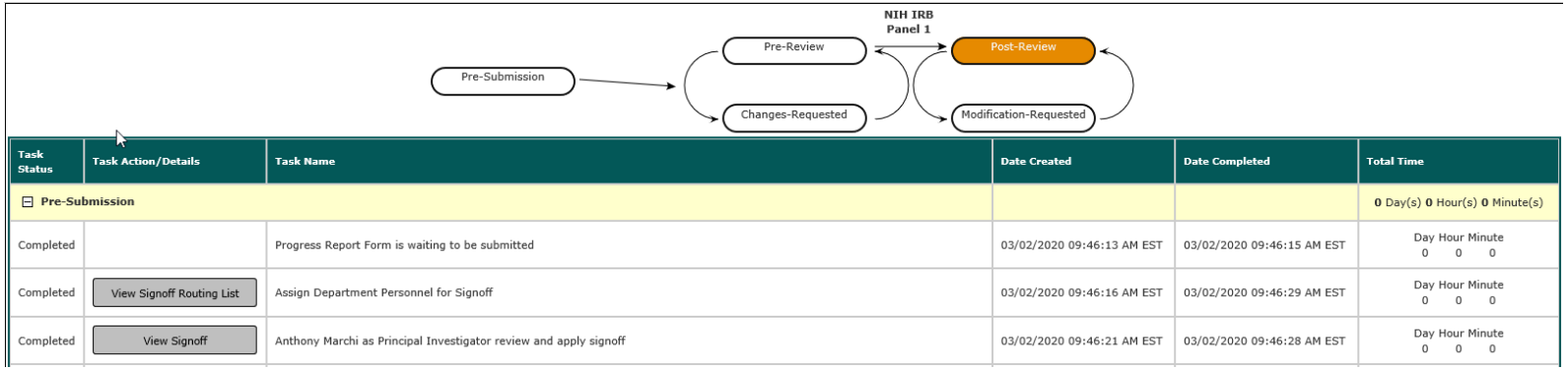
Separate forms now

Take place of many Miscellaneous forms

Questions about behavior/branching

(under discussion/considering branching these)

New workflow “bubble” graphics



Task Status	Task Action/Details	Task Name	Date Created	Date Completed	Total Time
Pre-Submission					**0** Day(s) **0** Hour(s) **0** Minute(s)
Completed		Progress Report Form is waiting to be submitted	03/02/2020 09:46:13 AM EST	03/02/2020 09:46:15 AM EST	Day Hour Minute 0 0 0
Completed	View Signoff Routing List	Assign Department Personnel for Signoff	03/02/2020 09:46:16 AM EST	03/02/2020 09:46:29 AM EST	Day Hour Minute 0 0 0
Completed	View Signoff	Anthony Marchi as Principal Investigator review and apply signoff	03/02/2020 09:46:21 AM EST	03/02/2020 09:46:28 AM EST	Day Hour Minute 0 0 0

Managing KSPs

Lots of Qs with revised AM form

Ongoing process of phasing out Section 4

Sect 4 users likely need accounts first to add to Section 3

Things to keep in mind:

We are almost there!

It will take some time.

Training data slowly getting updated too.

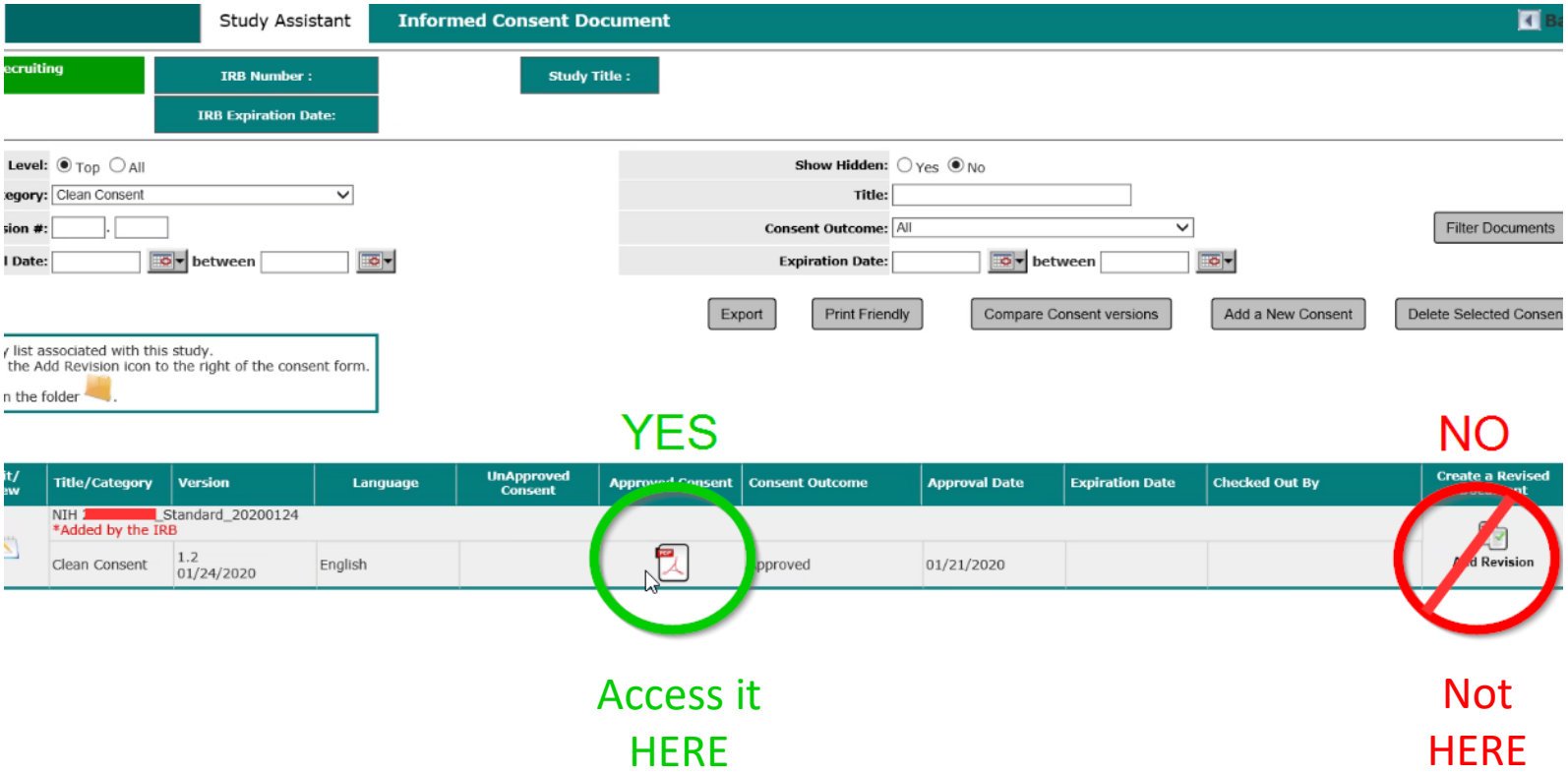
Stacking/versioning documents

We see a lot of documents versioning methods

Common reasons:

- Documents Added, not Revised
- Documents pulled from older versions
  (Not most recently approved)
- Researchers want a Word version of Stamped PDF Consent

So you want a copy of the approved consent?



Cleaning up iRIS documents

Ways to help!

IRBO is stamping consents (and marking clearly as APPROVED)

IRBO is slowly assisting teams in clean up

Study Team can now clean up their own study documents

iRIS Team is educating in a variety of ways…

iRIS Development Team


THANK YOU!
THANK YOU!
THANK YOU!

iRIS Resources/ Support

iRIS Trainers

Marianne Nogle

Jacqueline Claiborne

Anthony Marchi

New User Guides:

Requesting User Accounts

Redacting Signed Consents

Managing KSPs

Managing KSP Study “Pools”

Hiding Study Documents

Claiborne

Just in!
New
OHSRP Website

U.S. Department of Health and Human Services | National Institutes of Health

NIH Office of Intramural Research
Office of Human Subjects Research Protections

iRIS Login

Search

About | IRB Operations | Compliance and Training | Policy | Resources | Participants | News

Please carefully review our **COVID-19 information hub** for updates on IRB processes during the COVID-19 outbreak.

Office of Human Subjects Research Protections

The Office of Human Subjects Research Protections (OHSRP) carries out the day-to-day operations and regulatory oversight of human research activities within the Human Research Protections Program (HRPP). The OHSRP promotes the protection of rights, safety and welfare of human subjects, and the NIH's research mandate.

Learn More

https://irbo.nih.gov

IRB Operations

Templates and Forms

Policies & Guidance

iRIS Help & Updates

Please carefully review our **COVID-19 information hub** for updates on IRB processes during the COVID-19 outbreak.

iRIS Overview

About iRIS

Here you can find the latest news and information about iRIS, read our latest release notes, learn about iRIS's impact in the NIH Intramural Research community, register for training, and find user guides.

Need an account?

Please visit the iRIS Help Desk to request new or modified NIH iRIS accounts from the NIH iRIS IT team. Please note that the helpdesk site is only accessible when connected to the NIH Network or using the NIH VPN. The support team will process all requests in accordance with the iRIS account SOP.

Please carefully review our **COVID-19 information hub** for updates on IRB processes during the COVID-19 outbreak.

Resources

Account Management

You may access the NIH iRIS Training Site to independently explore and familiarize yourself with the new system (NIH login required).

Please visit the iRIS Help Desk to request new or modified NIH iRIS accounts from the NIH iRIS IT team. Please note that the helpdesk site is only accessible when connected to the NIH Network or using the NIH VPN. The support team will process all requests in accordance with the iRIS account SOP. .

Helpful Documents

The NIH iRIS training team has developed instruction sheets to supplement the information covered in training sessions and demonstration videos. The Process working group has developed checklists and user guides as resources to guide investigators, navigators, and study team members in identifying the materials to be included in various IRB submissions.

iRIS Helpful Documents

Demonstration Videos

A demonstration video will be released with each major update to the iRIS system and sent out to the community.

iRIS-Demonstration Videos

iRIS Helpful Documents

Instruction Sheets, Submission Checklists, and User Guides for the NIH iRIS system.

Instruction Sheets

File Name	Version	Doc Type	Doc Type	Size	Download
Instruction Sheet 1 - iRIS New Study Application.pdf		attachment	application/pdf	1.43 MB	
Instruction Sheet 2 - iRIS Attaching Study Documents.pdf		attachment	application/pdf	798 kB	
Instruction Sheet 3 - iRIS Routing for Signatures and Submission Status.pdf		attachment	application/pdf	1.16 MB	
Instruction Sheet 4 - iRIS Responding to Stipulations and Attaching Revised Documents.pdf		attachment	application/pdf	975 kB	
Instruction Sheet 5 - iRIS Reviewing Submissions and Apply Electronic Signature.pdf		attachment	application/pdf	980 kB	
Instruction Sheet 6-Adding an Amendment.pdf		attachment	application/pdf	2.76 MB	
Instruction Sheet 10- Response to Stipulations and Versioning Documents in iRIS.pdf		attachment	application/pdf	1.93 MB	

Submission Checklists

File Name	Version	Doc Type	Doc Type	Size	Download
Checklist Amendment submission.pdf	07/25/2019	attachment	application/pdf	822 kB	
Checklist Closure Report Submission.pdf	07/25/2019	attachment	application/pdf	818 kB	

Help/Support

iRIS Trainers

Training Inbox
(iris_training@od.nih.gov)

iRIS Help Desk (JIRA Ticketing)

Ask the Trainer brownbag sessions (*COMING SOON*)

We thank you!