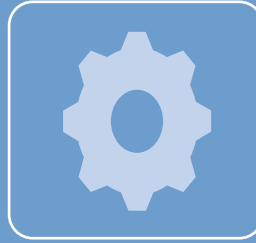


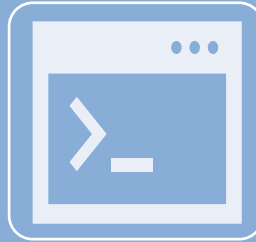
10.16.2026 QUARTERLY CALL AGENDA



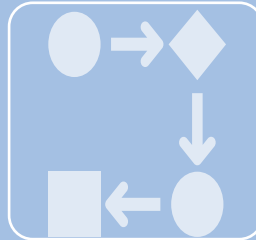
**Welcome &
Announcements**



New IREx Features



**Current & Upcoming
Development**



**Feature Highlight:
EFIC Workflow**

Welcome - About the IREx Quarterly Calls



hear • new • features

- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!



learn • new • trends

- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?



share • your • voice

- Give your opinion
- Ask your questions
- Express your needs

2027 Quarterly Calls



January 15, 2027

April 16, 2027

July 16, 2027

October 15, 2027

HRPP Collaborative + Review ◦ Community Portal



What is the HRPP CRCP Portal?



The **HRPP Collaborative Review Community Portal (CRCP)** is a free, online community for HRPP and IRB professionals to connect, share resources, and collaborate on single IRB and multisite research challenges.

Hosted by **Vanderbilt University Medical Center (VUMC)** with the support of The **Trial Innovation Network (TIN)**, the portal offers discussion forums and educational content to support learning, consistency, and efficiency across institutions, helping strengthen collaboration and best practices within the HRPP community – and some fun stuff too!

- Reputation Points: Learn, Contribute, Get Recognized!
- Welcome to the HRPP Collaborative Review Community Portal!

All Posts in HRPP Collaborative Review Community Portal

katelyn.benhoff (Katelyn Benhoff) posted • 4 hours ago • Training and Resources

Sharing - AI Webinar
hrp

0
Comments
2
Likes

taylor.budine (Taylor Budine) posted • 4 days ago • General

Shout-out time!
general shout out

0
Comments
2
Likes

katelyn.benhoff (Katelyn Benhoff) posted • 5 days ago • Training and Resources

NEW sIRB Resources Available!
continuingreviews reporting templates tools

0
Comments
4
Likes

hend.nadim (Hend Nadim) commented • 6 days ago • General

Have you found use of an sIRB to be beneficial to your IRB team and/or your study teams?
(Jump to latest comment)
sirb

1
Comments
2
Likes

linnea.rademaker (Linnea Rademaker) commented • 6 days ago • Training and Resources

Who is going to the AAHRPP Annual Conference?
(Jump to latest comment)
conference

4
Comments
1
Likes

katelyn.benhoff (Katelyn Benhoff) commented • 6 days ago • General

What Topics Would You Like to See Here? We Want Your Input!
(Jump to latest comment)
general topics

1
Comments
1
Likes

Welcome to the HRPP Collaborative Review Community Portal (CRCP)!

This is a space where we can all come together as HRPP specialists-whether expert or novice-designed with sIRB work at its core and offering dedicated support for both reviewing IRBs and relying sites engaged in multi-site research and single IRB processes.

HRPP CRCP Rules of Engagement

Need help navigating the REDCap Community Platform? [Click here!](#)

If something is not working or you have questions about the platform, please contact Taylor Budine at taylor.budine@vumc.org.

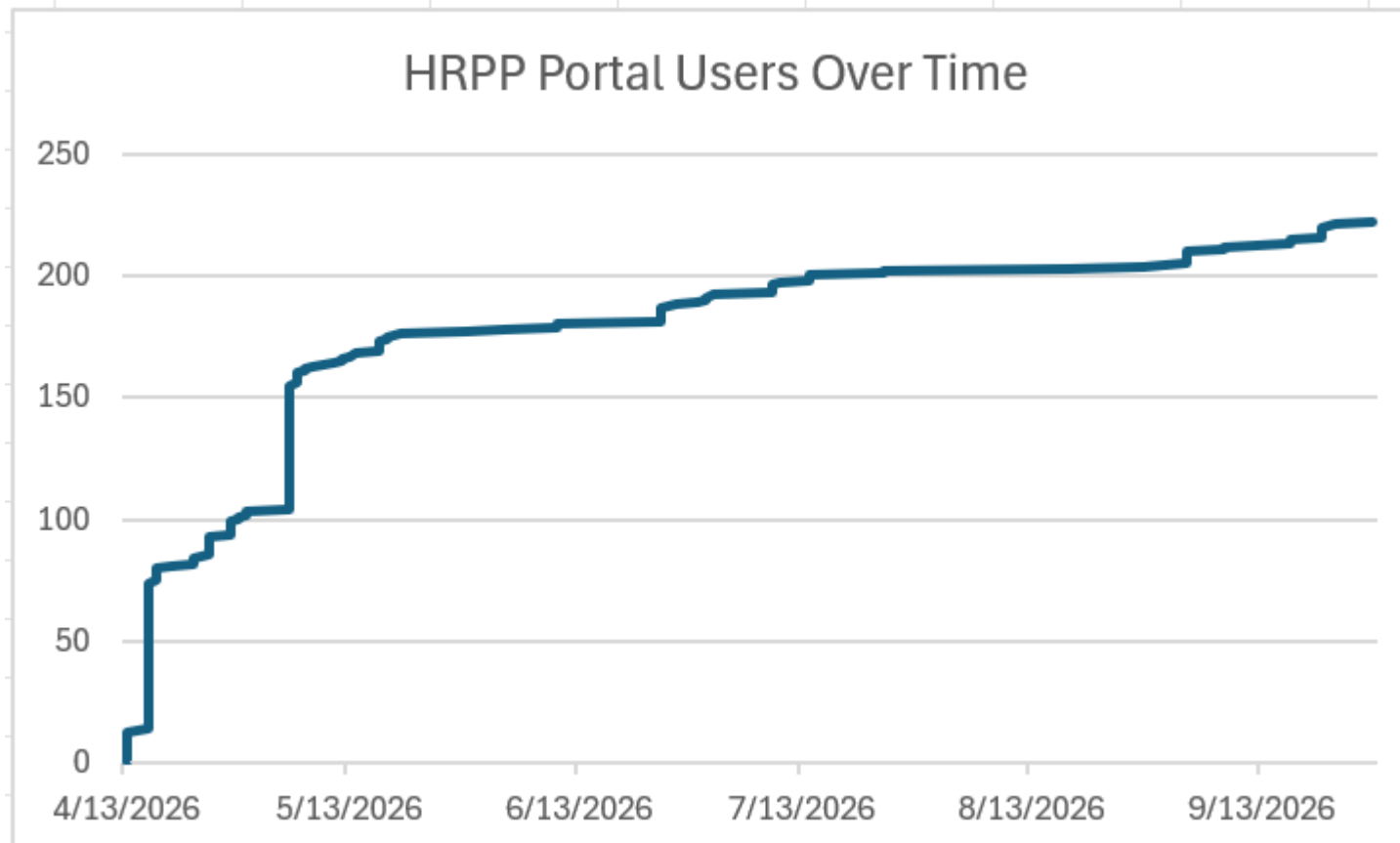
If you have any questions about the HRPP CRCP or want to get more involved, please contact Taylor Budine at taylor.budine@vumc.org.

INVITE YOUR HRPP COLLEAGUES:

If you know someone who is not currently a part of this group that would benefit from joining, please share [this link](#) and have them sign up for an account.

The HRPP Collaborative Review Community Portal (HRPP CRCP) is supported by the National Center for Advancing Translational Sciences, National Institutes of Health, under award number 5U24TR004437.

Metrics

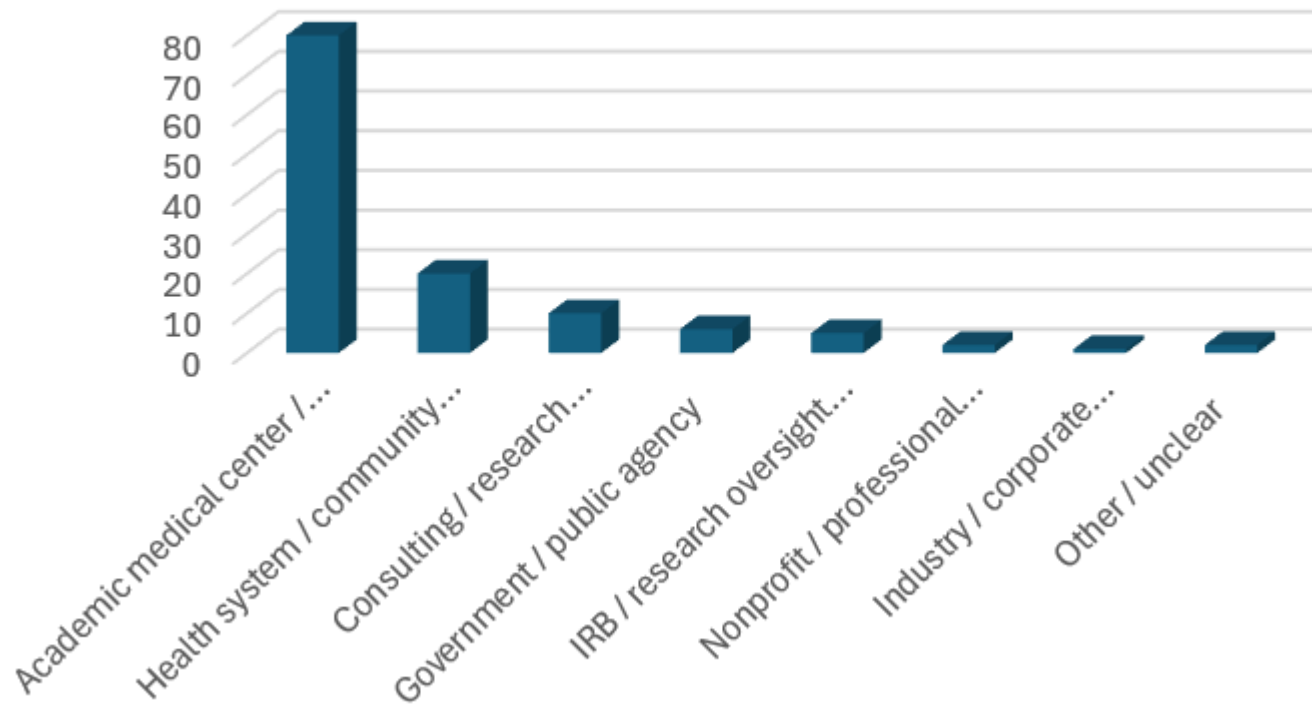


Launched: 04/16/2026
Users (excluding admin) : 222
Steering Committee: 77

Metrics



Types of Institutions Represented



**Unique Institutions
Represented: 126**

CTSA Hubs Represented: 42

**Welcome *Phoenix*
Children's Hospital
+
•
- NEWEST sIRB in
IREx!**



Who Else Created Studies in Q3?



- Indiana University – 1
- Nationwide Children’s Hospital - 2
- Pennington Biomedical Research Center – 2
- Phoenix Children’s Hospital - 1
- **UCSF – 10** 
- University of Colorado, Denver – 1
- University of Oklahoma Health Sciences Center – 1
- University of Utah – 3
- University of Wisconsin – Madison – 2
- Vanderbilt Health – 5
- Wake Forest University Health Sciences – 1

+ UCSF connected
◦ to IREX via API!



IREx API Features



Reminder of current connection points:

Functionality	Direction	Benefit
Create studies in IREx after the study is through pre-review	Reviewing IRB's eIRB → IREx	sIRB avoids creating study in IREx
Publish lead site approval from the sIRB	Reviewing IRB's eIRB → IREx	sIRB or Study Manager avoids uploading approval documents to IREx
Pull in the local context documentation from IREx (when indicated by study manager)	Reviewing IRB's eIRB ← IREx	Study Manager avoids downloading and uploading from IREx to Reviewing IRB's eIRB system <i>for each site!</i>
Publish participating site's approvals from the sIRB	Reviewing IRB's eIRB → IREx	Study Manager avoids uploading approval documents from Reviewing IRB's eIRB to IREx <i>for each site!</i>

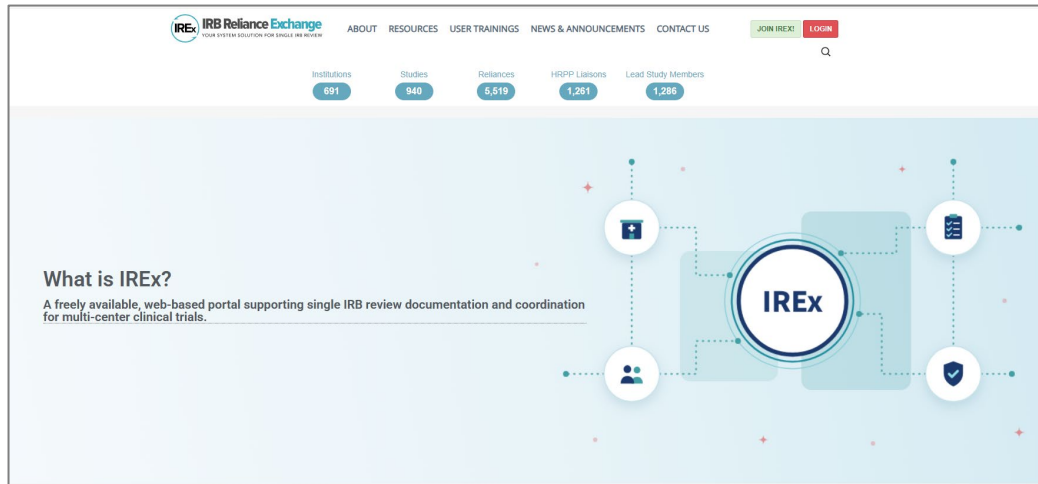


+ . New IREx ○ Features

Website Updates



IREx website background refresh



Request a Demo link for HRPP Liaisons

Find a Study

by Name:

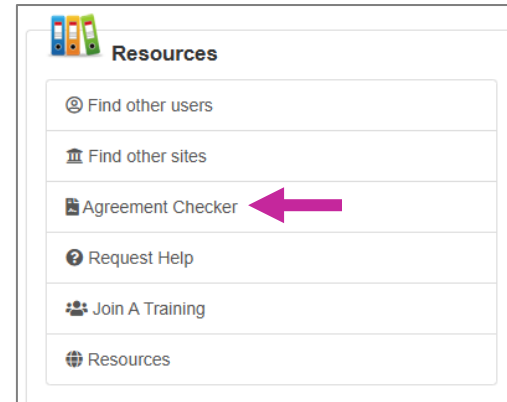
by Sponsor:

find

Create a Study

New to IREx? Create a test study as the Reviewing IRB to preview the workflow

Request a Demo



Agreement Checker now includes instructions

Agreement Checking Tool

What is the Agreement Checker, and when should I use it?

- The Agreement Checker uses information already in IREx to easily display what reliance agreements sites have signed, and whether that site is active in IREx.
- It is useful for lead study teams for:
 - Grant preparation
 - Assessing site readiness post-funding
 - Asking an sIRB to create a study in IREx so the Lead Study Team / Coordinating Center can use IREx to manage site communications and documents

To use the Agreement Checker:

- Select a single IRB.
- Add participating sites.
- View which version(s) of the SMART IRB Reliance Agreement sites have signed, if they have access to IREx, and if they have signed any existing indemnification agreements for the sIRB.
- Export the list (click **Download CSV**), if desired.
- Refresh the page to select a different sIRB.

Report Parameters

sIRB

Select a site

Add Participating Site

Select a site

Survey Signature Updates



By signing below, I attest that the information fulfills the relying institution's responsibilities, as outlined in the reliance agreement, for the provision of local context information and to the accuracy and completeness of the information provided herein.

 [Add signature](#)

[Submit](#)

Relying HRPPs can now type signature

Add signature

By signing below, I attest that the information fulfills the relying institution's responsibilities, as outlined in the reliance agreement, for the provision of local context information and to the accuracy and completeness of the information provided herein.

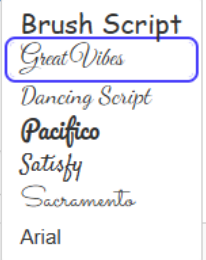
☒ Type signature ☐ Draw signature

Type your signature

Linda Tan

Linda Tan

[Save signature](#) [reset](#)



Draw signature option still available

Add signature

By signing below, I attest that the information fulfills the relying institution's responsibilities, as outlined in the reliance agreement, for the provision of local context information and to the accuracy and completeness of the information provided herein.

☐ Type signature ☒ Draw signature

Use a mouse, finger, or stylus to draw your signature in the area below.

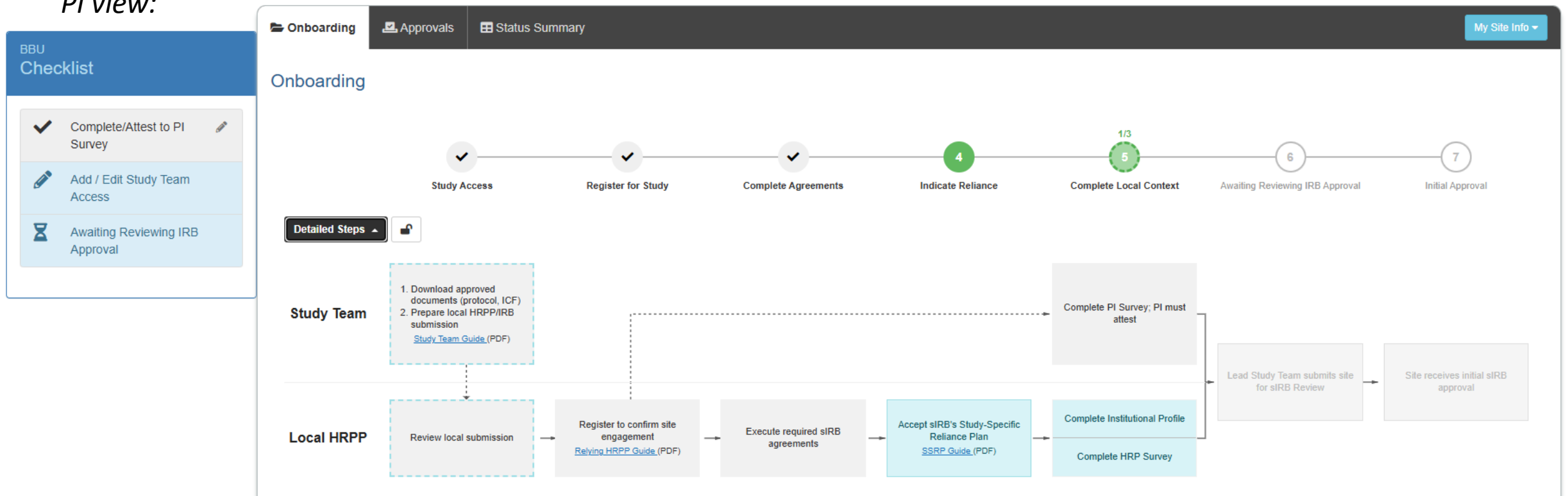


[Save signature](#) [reset](#)

New Relying Site Progress Bar

- Accessed from **Onboarding** tab on the study page
- **Detailed Steps** displays who is responsible and what action is needed

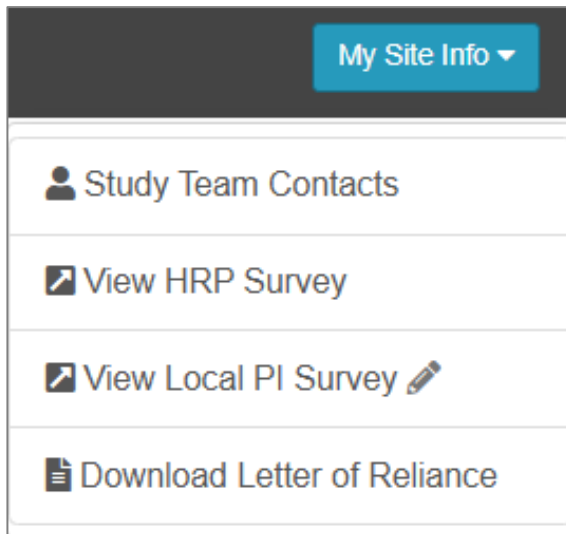
PI view:



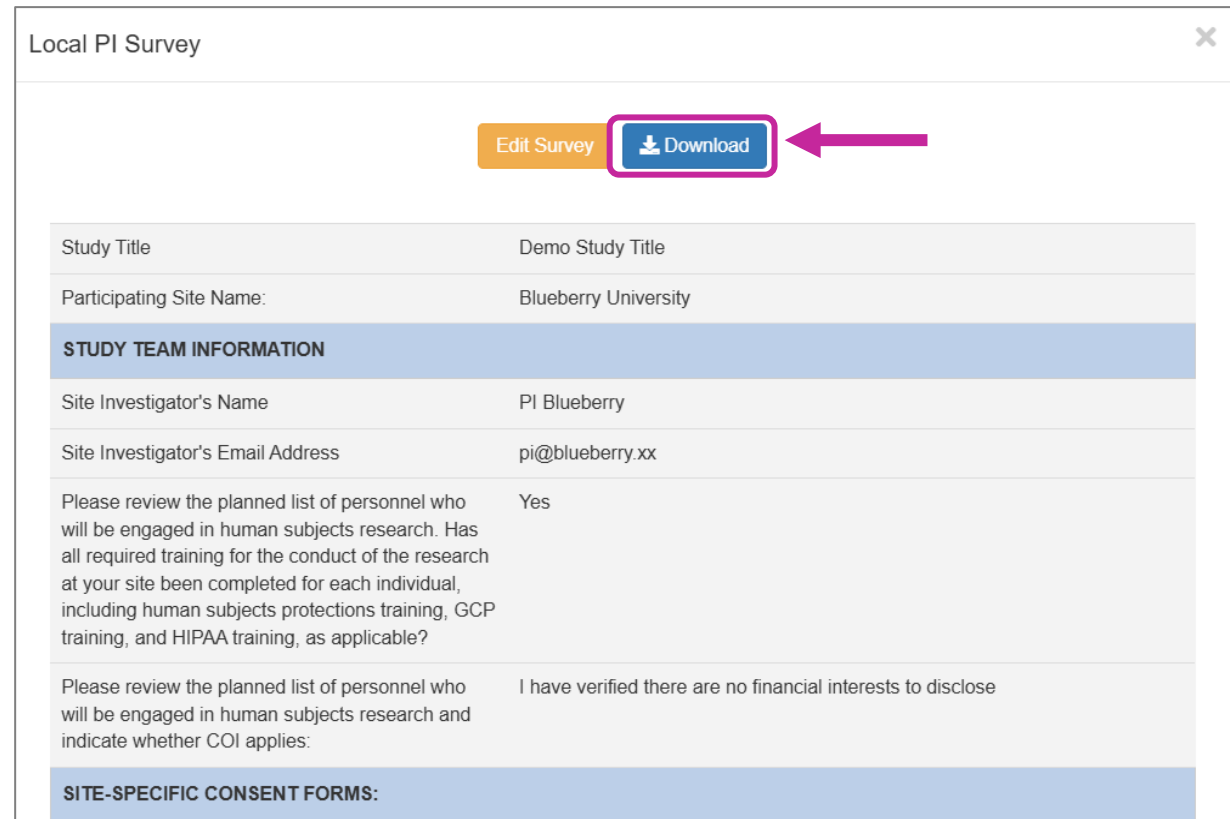
Relying sites can now download completed HRP and PI Surveys

- **Relying HRPP and Study Teams** can download surveys from the My Site Info menu and submit to their local eIRB systems

PI view:



The screenshot shows a dark header bar with a blue button labeled "My Site Info" with a downward arrow. Below the header is a white menu with four items: "Study Team Contacts" (with a person icon), "View HRP Survey" (with a document icon), "View Local PI Survey" (with a document icon and a pencil icon), and "Download Letter of Reliance" (with a document icon).



The screenshot shows a "Local PI Survey" form. At the top right is a close button (X). Below the title bar are two buttons: "Edit Survey" (orange) and "Download" (blue with a download icon). A pink arrow points to the "Download" button. The form contains several sections:

Study Title	Demo Study Title
Participating Site Name:	Blueberry University
STUDY TEAM INFORMATION	
Site Investigator's Name	PI Blueberry
Site Investigator's Email Address	pi@blueberry.xx
Please review the planned list of personnel who will be engaged in human subjects research. Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable?	Yes
Please review the planned list of personnel who will be engaged in human subjects research and indicate whether COI applies:	I have verified there are no financial interests to disclose
SITE-SPECIFIC CONSENT FORMS:	



- + .
-

Current & Upcoming Feature Development

Upcoming IREx Features



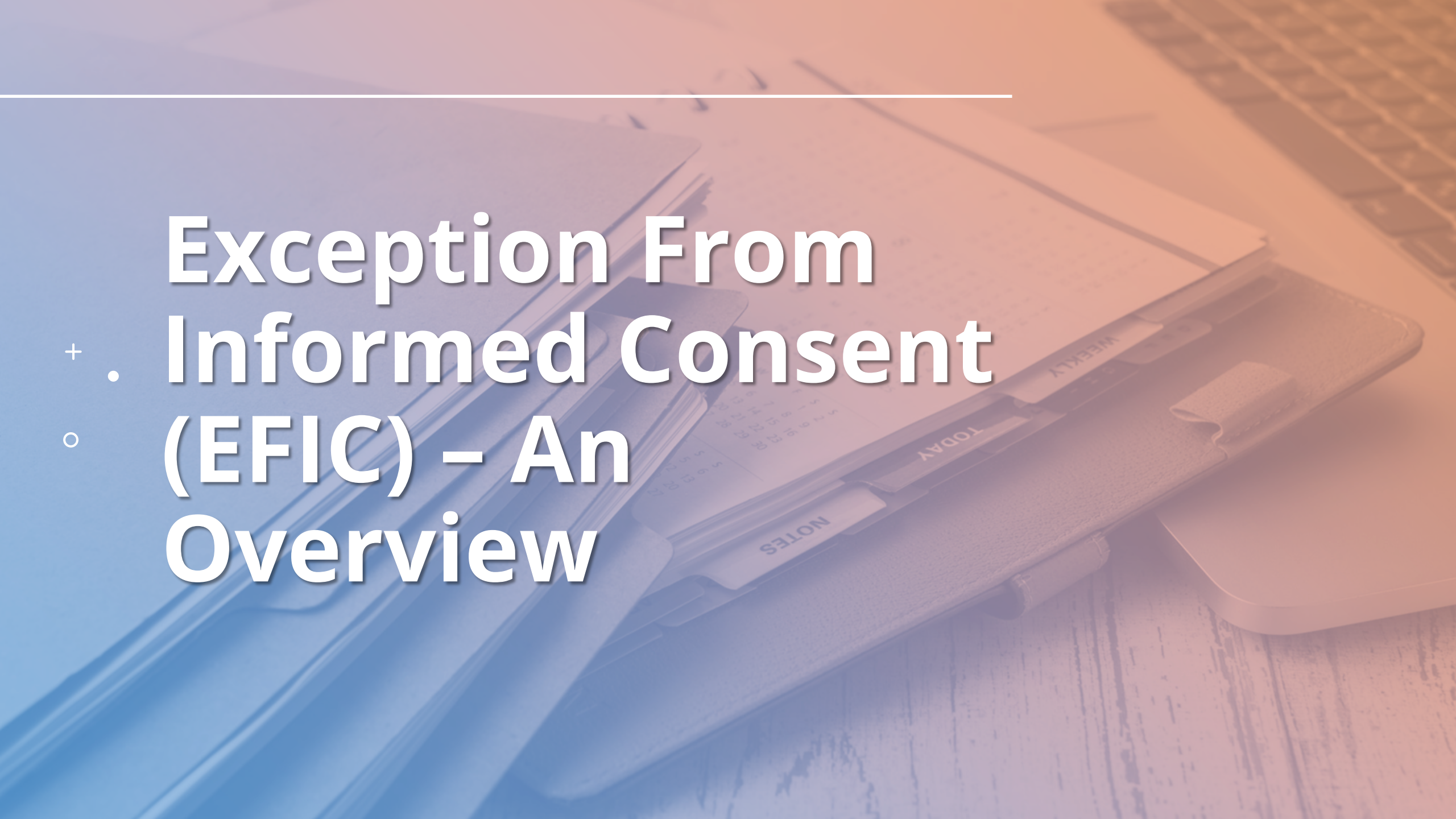
Allow Lead Study Teams to request changes to HRP / PI Surveys within IREx

Document History tab to organize relying sites approval documents by *type*

Lead Study Team dashboard/metrics overview



How can IREx better support you? Chat or email us your ideas or feature suggestions!



Exception From Informed Consent (EFIC) – An Overview

- +
-
-

What are EFIC Studies?



Emergency Research (aka No time to get informed consent from the patient of a loved one)



Outlined in 21 CFR 50.24

Allow research to begin BEFORE asking obtaining consent

There has to be good evidence the treatment might help the patient having a medical emergency



Study team approaches patient / loved one ASAP to:

Explain the study / what study activities have occurred so far

Explain what will happen moving forward, if study continues

Discuss potential risks / benefits

Ask for permission to continue with study

Community Consultation: A Necessary Part of EFIC



“...the IRB must find and document that additional protections of the rights and welfare of the subjects will be provided, including, at least, ‘consultation’... and public disclosure for each emergency research protocol in which an exception from informed consent is requested...”



“For a multisite trial, FDA expects the sponsor and investigator to hold community consultation activities for communities at all sites.”



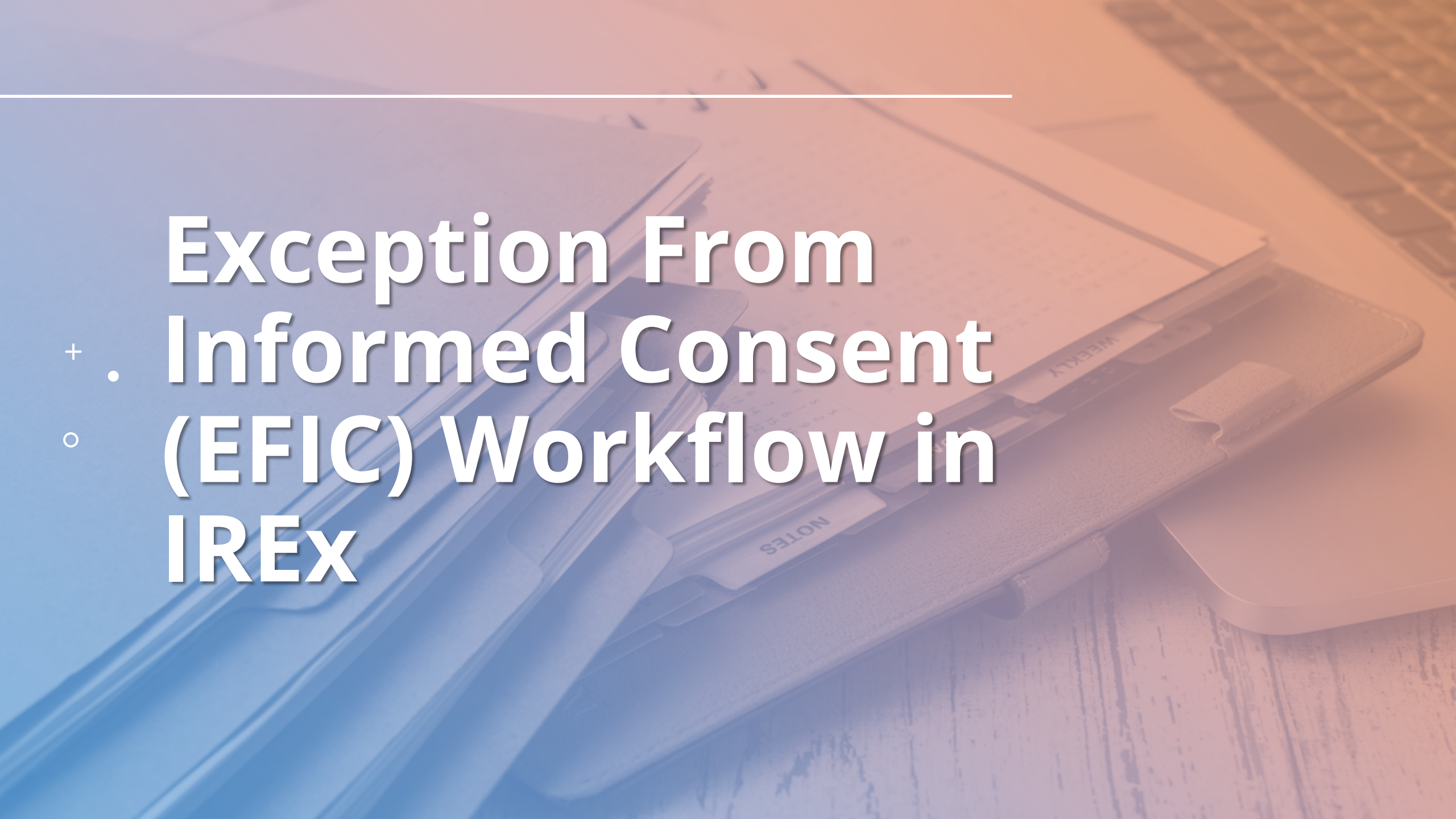
Forums / websites / other spaces that allow for a two-way dialogue about the study and its potential risks / benefits to the community

Social Media; In-person meetings; Online meetings; Surveys

Community Consultation: A Necessary Part of EFIC



- “For a multisite trial, FDA expects the sponsor and investigator to hold community consultation activities for communities ***at all sites.***”
- Along with the traditional sIRB dissemination (from lead site) and documentation (from relying sites), EFIC requires...
 - Dissemination of approved lead site Community Consultation Plan (CCP) / CCP Template (Lead Site → Relying Sites)
 - Submission and approval of ***each site’s*** proposed CCP (Relying → Lead)
 - Dissemination of approved CCP (Lead → Relying)
 - Submission of each site’s Summary of Results (Relying → Lead)
 - Dissemination of site approval (Lead → Relying)



The background of the slide features a blurred image of a workspace. On the right, a portion of a laptop keyboard is visible. In the center, there is a dark-colored notebook with a leather-like texture, which has a tab labeled 'NOTES' and another labeled 'WEEKLY'. To the left of the notebook is a blue folder. The entire scene is overlaid with a semi-transparent blue and orange gradient. A thin white horizontal line is positioned near the top of the slide.

Exception From Informed Consent (EFIC) Workflow in IREx

How does EFIC Workflow differ in IREx?



sIRB / Lead Study Team must disseminate CCP Template

Relying Site Study Team submits CCP to sIRB for review / acceptance

sIRB accepts CCP

Relying Site Study Team implements CCP

Relying Site Study Team uploads CCP Summary of Results in IREx

sIRB Reviews, issues Approval via IREx

Upload Community Consultation Plan (CCP) Template

+

sIRB indicates study is EFIC

sIRB/SM uploads
Community
Consultation Plan
Template (CCP) with
lead site approval

Relying HRPP
confirms review of
local CCP & Study
Team Uploads

SM uploads sIRB's
acceptance of CCP –
ready to implement

Study Team uploads
CCP Summary of
Results

SM submits CCP
Summary to sIRB for
approval

With the Lead Site Approval

Upload Documents

Drag file into document type or click a document type to upload.

IRB Approval Documentation

Required

IRB Application

Required

Consents & Assents

Consultation Plan Template

Grant Application

Meeting Notes

Investigators Brochure

Device Manual

Package Insert

Measures

Recruitment & Advertisements

Additional IRB Approved Documents

Others

Optional: Include on the Onboarding Tab

Onboarding

Approvals

Status Summary

Sites

Contacts

Edit Study Info

Onboarding

sIRB Instructions

sIRB Instructions

Additional Documents

+ Add Document

If applicable, relying sites can use the additional documents below to facilitate their local submission process. Please contact the Reviewing IRB Contact or Study Manager with any questions.

CCP Template 1.docx

Archive

CCP Template 2.docx

Archive

Site-specific consent form guidance.docx

Archive

sIRB Communication Plan.docx

Archive

Part II Consent.docx

Archive

PI Uploads CCP to PI Survey

+



Checklist

➔ Complete/Attest to PI Survey

➔ Awaiting Community Consultation Plan (CCP) Acceptance

➔ Upload/Attest to CCP Summary of Results

✎ Add / Edit Study Team Access

⌚ Awaiting Reviewing IRB Approval

SITE-SPECIFIC CONSENT FORMS:

IF YOUR SITE HAS CONSENT FORMS, ANSWER 'YES' BELOW AND INDICATE THE # OF CONSENTS YOU WILL UPLOAD.

Consent language should be verified by your local HRPP before uploading them here. If your HRPP has not yet verified your local consent language, skip this question, submit the survey, and return later to fill in this section of the survey.

Does your site have an informed consent form(s) (ICFs), including short forms, assent forms, permission forms, etc., for this study?

- ☐ Yes
☐ No

* must provide value

reset

Upload your Community Consultation Plan (CCP) that has been REVIEWED by your HRPP.

[Upload file](#)

If not, please return to this question after your HRPP has reviewed the CCP.

* must provide value

Status Summary: After Site Completes Initial Documentation†



Status Summary					Export Data ▼
Q Search:					
Site	Agreements	Reliance Decision ?	Local Considerations	Approval Status	
Apple Health	2 / 2 Agreements Complete ▼	Completed 7/18/2024	3 / 4 Surveys Complete ▼ ✓ Institutional Profile Confirmed: 7/18/2024 ✓ HRP Survey Completed: 7/18/2024 ✓ PI Survey Completed: 7/15/2024 PI Attested: 7/18/2024 ✗ CCP Summary of Results ✉ Email study personnel	Awaiting CCP Acceptance	

- ✓ Relying Sites Completed Reliance Documentation and Local Considerations
- Site is ready for sIRB review of CCP

Lead Study Team Uploads CCP Acceptance from sIRB

+



Relying Site Approvals

Apple Health

Apple Health

Community Consultation Plan

Status

Pending

Community Consultation Plan Accepted

Date Reviewed

mm/dd/yyyy

Date Approved

mm/dd/yyyy

Initial Review

Status

Review Type

Initial Study: Full Board

Is Site Enrolling?

Yes

No

Date Submitted

mm/dd/yyyy

Add pre-review exchanges with PI

Date Pre-Reviewed

mm/dd/yyyy

Date Reviewed

mm/dd/yyyy

Add post-review exchanges with PI

Add another Review Date

Date Approved

mm/dd/yyyy

Cancel

Save

After CCP implementation, Study Team Uploads CCP Summary of Results



Study Team Member Checklist

PI Checklist

Checklist

- ✓ Complete/Attest to PI Survey
- ✓ Community Consultation Plan Accepted (CCP)
- ➔ Upload/Attest to CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Checklist

- ✓ Start PI Survey for Baystate
- ✓ Awaiting PI Attestation
- ➔ Awaiting PI Attestation of CCP Summary of Results
- ✎ Add / Edit Study Team Access
- ⌚ Awaiting Reviewing IRB Approval

Coordinator can upload CCP Summary of Results, but PI must attest

Use this form to upload the Community Consultation Plan Summary of Results, along with documentation your local HRPP has reviewed and provided feedback on this document.

Has your local HRPP REVIEWED and provided feedback on your Community Consultation Plan Summary of Results?

☒ Yes

1

If not, please return to this question when ready to submit your CCP Summary of Results.

* must provide value

Please upload documentation that confirms your HRPP has reviewed the CCP Summary of Results

2

* must provide value

Please upload the CCP Summary of Results

3

* must provide value

Do you have any additional files to upload?

☐ Yes
☐ No

4

* must provide value

Submit

reset



Multi-site EFIC Study Lead Site IREx Experience

Sharnia Lashley, MS

Clinical Operations Manager
Department of Surgery, Northwestern University
Clinical Trial Manager, FIT-BRAIN Trial

- + • **Multi-institutional Phase 2/3 Trial of Fresh Frozen Plasma (FFP) in Patients with Moderate to Severe Traumatic Brain Injury (TBI)**
- **FFP In Traumatic BRAin INjury (FIT-BRAIN) Trial – Overview**



**FFP In Traumatic
BRAIn INjury
(FIT-BRAIN) Trial**

What is the (EFIC) FIT-BRAIN Trial?

- The goal of this clinical trial is to learn about treatment with fresh frozen plasma (FFP) in individuals with moderate to severe traumatic brain injury.
 - Is the FFP treatment safe?
 - Does the FFP treatment impact the 24-hour, 3-month and 6-month outcomes, intensive-care free days, mortality, and hospital brain and physical function at discharge?
- Inclusion: Local ED patients with mod to severe TBI (GCS & CT scan confirmed) aged 18-65 years with no refusal of blood products
- Patients with moderate to severe TBI meeting inclusion criteria randomly receive:
 - Standard of care treatment
 - Standard of care treatment + 2 units of FFP
- Treatment must begin within 60 minutes of arrival at the hospital

FIT-BRAIN Trial Community Consultation and Public Disclosure (CCPD)



EIGHT SITES

- Northwestern University (NU)
- Vanderbilt University Medical Center (VUMC)
- University of Southern California (USC)
- Oregon Health & Sciences University (OHSU)
- Medical College of Wisconsin (MCW)
- University of Texas Southwestern (UTSW)
- University of California – Davis (UCD)
- University of Alabama at Birmingham (UAB)

FIT-BRAIN Trial Exception From

- + . Informed Consent
- (EFIC) sIRB & IREx
setup

FIT-BRAIN Trial sIRB setup



- NU - Lead Site
- VUMC – Site & sIRB
- UAB – Site & Community Consultation & Public Disclosure (CCPD - social media /online meeting based) Vendor
- Initial application - 03/19/2024
- Key Inclusions: Single EFIC CCPD Plan, 11 General CCPD Documents - English/Spanish (3 Templates), Two-Part Consent: Part 1 Master Consent, Part 2 Local Context Consent
- Deferral to complete the CCPD campaign – 06/04/2024
- Lead site sIRB approval – 07/31/2024

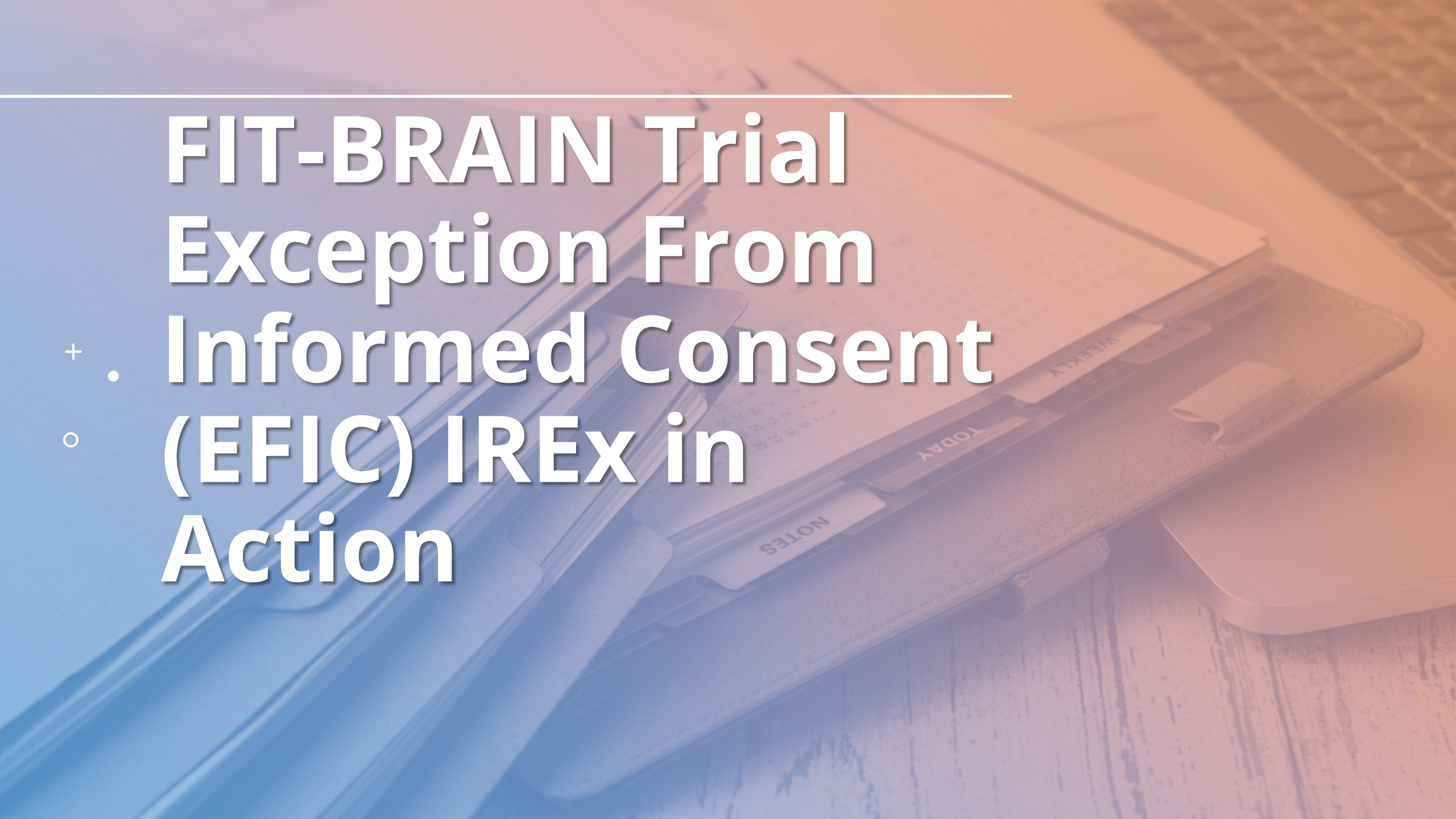
FIT-BRAIN Trial IREx setup



- Nine sites in IREx
- NU – External Lead Site
- VUMC - “Admin Only”

A screenshot of a web application interface. At the top, it says "Status Summary". Below that is a search bar with a magnifying glass icon and the text "Search:". Under the search bar is a section labeled "Site". Below "Site" is a text input field containing the text "Admin Only VUMC".

- Single EFIC CCPD Plan, 11 General CCPD Documents - English/Spanish (3 Templates), Two-part Consent: Part 1 Master Consent, Part 2 Local Context Consent



FIT-BRAIN Trial Exception From Informed Consent (EFIC) IREx in Action

- +
-
-

FIT-BRAIN Trial in IREx Notes and Recommendations



- NU - Lead site Study Manager
- IRB-approved global trial documents, template email/access, instructions to sites through a single submission
- IREx prompts (reliance instructions) to sites using visible dates associated with previous IREx email contact

Reliance Decision ?	Local Considerations
Started 12/19/2024	2 / 4 Surveys Complete ▾
Started 10/17/2024	0 / 4 Surveys Complete ▾
Completed 4/24/2024	4 / 4 Surveys Complete ▾
Contacted 11/20/2024	



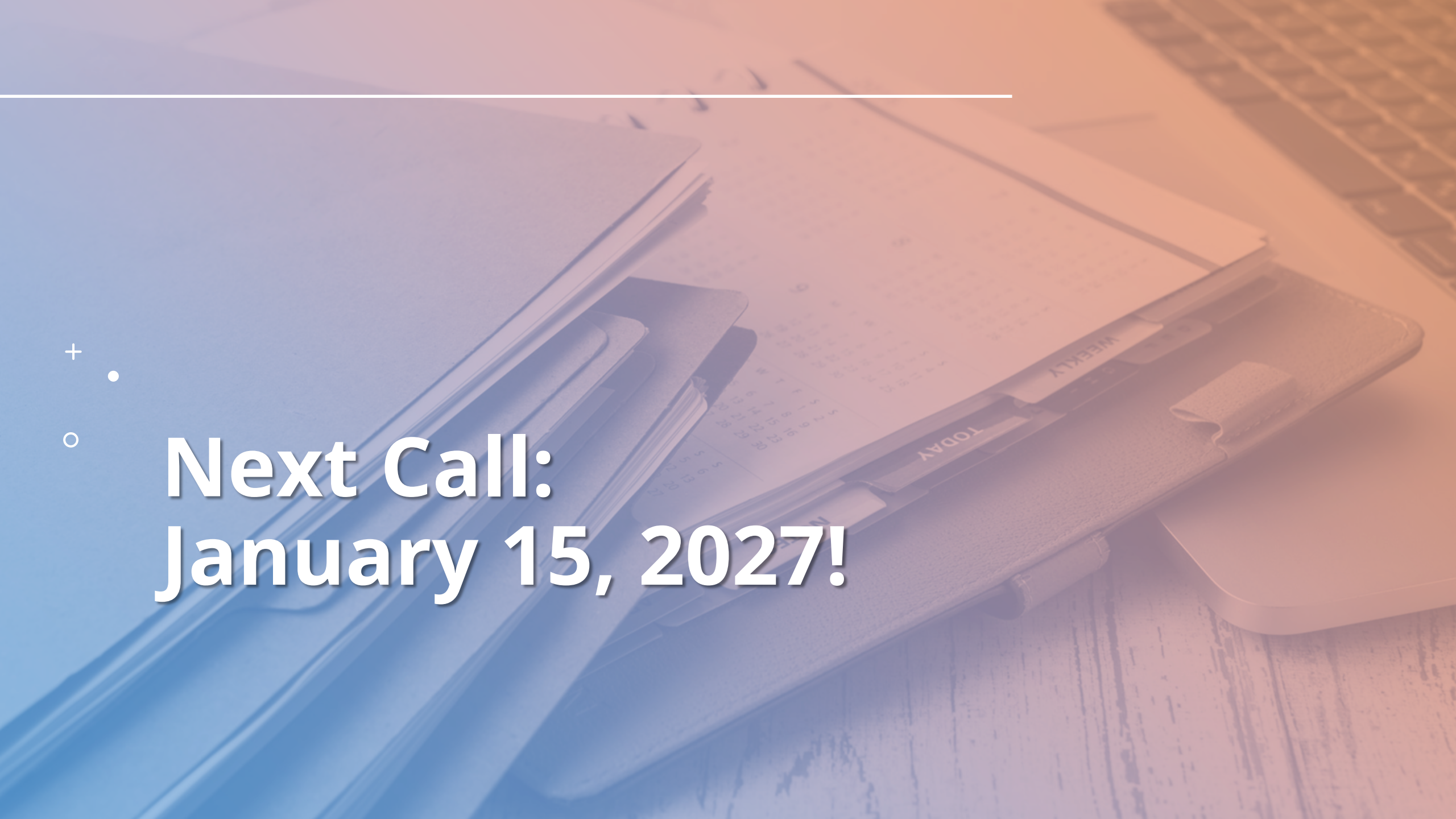
FIT-BRAIN Trial in IREx Notes and Recommendations



- All-site onboarding materials repository/document source of truth
- IREx Local Considerations (reliance documentation) easily transferred to the VUMC sIRB application
- sIRB IREx approval push
- Reliance instructions – Site Differences
- Master or Single EFIC CCPD Plan Option



Thank you. Questions?



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○

**Next Call:
January 15, 2027!**