



IRB Reliance Exchange

YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

QUARTERLY CALL FOR HRPPS

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

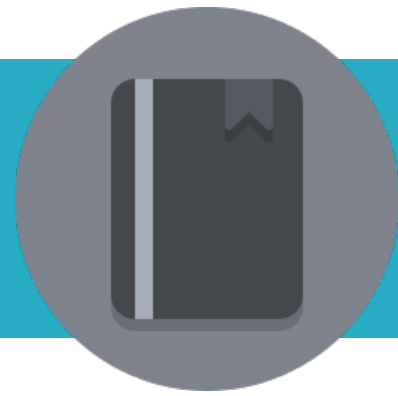


- Application Developer

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



7 average sites
per study in IREx

571



new
reliances

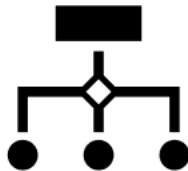


412
sites received
initial approval

2043 users
added



5



average studies
per relying site



9

major system
enhancements

12

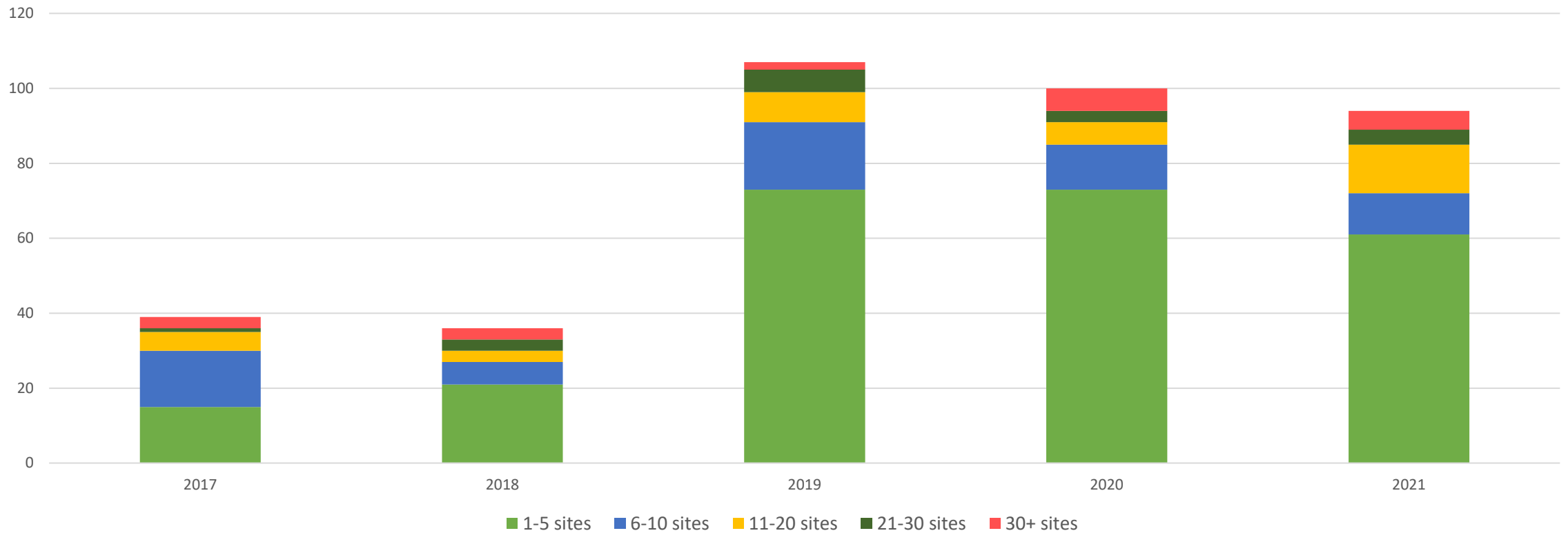


median days from sIRB
submission to approval
for relying sites

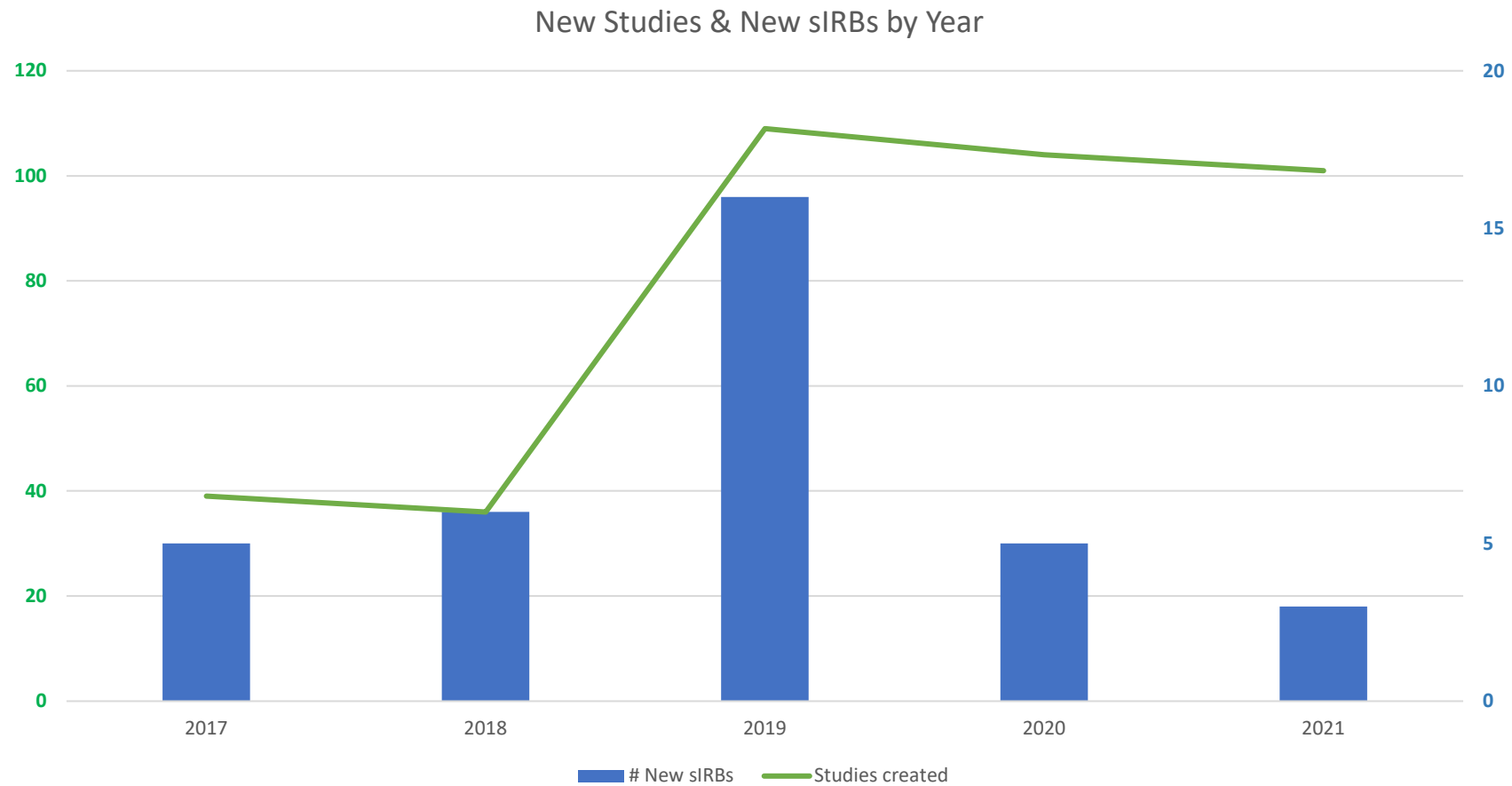
YEAR END METRICS



Study Size by Year



YEAR END METRICS



YEAR END METRICS



Single IRB Trendsetters

- **Pennington Biomedical** added their **40th** study
- **UC San Francisco** added **16** studies in 2021
- **UM Baltimore** added their **1st** study & approved all sites within **3 months** of the lead site approval
- **UW-Madison** launched their **1st** study in IREx
- **Vanderbilt** exceeded over **100** studies in IREx
- **Wake Forest** is the sIRB in IREx for **>140** relying sites

YEAR END METRICS – Run your own!



PENNINGTON BIOMEDICAL RESEARCH CENTER

35 reviewer
Your site is the reviewer for 35 studies

14 participant
Your site is a participant in 14 studies

45 users
There are 45 users at your site

[Dashboard](#) [Home](#)

Reviewing Site's Studies

Search: crea

All Studies **Export**

- Overall Study Report (CSV)
- Participating Site Report (CSV)

| IRB # | Study Title | Participating Sites | Approved Sites | Expiration | To Do |
|----------|--|---------------------|----------------|------------|------------------------|
| 2019-015 | Creation and maintenance of integrated biorepository databases (IBD) to support research usage of biorepository samples. | 2 | 2 | 4/11/2022 | No Outstanding Actions |
| 2020-004 | Pancreatic Tissue Collection | 1 | 1 | 1/30/2023 | No Outstanding Actions |

Overall Study Report includes all studies where your site is the sIRB

- Count # of studies, by year created/approved
- Count # of studies by risk type
- Count # of total relying sites across all studies
- Count # of sites with initial approval

Participating Site Report lists all approvals (initial, CR, mod) for all sites on all studies where your site is the sIRB

- Count # of unique relying sites
- Calculate time to approval metrics
- Calculate time from site's local HRPP submission/review to sIRB submission/approval

YEAR END METRICS – Run your own!



PENNINGTON BIOMEDICAL RESEARCH CENTER

35 Your site is the **reviewer** for 35 studies
14 Your site is a **participant** in 14 studies
45 There are 45 **users** at your site

[Dashboard](#) [Home](#)

Participating Site's Studies

Search:

All Studies **Export**

Participating Site Report (CSV)

| Study Title | PI | Reviewing IRB | Expiration Date | To Do |
|---|----------------------|----------------------|-----------------|--|
| 3D Body Pilot Study | | LA State Univ A & M | | Register |
| Health Behaviors Syndrome Pilot Study | John W. Apolzan, PhD | LSUHSC at Shreveport | 9/27/2021 | Approved 6/23/2021 |
| Urinalysis and STI Association in Adolescent Psychiatric Patients | Ron Horswell | LSU HSC New Orleans | | Remind PI To Complete Survey |

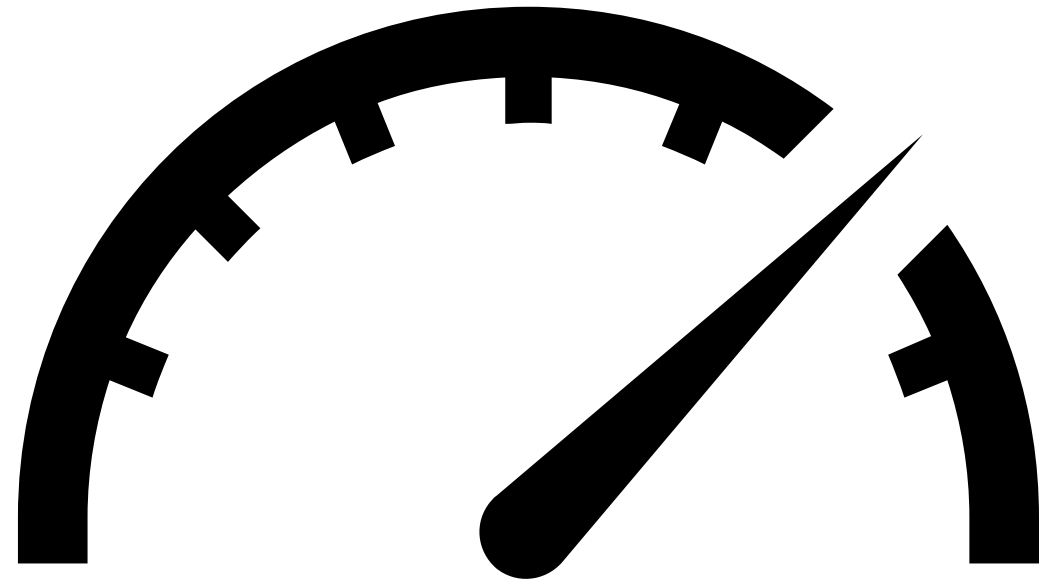
Participating Site Report lists all approvals from studies where your site is relying on an sIRB:

- Count the # of unique sIRBs for your site
- Reference dates of each sIRB approval for your site (initial, CR, mods)
- Calculate # of days from when your site was notified/contacted about study to
 - Date the study was submitted for local submission/review
 - Date your HRP and PI Surveys completed
 - Date of sIRB approval

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
<https://redcap.vanderbilt.edu/?url=/H8XMMD7KT>
- IREx Outreach:
 - Each time the
 - to the study
 - Reminders &
- FYI – available for
presentation to relying site study teams
on using sIRB & IREx

Are there any resource gaps we should fill in with training or educational offerings?

USER TRAININGS

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

How
2 mins – Watch Now
ch Now
Watch Now *NEW*

HRPP Training
Videos

- 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

+

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○

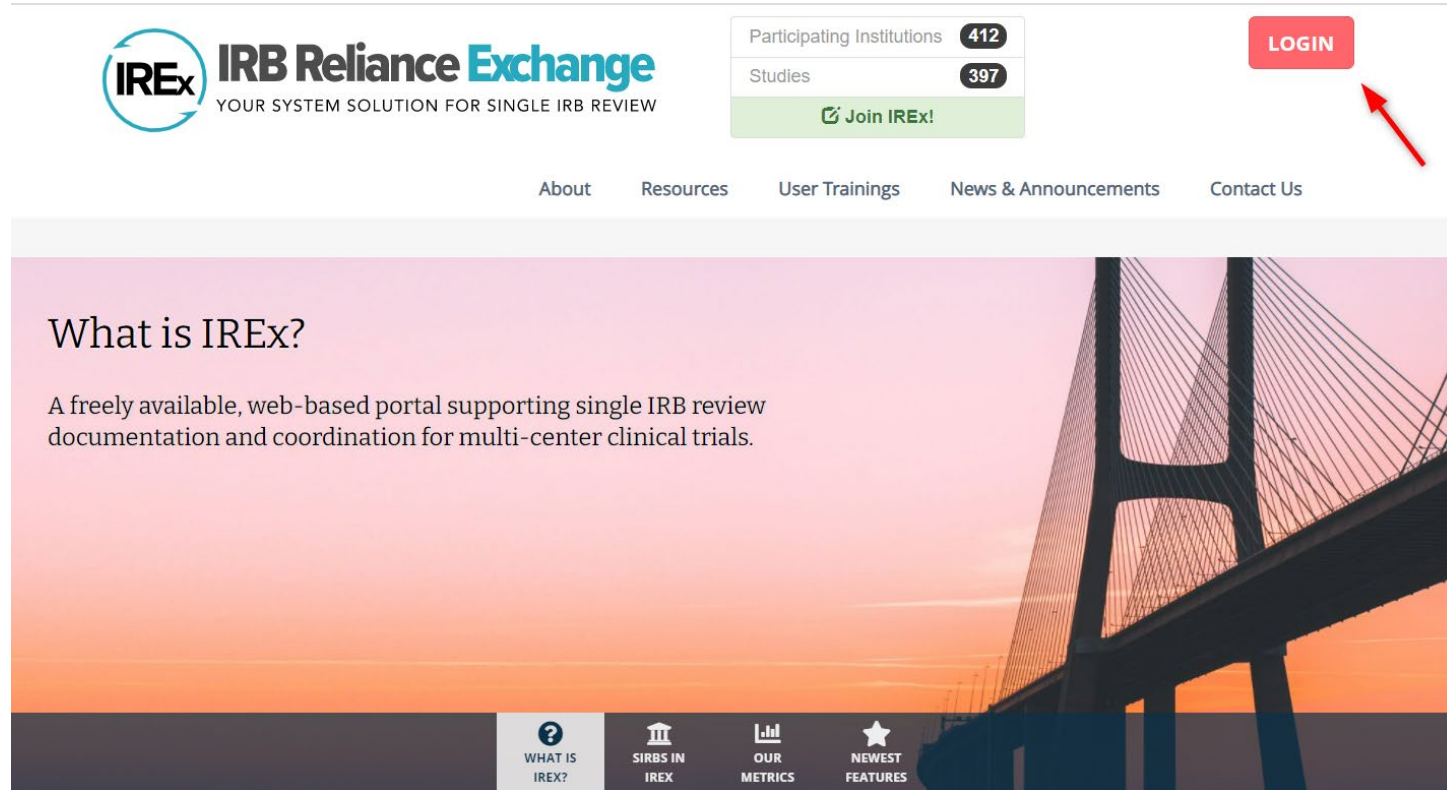
Join the IREx User Feedback Group!

- 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 with the tagline "YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW". To the right of the logo is a statistics box showing "Participating Institutions 412" and "Studies 397", with a green "Join IREx!" button below. Further right is a red "LOGIN" button with a red arrow pointing to it. Below the header is a navigation menu with links: "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 is a dark footer with four icons and labels: "WHAT IS IREX?", "SIRBS IN IREX", "OUR METRICS", and "NEWEST FEATURES".



IRB Reliance Exchange member login

Login

[Forgot your password?](#)




You have successfully logged out.

Login again

Return home

2. PRIMARY LIAISON LISTED IN EXPORT

 ALBERT EINSTEIN COLLEGE OF MEDICINE

68
reviewer

1 Your site is the **reviewer** for 68 studies

Reviewing Site's Studies

Q Search:

All Studies ▾

Export ▾

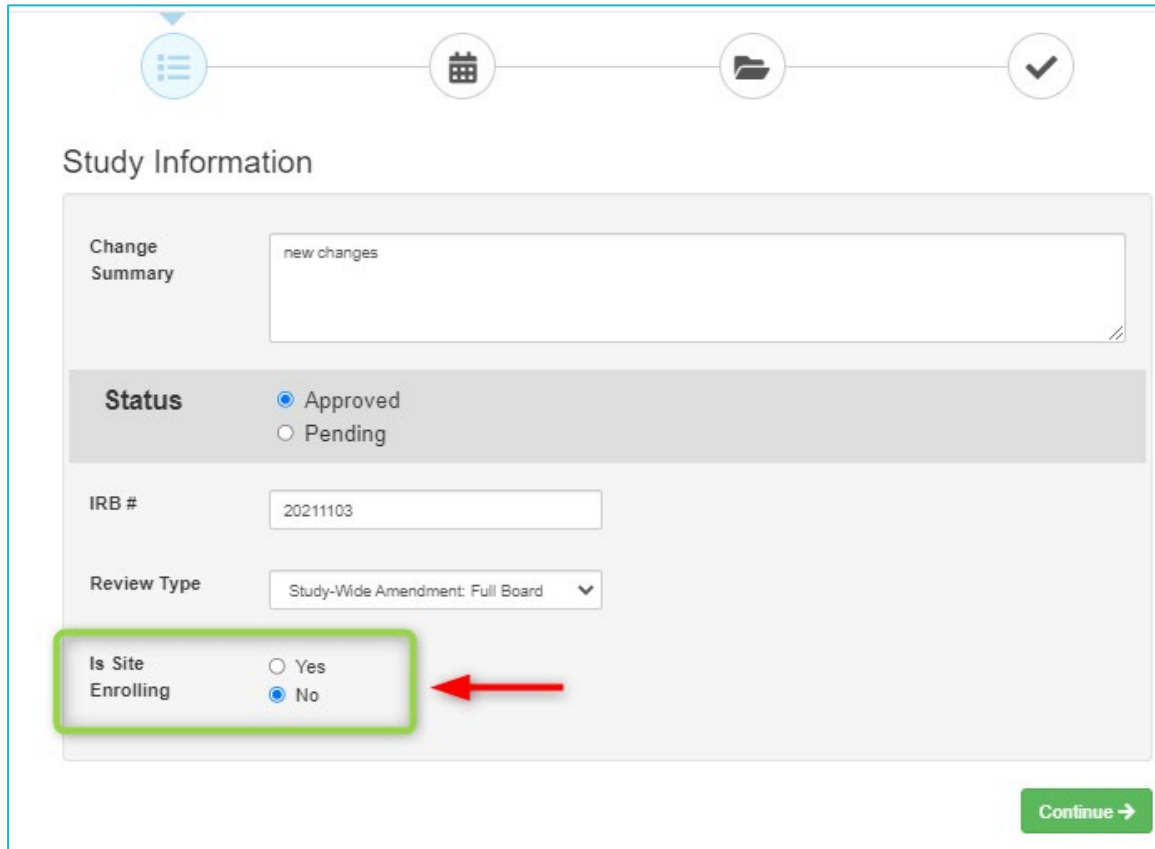
2
Overall Study Report (CSV)
Participating Site Report (CSV)

| A | B | C | D | E | F | G | H | I | J | K | L |
|-----------|---------------------------|---------------------------|-------------|--------------|-------|----------------------|-----------------|------------|--------------------|---------------------|---------------------|
| projectId | shortTitle | longTitle | dateCreated | isCollecting | isTIn | riskType | minRiskCategory | isReviewed | reviewingIRB | reviewingIRBContact | reviewingIRBContact |
| 74 | CPCCRN 082: PICU Outcomes | CPCCRN 082: PICU Outcomes | ##### | 1 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 24 | CPCCRN 077: SiRD Study | CPCCRN 077: SiRD Study | 2/3/2017 | 0 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 12 | CPCCRN 041: PICQ CPR | CPCCRN 041: PICQ CPR | ##### | 0 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 14 | CPCCRN 065: VAP | CPCCRN 065: VAP | ##### | 0 | 1 | minimal | (f)(2), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 15 | CPCCRN 064: GIFT | CPCCRN 064: GIFT | ##### | 0 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 16 | CPCCRN 068: ICU-RESUS | CPCCRN 068: ICU-RESUS | ##### | 0 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 20 | CPCCRN 047: PHENOMS | CPCCRN 047: PHENOMS | 2/2/2017 | 0 | 1 | minimal | (f)(2), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 18 | CPCCRN 059: PEACE | CPCCRN 059: PEACE | 2/2/2017 | 0 | 1 | minimal | (f)(4), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 9 | ValEAR | Randomized | ##### | 0 | 1 | greater than minimal | (f)(5), (f)(6) | 1 | University of Utah | 3745 | Lisa Rigtrup |
| 22 | CPCCRN 053: LAPSE | CPCCRN 053: LAPSE | 2/2/2017 | 0 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 21 | CPCCRN 066: IRA | CPCCRN 066: IRA | 2/2/2017 | 0 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 416 | AZ-SWED | PECARN 043 | ##### | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Lisa Rigtrup |
| 125 | CPCCRN GRACE | CPCCRN GRACE | ##### | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 119 | PECARN: C-Spine | PECARN: C-Spine | ##### | 1 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 104 | PECARN: STIs in Peds ED | PECARN: STIs in Peds ED | 6/6/2018 | 1 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Gary Henderson |
| 323 | P-RAPP | Procalcitonin | 5/7/2020 | 1 | 0 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Lisa Rigtrup |
| 432 | STARt | PECARN 043 | 2/8/2021 | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Ammon Pate |
| 368 | BEEPER | PECARN 043 | ##### | 1 | 0 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 208 | RADIANT | Rare and A | ##### | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Lisa Rigtrup |
| 253 | TTRAPP Study | TTR Amyloid | ##### | 1 | 0 | minimal | (f)(5), (f)(6) | 1 | University of Utah | 3745 | Lisa Rigtrup |
| 267 | | Lipoic acid | ##### | 1 | 0 | greater than minimal | (f)(5), (f)(6) | 1 | University of Utah | 3745 | Lisa Rigtrup |
| 83 | PECARN 043 | PECARN 043 | ##### | 1 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Lisa Rigtrup |
| 367 | HEADACHE | Headache | ##### | 1 | 0 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Lisa Rigtrup |
| 425 | F-AraG-PET Pilot | A pilot study | ##### | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Gary Henderson |
| 421 | SPAN | Study of P | 1/5/2021 | 1 | 0 | | (f)(5), (f)(6) | 1 | University of Utah | 3745 | Lisa Rigtrup |
| 457 | KALPAS | Optimizing | 5/3/2021 | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Ammon Pate |
| 459 | PRECISE | Personalized | 5/5/2021 | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 476 | Pedi-DOSE | PECARN S | ##### | 1 | 1 | greater than minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Annie Risenmay |
| 479 | | Understand | 7/6/2021 | 1 | 0 | minimal | (f)(7), (f)(6) | 1 | University of Utah | 3745 | Lisa Rigtrup |
| 482 | ACHD Gaps | Utilizing P | 7/8/2021 | 1 | 1 | minimal | (f)(5), (f)(6) | 0 | University of Utah | 3745 | Lisa Rigtrup |

3. 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 the 'Study Information' form for a Lead Site. At the top, there is a progress bar with four icons: a list, a calendar, a folder, and a checkmark. The form includes a 'Change Summary' text area with the placeholder 'new changes'. Below this is the '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?' section has radio buttons for 'Yes' and 'No' (selected), which is highlighted with a green box and a red arrow. A green 'Continue' button is at the bottom right.

Study Information

Change Summary: new changes

Status: ☒ Approved ☐ Pending

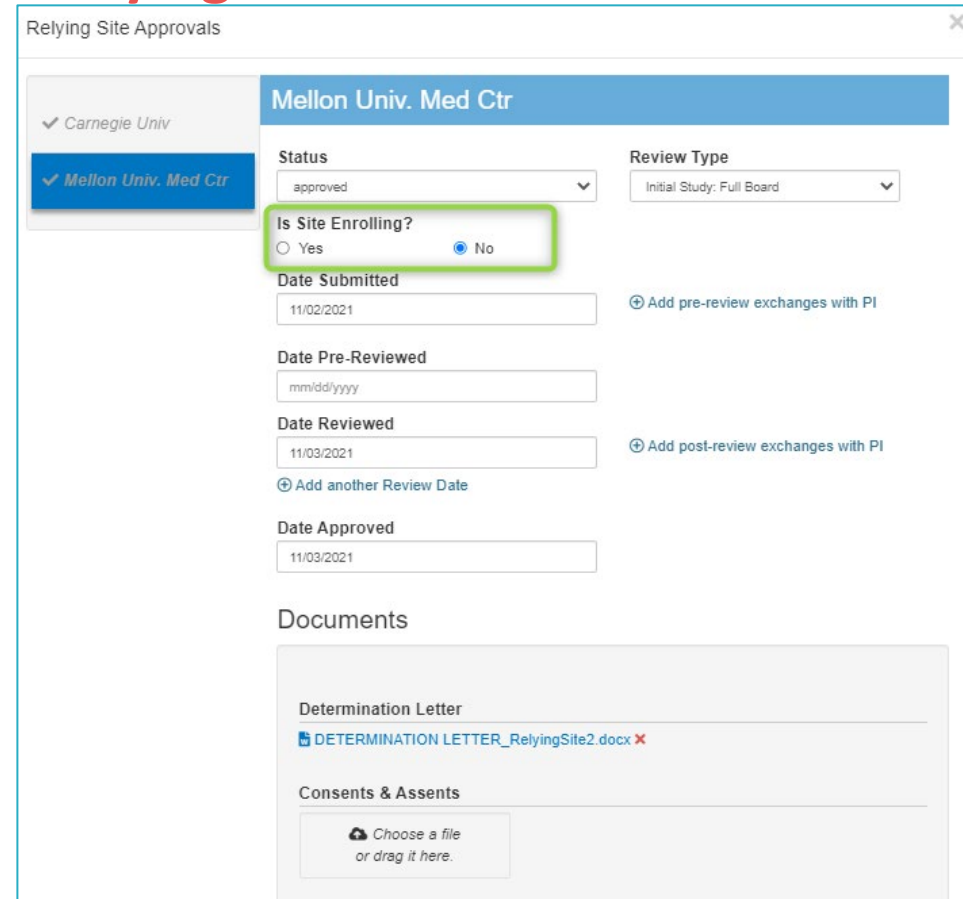
IRB #: 20211103

Review Type: Study-Wide Amendment: Full Board

Is Site Enrolling: ☐ Yes ☒ No

Continue →

Relying Site



The screenshot shows the 'Relying Site Approvals' form. It lists two sites: 'Carnegie Univ' and 'Mellon Univ. Med Ctr', with the latter selected. The 'Status' dropdown is set to 'approved'. The 'Review Type' dropdown is set to 'Initial Study: Full Board'. The 'Is Site Enrolling?' section has radio buttons for 'Yes' and 'No' (selected), highlighted with a green box. 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 links to '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.

Relying Site Approvals

✓ Carnegie Univ

✓ Mellon Univ. Med Ctr

Status: approved

Review Type: Initial Study: Full Board

Is Site Enrolling?: ☐ Yes ☒ No

Date Submitted: 11/02/2021

Date Pre-Reviewed: mm/dd/yyyy

Date Reviewed: 11/03/2021

Date Approved: 11/03/2021

Documents

Determination Letter

DETERMINATION LETTER_RelyingSite2.docx

Consents & Assents

Choose a file or drag it here.

3. INDICATE WHEN SITES ARE NOT ENROLLING PARTICIPANTS

Study-Wide Amendment: Full Board (Approved)

Current

Site Not Enrolling

Edit review

Site approvals

Study Info

Role: Reviewing IRB
IRB Number: 20211103
Status: approved
Submission Type: Study-Wide Amendment: Full Board
Review Cycle: No Further Review Required
Change Summary: new changes
Site is not enrolling

Key Dates

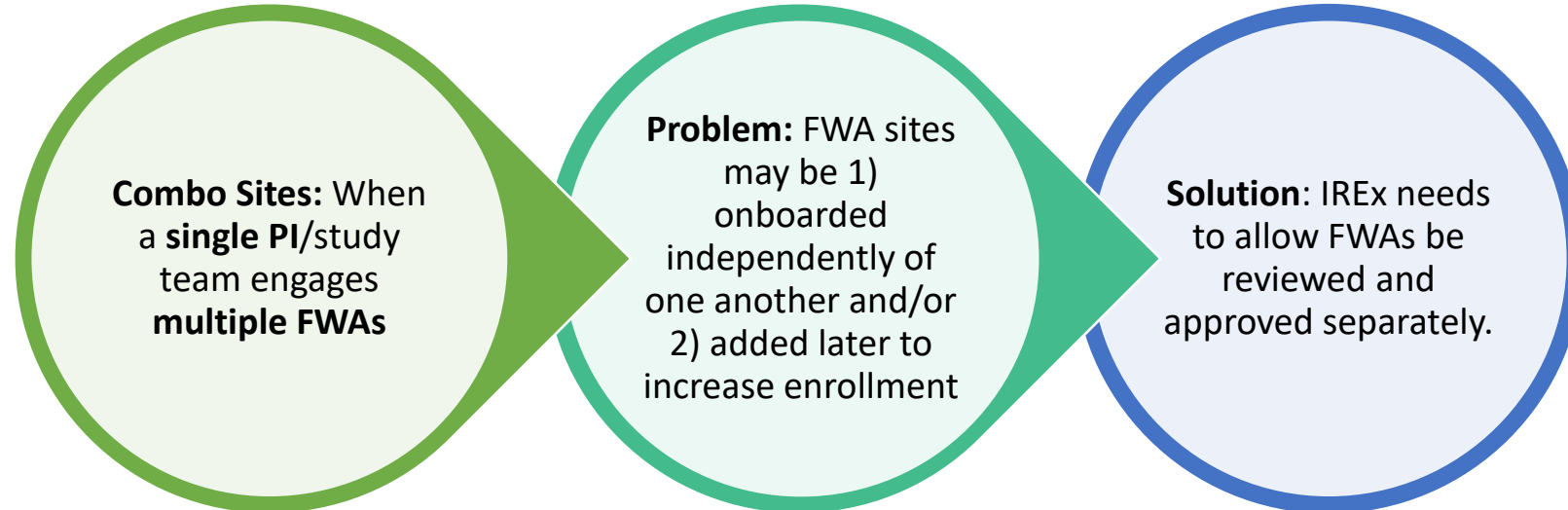
Submitted: 11/9/2021
Pre-Reviewed:
Reviewed: 11/10/2021
Approved: 11/10/2021
Expires:

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

4. ADDED FLEXIBILITY FOR COMBO SITE DOCUMENTATION



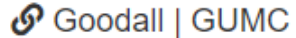
| Site | Reliance Agreement ? | IREx Access ? | Reliance Decision ? | Local Considerations | Approval Status (current version) |
|--|----------------------|---------------|------------------------|------------------------|-----------------------------------|
| Anderson Medical Center Baylor College Med | 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 | | |

4. ADDED FLEXIBILITY FOR COMBO SITE DOCUMENTATION

| <div>Study-wide IRB Approvals</div> <div>Site-specific IRB Approvals</div> <div>Status Summary</div> | | | | | | |
|--|--|----------------------|---------------|------------------------|--------------------------|-----------------------------------|
| Participant Status Summary | | | | | | Export Data ▾ |
| Q Search: <input type="text"/> | | | | | | |
| 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 GUMC | | SMART 2 | ✓ | Completed 1/19/2022 | 3 / 3 Surveys Complete ▾ | Approved |
| Goodall University Medical Center Goodall | | SMART 2 | ✓ | Started | 0 / 3 Surveys Complete ▾ | Not Approved |

4. ADDED FLEXIBILITY FOR COMBO SITE DOCUMENTATION

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



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



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**

4. 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:

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

5. CUSTOMIZE DOCUMENT TYPES

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

Review - Mellon

Please describe the document type

Consents & Assents - LIVING DONOR ICF

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 & Advertisements

Additional IRB Approved Documents Others

Uploaded Documents

| Type | Document | |
|-----------------------------------|-------------------------------------|----------|
| Protocol [20Jan2022, version 1.0] | 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 |

5. CUSTOMIZE DOCUMENT TYPES

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

The image displays two side-by-side screenshots of a document management interface, illustrating how to customize document types. Both screenshots show a modal dialog titled "Please describe the document type" with a text input field and "Cancel" and "OK" buttons. A red arrow points from the "Additional IRB Approved Documents" category in the left screenshot to the "Recruitment Materials" text in the modal. Another red arrow points from the "Others" category in the left screenshot to the "Cognitive Battery" text in the modal. A red box highlights the "Participant Questionnaire" and "Additional IRB Approved Documents" categories in the left screenshot. A red box highlights the "Others" category in the right screenshot. A red callout box in the center of the left screenshot reads: "Customize the Type for 'additional IRB approved documents and 'other documents'".

Left Screenshot:

- Modal dialog: "Please describe the document type" with input "Recruitment Materials".
- Upload Documents section: "Additional IRB Approved Documents" and "Others" categories are highlighted with red boxes.
- Uploaded Documents table:

| Type | Document | Action |
|---------------------------------------|-------------------------------------|--------|
| 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 |

Right Screenshot:

- Modal dialog: "Please describe the document type" with input "Cognitive Battery".
- Upload Documents section: "Others" category is highlighted with a red box.
- Uploaded Documents table:

| Type | Document | Action |
|---------------------------------------|-------------------------------------|--------|
| 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 |

5. 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

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





Key Dates

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

^ Documents

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

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



Upload Documents

Drag file into 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 | CONSENT FORM - Assent.docx | 5/6/2021 | Delete |
| Protocol [1.1] | | 4/3/2020 | |
| Study Material | | 4/3/2020 | Delete |
| Study Material | Recruitment.docx | 4/3/2020 | Delete |
| Amendment Application | AMENDMENT APPLICATION.docx | | Delete |
| Consents & Assents | CONSENT FORM Spanish.docx | | Delete |
| IRB Approval Documentation | IRB APPROVAL_Leadsite.docx | | Delete |

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

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

Change Summary: some changes

Key Dates

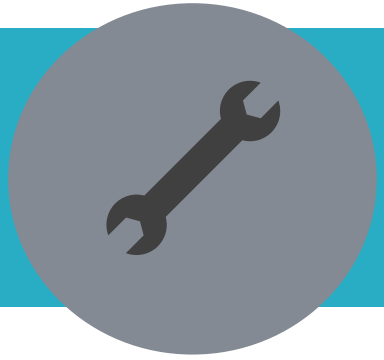
Submitted: 1/5/2022
Pre-Reviewed:
Reviewed: 1/6/2022
Approved: 1/6/2022
Expires: 5/5/2022

Documents

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

Download All

New and Updated Resources for HRPPs



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 for sIRBs](#)
- [IREx Notifications Encyclopedia for Relying HRPPs](#)

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 sIRBs](#)
- [General Resources for Relying HRPPs](#)

Next Call: April 15 , 2022