



# IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

## QUARTERLY CALL FOR STUDY MANAGERS

January 21, 2022

- Study & User Support
- Materials Development

*Katelyn Benhoff*



- Training & User Support

*Natalie Dilts*



- Lead Application Developer

*Bryce Embry*



- Study Support
- New Features

*Carrie Smith*



- Project Director

*Emily Serdoz*



- Onboarding
- Study & User Support

*David Crenshaw*



- Onboarding
- Study Support

*Bridget Swindell*



- System Development
- Study Support

*Linda Tan*



- Application Developer

*Jason Tan*



- Application Developer

*Evan Wimberly*



# QUARTERLY CALL AGENDA



- **Welcome**
- **Year End Metrics**
- **Feedback Needed**
- **Recent System Updates**



# New IREx Team Member: Carrie Smith

---

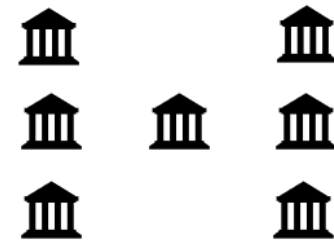
- Formerly an IREx Study Manager for the APOLLO study with >100 study sites (Wake Forest sIRB)!
- Will support new Lead Study Teams and Coordinating Centers using IREx
- Will inform feature development for lead study teams and coordinating centers
- Also driving master contracting & budgeting tool initiatives (non-IREx)

# YEAR END METRICS



**45** sites joined 

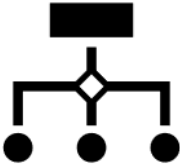
**99** studies created 



**571** new reliances 

**412** sites received initial approval 

**7** average sites per study in IREx

**5** average studies per relying site 

**2043** users added 

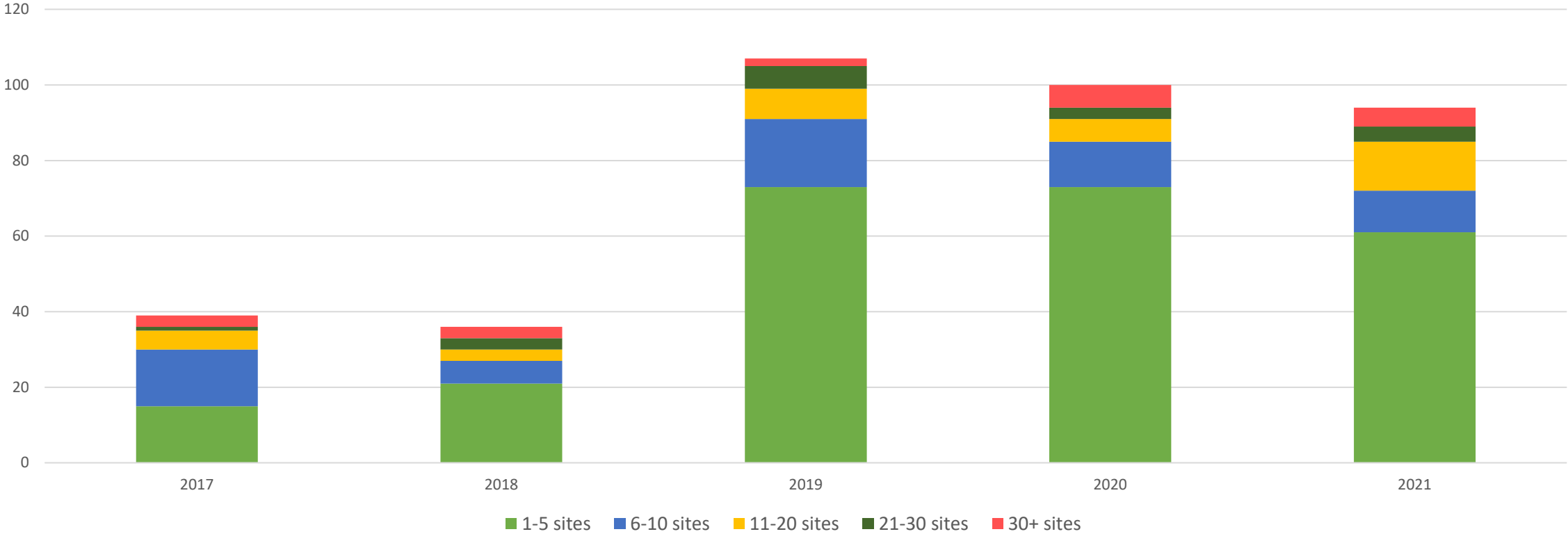
**12** median days from sIRB submission to approval for relying sites 

**9** major system enhancements 

# YEAR END METRICS



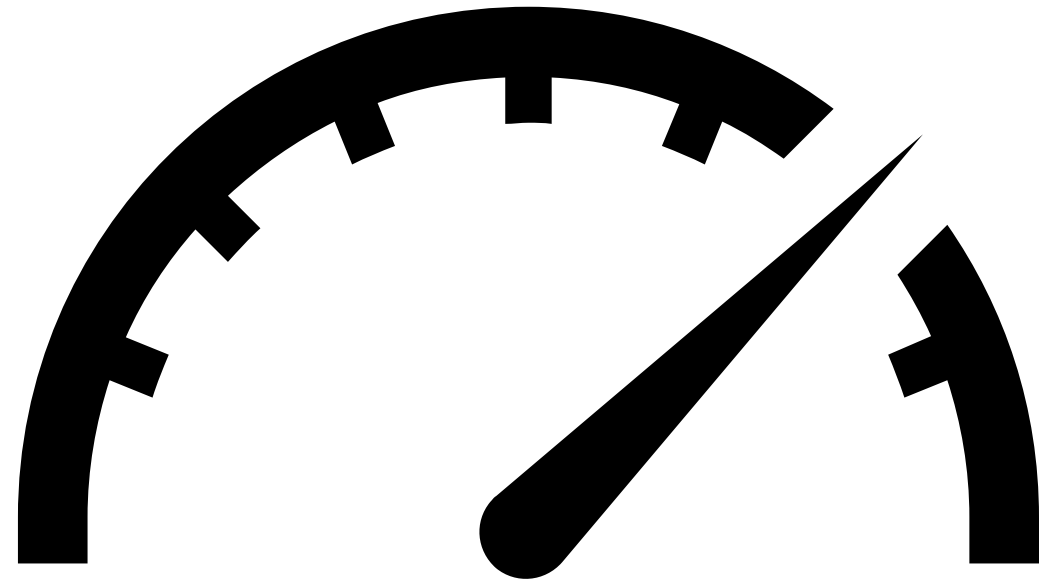
Study Size by Year



**Request for Feedback!**

# IREx SATISFACTION SURVEYS

- **Respondents**
  - **sIRB Liaisons**, after uploading lead site approval
  - **Study managers**, after a few relying sites get approval
  - **PSite HRPPs**, after receiving approval from sIRB
- **Satisfaction with using IREx...**
  - on THIS study
  - in general
  - resources
- **Are there features we should improve/add**
- **Participating Site experience**



# SUPPORT & TRAINING

- On demand videos available by user:  
<https://www.irbexchange.org/p/sign-up-for-training/>
- Request a live training or demo:  
<https://redcap.vanderbilt.edu/surveys/?s=H8XMMD7KTX>
- IREx Outreach:
  - Each time there's a new sIRB study, we reach out to the study manager
  - Reminders & prompts for sites in study start up
- FYI – available for **20-minute overview presentation to relying site study teams** on using sIRB & IREx

## USER TRAININGS

Select a training below that works best for you. Don't see a training? [Contact us.](#)

- ◀ Reviewing IRB Trainings
  - Reviewing IRB Training | 11:40 mins – Watch Now
  - How do sIRBs use their IRB Dashboard? | 1:30 mins – Watch Now
  - How do sIRBs and Study Managers close a study in IREx? | 1:40 mins – Watch Now
  - How do sIRBs and Study Managers close a site? | 2 mins – Watch Now
  - How do I add a Site Amendment approval in IREx? | 1:20 mins – Watch Now \*NEW\*
- ▶ IREx Study Manager Trainings
- ◀ Relying Site HRPP Training
  - Capturing Local Considerations in IREx | 8 mins – Watch Now
  - Relying HRPP Training | 4:30 mins – Watch Now
  - Introduction to sIRB Review | 5 mins – Watch Now
  - How do Relying HRPPs register for a study in IREx? | 2 mins – Watch Now
  - Uploading Consent Forms in IREx | 1 min – Watch Now
  - How do Relying HRPPs use their IRB Dashboard? | 1 min – Watch Now
  - Getting Approved & Accessing Approvals in IREx | 1 min – Watch Now
- ▶ Relying Site Study Team Trainings

**HRPP Training Videos**



+

•

○

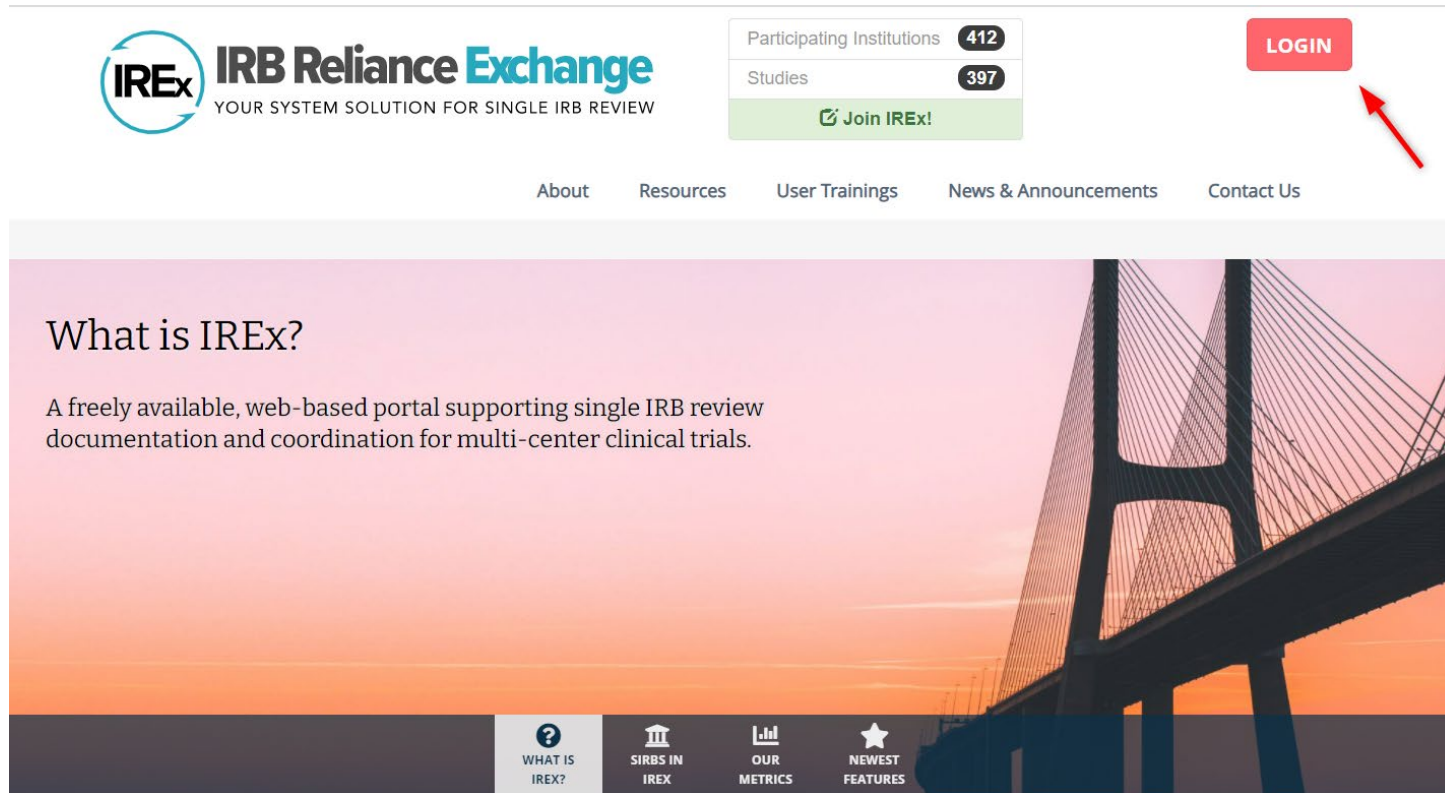
# Join the IREx User Feedback Group!

- Open to HRPP Liaisons and Study Managers
- Members provide input on upcoming features and priorities.
- Current membership includes:
  - Indiana
  - Johns Hopkins
  - Ohio State
  - Oregon
  - Pennington Biomedical
  - Utah
  - Vanderbilt
  - Wake Forest
  - WashU
- Meets the 3rd Friday each month at 1 ET.
- [Sign up here](#)

# Recent System Updates

Since October 2021

# 1. NEW IREX LOGIN SCREEN (for enhanced security)



The screenshot shows the IREx website home page. At the top left is the IREx logo and the text "IRB Reliance Exchange YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW". To the right, there are two statistics: "Participating Institutions 412" and "Studies 397", with a "Join IREx!" button below. A red arrow points to a "LOGIN" button in the top right corner. Below the header is a navigation menu with "About", "Resources", "User Trainings", "News & Announcements", and "Contact Us". The main content area features a large image of a bridge at sunset with the heading "What is IREx?" and the text "A freely available, web-based portal supporting single IRB review documentation and coordination for multi-center clinical trials." At the bottom, there is a footer with icons and text for "WHAT IS IREX?", "SIRBS IN IREX", "OUR METRICS", and "NEWEST FEATURES".



IREx IRB Reliance Exchange  
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

IRB Reliance Exchange member login

Login

[Forgot your password?](#)



IREx IRB Reliance Exchange  
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

You have successfully logged out.

Login again

Return home

# 2. STUDY MANAGER DASHBOARDS

**MELLON UNIVERSITY MEDICAL CENTER**

**1** Managing  
You are managing 1 study

**1** Participant  
You are participating in 1 study

**52** users  
There are 52 users at your site

[Home](#)

**New February 2024**  
IREx can... [Read more](#) or [Watch a video](#)

**Find a Study**  
by Name:   
[Study Manager Dashboard](#)  
[find](#)

**Your Institution**  
Mellon University Medical Center  
[Profile](#) [Components](#)

**Resources**  
[Find other users](#)  
[Find other sites](#)

**Studies where you are the Lead/Coordinating Center**

**Studies where you are a relying site coordinator**

# 2. STUDY MANAGER DASHBOARDS

## Study Manager Dashboard

Q Search:

Study Title	Sites	Signed Agreements	Reliance	Local Consid.	Current Approvals	Expires
ZEDS document loading <i>Project ID: 1635963</i>	4 / 4 Registered	SMART IRB 4 Indemnification 5 IREx 4	3	3	2 10/6/2021	10/7/2022

MELLON UNIVERSITY MEDICAL CENTER

1 Managing  
You are managing 1 study

1 Participant  
You are participating in 1 study

52 users  
There are 52 users at your site

[Home](#)

## Related Studies

Q Search:

Study Title	Sponsor	Sites	Reviewing IRB
<a href="#">Noncoding RNA modulator on Autoimmune Diseases</a>	Investigator	4	GUMC

Showing 1 to 1 of 1 entries

Previous 1 Next

Coordinator Dashboard

# 3. NEW PI DASHBOARD

 FARADAY INSTITUTE OF RESEARCH, SCIENCE AND TECHNOLOGY

**24**  
studies

You are participating in 24 studies

[Home](#)

## PI Dashboard

Q Search:

Study Title	Your Site	Reviewing IRB	Expiration Date	To Do
<a href="#">20210420_where are the review dates</a>	Faraday Inst	Mellon University Medical Center	4/4/2022	Site Closed
<a href="#">20210913 - PrecISE example study</a>	Faraday Inst	Mellon University Medical Center	8/17/2022	Site Closed
<a href="#">20210825_Allow SM to close a site</a>	Faraday Inst-Physics Lab	Carnegie University Medical Center	8/2/2022	Site Closed
<a href="#">Baking Analysis of Kinetic Energy (BAKE)</a>	Faraday Inst	Mellon University Medical Center	5/13/2022	Approved
<a href="#">Study URI tEst (SURE)_kb_03162021</a>	Faraday Inst	Vanderbilt University Medical Center	6/1/2021	Approved 3/3/2021
<a href="#">Photosensitivity Exposure Assessment Study (PEAS)</a>	Faraday Inst	Mellon University Medical Center	7/6/2021	Approved
<a href="#">Study 10</a>	Faraday Inst	Vanderbilt University Medical Center	8/3/2022	Approved 10/15/2021
<a href="#">20211101_Study Specific ORAs are not saving on a study in IREx setup</a>	Faraday Inst	Albert Einstein College of Medicine		Approved
<a href="#">20210908_study team access view after site closure</a>	Faraday Inst	Mellon University Medical Center		Approved 9/8/2021
<a href="#">20210927_can non-primary hrpp see docs without LC?</a>	Middle-earth College	Mellon University Medical Center	9/22/2022	Validate Study Team

# 4. INDICATE WHEN SITES ARE NOT ENROLLING PARTICIPANTS

- Use Cases:**
- Sites are engaged, but not enrolling
  - Studies are closed to enrollment

## Lead Site

The screenshot shows a 'Study Information' form for a Lead Site. At the top, there are four navigation icons: a list, a calendar, a folder, and a checkmark. The form includes a 'Change Summary' text area with the text 'new changes'. Below this is a 'Status' section with radio buttons for 'Approved' (selected) and 'Pending'. The 'IRB #' field contains '20211103'. The 'Review Type' dropdown is set to 'Study-Wide Amendment: Full Board'. At the bottom, the 'Is Site Enrolling?' field has radio buttons for 'Yes' and 'No', with 'No' selected. A red arrow points to the 'No' option. A green 'Continue' button is at the bottom right.

## Relying Site

The screenshot shows a 'Relying Site Approvals' window for 'Mellon Univ. Med Ctr'. The 'Status' dropdown is set to 'approved'. The 'Review Type' dropdown is set to 'Initial Study: Full Board'. The 'Is Site Enrolling?' field has radio buttons for 'Yes' and 'No', with 'No' selected. Below this are fields for 'Date Submitted' (11/02/2021), 'Date Pre-Reviewed' (mm/dd/yyyy), 'Date Reviewed' (11/03/2021), and 'Date Approved' (11/03/2021). There are also links for 'Add pre-review exchanges with PI' and 'Add post-review exchanges with PI'. The 'Documents' section shows a 'Determination Letter' with a file named 'DETERMINATION LETTER\_RelyingSite2.docx'. The 'Consents & Assents' section has a 'Choose a file or drag it here.' button.

# 4. INDICATE WHEN SITES ARE NOT ENROLLING PARTICIPANTS

Study-Wide Amendment: Full Board (Approved) Current

Site Not Enrolling

Edit review Site approvals

---

**Study Info** **Key Dates**

Role:	Reviewing IRB	Submitted:	11/9/2021
IRB Number:	20211103	Pre-Reviewed:	
Status:	approved	Reviewed:	11/10/2021
Submission Type:	Study-Wide Amendment: Full Board	Approved:	11/10/2021
Review Cycle:	No Further Review Required	Expires:	

Change Summary: new changes

Site is not enrolling

---

**Documents**

Type	Name	Date Added	Size
Protocol 1	PROTOCOL_v1.docx	11/12/2021	12535
Determination Letter	DETERMINATION LETTER_Amendment.pdf	11/12/2021	34351
Amendment Application	AMENDMENT APPLICATION.docx	11/12/2021	11377

Download All



# 5. ADDED FLEXIBILITY FOR COMBO SITE DOCUMENTATION

**Combo Sites:** When a **single PI/study** team engages **multiple FWAs**

**Problem:** FWA sites may be 1) onboarded independently of one another and/or 2) added later to increase enrollment

**Solution:** IREx needs to allow FWAs be reviewed and approved separately.

Site	Reliance Agreement ?	IREx Access ?	Reliance Decision ?	Local Considerations	Approval Status (current version)
Anderson Medical Center Baylor College Med	SMART 2	✓	Started 10/1/2021	0 / 3 Surveys Complete	Not Approved
Baylor College of Medicine Anderson Med Ctr	SMART 2	✓	Contacted 10/1/2021		

# 5. ADDED FLEXIBILITY FOR COMBO SITE DOCUMENTATION

Study-wide IRB Approvals   Site-specific IRB Approvals   **Status Summary**


## Participant Status Summary Export Data ▾

Q Search:

Site	Reliance Agreement	IREx Access	Reliance Decision	Local Considerations	Approval Status (current version)
Faraday Institute of Research, Science and Technology	SMART 2	✓	Completed 5/12/2021	2 / 3 Surveys Complete ▾	Approved
Goodall University 	SMART 2	✓	Completed 1/19/2022	3 / 3 Surveys Complete ▾	Approved
Goodall University Medical Center 	SMART 2	✓	Started	0 / 3 Surveys Complete ▾	Not Approved

# 5. ADDED FLEXIBILITY FOR COMBO SITE DOCUMENTATION

HRPPs can copy the answers from one HRP Survey to another for a combo site

 Goodall | GUMC

The sIRB needs local considerations/reviews for Goodall University Medical Center - FWA#78899657.

As a non-primary HRPP for this combo site, please indicate how you would like to proceed:

Complete the survey from scratch.

Copy & edit responses from Goodall

**\*NEW\*** PIs must provide a PI Survey for each FWA, and they can copy the answers from one to another

When PI completes 2nd PI survey, they have the option to copy their answers

 Goodall | GUMC

The sIRB needs a PI Survey for Goodall University Medical Center.

You have already completed a PI survey for this combo site. Please indicate how you would like to proceed:

Complete the survey from scratch.

Copy & edit responses from Goodall

 Goodall | GUMC  
GETTING STARTED

✓ Verify Study Team Access

✓ Complete PI Survey for Goodall

➔ Complete PI Survey for GUMC

✓ HRPP Validates PI Survey for Goodall

➔ HRPP Validates PI Survey for GUMC

👁 View Status Summary

Study-wide IRB Approvals

Site-specific IRB Approvals

Status Summary

Protocol Version: 1.02, 20200703

Goodall University

^ Initial Study: Full Board

Current

☰ Study Info

Role: Relying Site  
IRB Number:  
Status:

📅 Key Dates

Submitted for Local Review:  
Local Review Conducted:  
Local Review Completed:

# 5. ADDED FLEXIBILITY FOR COMBO SITE DOCUMENTATION

Study-wide IRB Approvals | **Site-specific IRB Approvals** | Status Summary

Protocol Version: 1.02, 20200703 Manage Version ▾

**Faraday Institute of Research, Science and Technology** ⋮

▼ Initial Study: Expedited (exp. 4/11/2022) Current

**Goodall University** ⋮

▼ Initial Study: Expedited (exp. 4/11/2022) Current

**Goodall University Medical Center**

▼ Initial Study: [REDACTED]

**Goodall and Goodall MC can have approval documents posted at different times**



# 6. CUSTOMIZE DOCUMENT TYPES

1. Upload ICF
2. Use pencil to add descriptors to help with sorting

The screenshot shows a web interface for uploading documents. A modal dialog is open, titled "Please describe the document type". It has a dropdown menu currently showing "Consents & Assents -" and a text input field containing "LIVING DONOR ICF". There are "Cancel" and "OK" buttons at the bottom right of the dialog. A red arrow points from the "Consents & Assents" dropdown in the dialog to the "Consents & Assents" button in the background interface. The background interface includes a header "Review - Mellon", a menu icon, and a section titled "Upload Documents" with instructions "Drag file into document type or click a document type to upload." Below this are several buttons for document types: "Consents & Assents", "Grant Application", "Meeting Notes", "Investigators Brochure", "Device Manual", "Package Insert", "Measures", "Recruitment & Advertisements", "Additional IRB Approved Documents", and "Others". At the bottom, there is a table titled "Uploaded Documents" with columns for "Type", "Document", and "Action".

Type	Document	Action
Protocol [20Jan2022, version	Protocol_version 1.0_20Jan2022.docx	
IRB Approval Documentation	IRB Approval Memo_20Jan2022.docx	✗ Delete
IRB Application	IRB Application_20Jan2022.docx	✗ Delete
Consents & Assents	ADULT ICF_20Jan2022.docx	✗ Delete

# 6. CUSTOMIZE DOCUMENT TYPES

Customize document TYPE for 'Additional IRB Approved Documents' + 'Others'

Please describe the document type

Recruitment Materials

Cancel OK

Upload Documents

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

Consents & Assents Grant Application Meeting Notes Investigators Brochure

Device Manual Package Insert Measures Recruitment & Advertisemen

Additional IRB Approved Documents Others

Upload Documents

Please describe the document type

Cognitive Battery

Cancel OK

Upload Documents

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

Consents & Assents Grant Application Meeting Notes Investigators Brochure

Device Manual Package Insert Measures Recruitment & Advertisemen

Additional IRB Approved Documents Others

Upload Documents

Type	Document	Actions
Protocol [20Jan2022, version 1]	Protocol_version 1.0_20Jan2022.docx	
IRB Approval Documentation	IRB Approval Memo_20Jan2022.docx	✕ Delete
IRB Application	IRB Application_20Jan2022.docx	✕ Delete
Consents & Assents	ICF_CREOLE_20Jan2022.docx	✕ Delete
Consents & Assents	ICF_SPANISH_20JAN2022.docx	✕ Delete
Consents & Assents	ASSENT_AGES 10-15_20Jan2022.docx	✕ Delete
Consents & Assents - LIVING DONOR ICF	ADULT ICF_20Jan2022.docx	✕ Delete
Participant Questionnaire	Medical History_20Jan2022.docx	✕ Delete
Additional IRB Approved Documents	Recruitment Flyer_20Jan2022.docx	✕ Delete

Customize the Type for "additional IRB approved documents and "other documents"

Type	Document	Actions
Protocol [20Jan2022, version 1]	Protocol_version 1.0_20Jan2022.docx	
IRB Approval Documentation	IRB Approval Memo_20Jan2022.docx	✕ Delete
IRB Application	IRB Application_20Jan2022.docx	✕ Delete
Consents & Assents	ICF_CREOLE_20Jan2022.docx	✕ Delete
Consents & Assents	ICF_SPANISH_20JAN2022.docx	✕ Delete
Consents & Assents	ASSENT_AGES 10-15_20Jan2022.docx	✕ Delete
Consents & Assents - LIVING DONOR ICF	ADULT ICF_20Jan2022.docx	✕ Delete
Others	Cognitive Battery_20Jan2022.docx	✕ Delete
Participant Questionnaire	Medical History_20Jan2022.docx	✕ Delete
Recruitment Materials	Recruitment Flyer_20Jan2022.docx	✕ Delete

# 6. CUSTOMIZE DOCUMENT TYPES

Protocol Version: 20Jan2022,  
version 1

Manage Version ▾

SIRB: Mellon University Medical Center

Lead Site: Mellon University Medical Center

^ Initial Study: Full Board (exp. 1/19/2023)

Current

Edit review

Site approvals

Study Info

Key Dates

Role: Reviewing IRB  
IRB Number: 29110310  
Status: approved  
Submission Type: Initial Study: Full Board  
Review Cycle: 12 mo

Submitted: 1/18/2022  
Pre-Reviewed:  
Reviewed: 1/20/2022  
Approved: 1/20/2022  
Expires: 1/19/2023

^ Documents

Type	Name	Date Added	Size
Protocol 20Jan2022, version 1	<a href="#">Protocol_version 1.0_20Jan2022.docx</a>	1/20/2022	12811
IRB Approval Documentation	<a href="#">IRB Approval Memo_20Jan2022.docx</a>	1/20/2022	12830
IRB Application	<a href="#">IRB Application_20Jan2022.docx</a>	1/20/2022	12826
Consents & Assents - LIVING DONOR ICF	<a href="#">ADULT ICF_20Jan2022.docx</a>	1/20/2022	12847
Consents & Assents	<a href="#">ICF_CREOLE_20Jan2022.docx</a>	1/20/2022	12822
Consents & Assents	<a href="#">ICF_SPANISH_20JAN2022.docx</a>	1/20/2022	12824
Consents & Assents	<a href="#">ASSENT_AGES 10-15_20Jan2022.docx</a>	1/20/2022	12828
Recruitment Materials	<a href="#">Recruitment Flyer_20Jan2022.docx</a>	1/20/2022	12825
Participant Questionnaire	<a href="#">Medical History_20Jan2022.docx</a>	1/20/2022	12832
Cognitive Battery	<a href="#">Cognitive Battery_20Jan2022.docx</a>	1/20/2022	12829

# 7. DOCUMENT “DATE OF APPROVAL” (COMING SOON!)

Upload Documents

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

Consents & Assents Grant Application Meeting Notes Investigators Brochure

Device Manual Recruitment & Advertisements Additional IRB Approved Documents Others

Package Insert Measures

Uploaded Documents

Type	Document	Date Approved	
Consents & Assents	<a href="#">CONSENT FORM - Assent.docx</a>	5/6/2021	<a href="#">Delete</a>
Protocol [1.1]		4/3/2020	
Study Material		4/3/2020	<a href="#">Delete</a>
Study Material	<a href="#">Recruitment.docx</a>	4/3/2020	<a href="#">Delete</a>
Amendment Application	<a href="#">AMENDMENT APPLICATION.docx</a>		<a href="#">Delete</a>
Consents & Assents	<a href="#">CONSENT FORM Spanish.docx</a>		<a href="#">Delete</a>
IRB Approval Documentation	<a href="#">IRB APPROVAL_Leadsite.docx</a>		<a href="#">Delete</a>

New documents uploaded does not yet show date approved until published

Continue →

SIRB: Mellon University Medical Center

Lead Site: Mellon University Medical Center

Study-Wide Amendment: Expedited (exp. 5/5/2022) **Current**

Edit review Site approvals

Study Info Key Dates

Role: Reviewing IRB  
IRB Number: 654321  
Status: approved  
Submission Type: Study-Wide Amendment: Expedited  
Review Cycle: 12 mo  
Change Summary: some changes

Submitted: 1/5/2022  
Pre-Reviewed:  
Reviewed: 1/6/2022  
Approved: 1/6/2022  
Expires: 5/5/2022

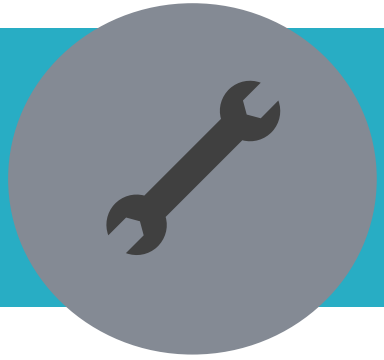
Documents

Type	Name	Date Approved
Protocol 1.1	<a href="#">PROTOCOL_v1.1.docx</a>	4/3/2020
IRB Approval Documentation	<a href="#">IRB APPROVAL_Leadsite.docx</a>	1/6/2022
Amendment Application	<a href="#">AMENDMENT APPLICATION.docx</a>	1/6/2022
Consents & Assents	<a href="#">CONSENT FORM - Assent.docx</a>	5/6/2021
Consents & Assents	<a href="#">CONSENT FORM Spanish.docx</a>	1/6/2022
Others - Study Material	<a href="#">Flyer.png</a>	4/3/2020
Others - Study Material	<a href="#">Recruitment.docx</a>	4/3/2020

Download All



# New and Updated Resources for Study Managers



## *Quick Guides*

- [How to Document a Site Closure](#)
- [How to Upload the Initial Site Approval for Relying Sites](#)
- [How to Upload a Site Amendment Approval](#)
- [How to Upload Continuing Review Approvals](#)
- [How to Upload Study-wide Amendment Approvals](#)
- [IREx Combo Sites Overview](#)

## *Overviews*

- [Study-wide and Site-specific Document Types](#)
- [IREx Notifications Encyclopedia](#)

## *Quick Vids*

(90 seconds or less!)



- [How to Upload a Site Amendment Approval](#)
- [How do sIRBs & Study Managers Close a Site on a Study?](#)
- [How do Relying HRPPs Register for a Study?](#)

## *General Resources*

- [General Resources for Study Managers](#)

**Next Call: April 15 , 2022**