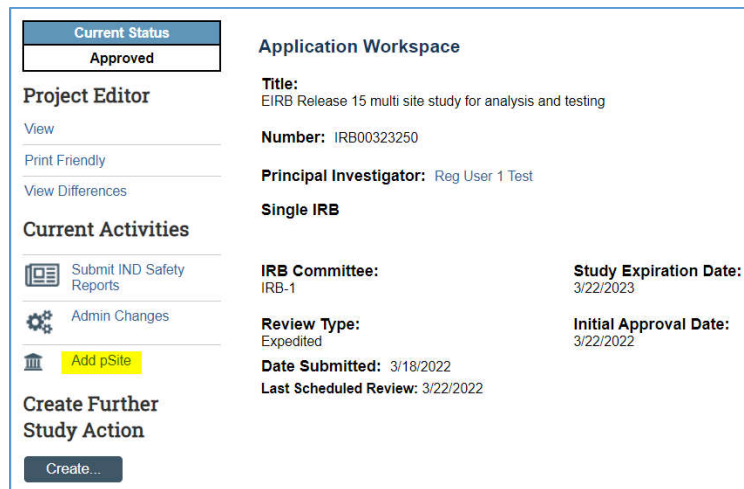


## Addition of Participating Site Process and Workflow [JHM SIRB]

**Please Note: You must receive your initial IRB approval stating that JHM IRB will serve as the Single IRB for your study before participating sites can be added via this process.**

- 1) First, determine whether you want pSites to have direct access to eIRB. Direct access allows the designated site PI and lead site study team contact to complete and submit their pSite application, access site approval documents, submit site modifications and problem events direct to JHM IRB for review. The parent study PI and lead study coordinators will also have the same edit and submit access. If direct access is desired, please contact [JHMIRBReliance@jhmi.edu](mailto:JHMIRBReliance@jhmi.edu) to assist with account creation instructions. Once accounts are created, move to step 2.
- 2) The Lead PI/coordinating center will initiate a Participating Site [pSite] application in eIRB2.
- 3) On the parent application workspace, the investigator will select “Add pSite”, selecting the \*site name [Institutional Profile], site PI and site lead study team contact.



**Current Status**  
Approved

**Project Editor**  
View  
Print Friendly  
View Differences

**Current Activities**  
Submit IND Safety Reports  
Admin Changes  
Add pSite

**Create Further Study Action**  
Create...

**Application Workspace**  
Title: EIRB Release 15 multi site study for analysis and testing  
Number: IRB00323250  
Principal Investigator: Reg User 1 Test  
Single IRB  
IRB Committee: IRB-1  
Study Expiration Date: 3/22/2023  
Review Type: Expedited  
Initial Approval Date: 3/22/2022  
Date Submitted: 3/18/2022  
Last Scheduled Review: 3/22/2022

- If the site PI and site lead study team contact are not listed in the drop-down, and you have elected to not utilize the direct access feature mentioned in item 1 above, use the “Click to create new contact” link to create profiles for these individuals. They will receive email notifications but will not have direct access to eIRB.

- 4) Click “OK” to create the pSite application.

*\*If the Institutional Profile is not available in the drop-down menu, please send an email to [JHMIRBReliance@jhmi.edu](mailto:JHMIRBReliance@jhmi.edu) to assist.*

## Addition of Participating Site Process and Workflow [JHM SIRB]

The screenshot shows a dialog box titled "Add pSite" with the following content:

- Add Participating Site:**
- Institutional Profile:** [Dropdown menu]
- \* Site Principal Investigator:** [Dropdown menu]
- \* Site Lead Study Team Contact:** [Dropdown menu]
- If you are unable to find the person click link below:**  
[Click to create new contact](#)
- Buttons:** OK, Cancel

- 5) Confirm Reliance: The IRB Reliance Team will receive an email notification when the pSite has been added and will confirm the pSite has met all requirements to rely on JHM IRB.
- 6) Send to pSite: After the reliance team confirms that a reliance agreement is in place to cover the site, the Lead PI/coordinating center will receive a confirmation email and will run the “**Send to pSite**” activity. This activity is used to notify the pSite that their pSite application is ready for completion.

## Addition of Participating Site Process and Workflow [JHM SIRB]

**Send to pSite**

Use this activity to send materials to pSite - Reliance MUST be confirmed first.


1.0 **Select written consent templates to be included as part of the notification:**

| Title                    | Description | Date Modified     |
|--------------------------|-------------|-------------------|
| <input type="checkbox"/> | [REDACTED]  | 3/12/2020 3:28 PM |
| <input type="checkbox"/> | [REDACTED]  | 3/12/2020 3:28 PM |

2.0 **Select any optional supplemental documents to be included as part of the notification:**

| Title                    | Description | Date Modified    |
|--------------------------|-------------|------------------|
| <input type="checkbox"/> | [REDACTED]  | 2/4/2020 9:01 AM |

3.0 **The following protocol document(s) will be included as part of the notification:**

| Title   | Date Modified     | Version Status |
|---|-------------------|----------------|
| <a href="#">View</a>  [REDACTED] | 5/25/2021 3:59 PM | 0.15 Submitted |

4.0 **The following local context questionnaire(s) will be included as part of the notification:**

| Title                         | Description | Modified Date |
|-------------------------------|-------------|---------------|
| There are no items to display |             |               |

5.0 **The following site specific consent information document(s) will be included as part of the notification:**

| Title                         | Description | Modified Date |
|-------------------------------|-------------|---------------|
| There are no items to display |             |               |

6.0 **Comments (optional):**

- 7) Awaiting Site Materials: The pSite application will transition to an “**Awaiting Site Materials**” state, allowing the Lead PI/coordinating center or the pSite PI/pSite lead study team contact to complete the pSite application and upload any site-specific materials [e.g., Local Context Questionnaire; Site-Specific Consent Information form]. Select “View/Edit” to access the application.

## Addition of Participating Site Process and Workflow [JHM SIRB]

Current Status

Awaiting Site Materials

**Project Editor**

View/Edit

Print Friendly

View Differences

**Current Activities**

Test Activity

Submit

### pSite Workspace

**Title:**  
SITE FOR: [REDACTED]

**Parent Study Title:**  
[REDACTED]

**Parent ID:** IRB00 [REDACTED]

**Number:** SITE00000 [REDACTED]

**Principal Investigator:** [REDACTED]  
**Site Lead Contact:** [REDACTED]

**Institution Profile:** [REDACTED]

**IRB Committee:**  
IRB-X

8) In “Site Specific Documents”, the investigator must upload the following:

- Question 1 – The completed Site-Specific Consent Information [SSCI] form **or** a site-specific oral consent script *[if the site will obtain consent]*
- Question 2 – Any site-specific recruitment materials supplied by the pSite
- Question 3 – A copy of the pSite’s completed local context questionnaire [LCQ]
- Question 4 – Any other site-specific documents that require IRB approval

Validate Compare

### Editing: SITE00000783

Go to forms menu Print Icons Help

Site Specific Documents

- 1. Consent Forms:**

+ Add

| Title  | Date Modified    | Category      | Version | Status    |
|--|------------------|---------------|---------|-----------|
| Site-Specific Consent Information [SSCI](0.01) | 6/1/2022 3:54 PM | Local Consent | 0.01    | Submitted |
- 2. Recruitment Materials:** (add all material to be seen or heard by subjects, including ads)

+ Add

| Title                         | Date Modified | Category | Version | Status |
|-------------------------------|---------------|----------|---------|--------|
| There are no items to display |               |          |         |        |
- 3. Local Context Questionnaire:**

+ Add

| Title                             | Date Modified    | Category                    | Version | Status    |
|-----------------------------------|------------------|-----------------------------|---------|-----------|
| Local Context Questionnaire(0.01) | 6/1/2022 3:55 PM | Local Context Questionnaire | 0.01    | Submitted |
- 4. Other Attachments:**

+ Add

| Title                          | Date Modified    | Category                | Version | Status    |
|--------------------------------|------------------|-------------------------|---------|-----------|
| Reliance Approval Letter(0.01) | 6/1/2022 3:55 PM | Local Other Attachments | 0.01    | Submitted |

Exit Save Continue

## Addition of Participating Site Process and Workflow [JHM SIRB]

9) The Lead PI/coordinating center PI or the pSite PI will submit the pSite application for review.

The screenshot shows a web application interface for editing a pSite application. The main heading is 'Editing: SITE00000783'. Below this, there is a section titled 'Site Specific Documents'. The interface is divided into four main sections, each with an 'Add' button and a table of existing documents:

- 1. Consent Forms:** Contains one document: 'Site-Specific Consent Information [SSCI](0.01)' with a date modified of 6/1/2022 3:54 PM and a status of 'Submitted'.
- 2. Recruitment Materials:** Contains no items, with the text 'There are no items to display'.
- 3. Local Context Questionnaire:** Contains one document: 'Local Context Questionnaire(0.01)' with a date modified of 6/1/2022 3:55 PM, a category of 'Local Context Questionnaire', a version of '0.01', and a status of 'Submitted'.
- 4. Other Attachments:** Contains one document: 'Reliance Approval Letter(0.01)' with a date modified of 6/1/2022 3:55 PM, a category of 'Local Other Attachments', a version of '0.01', and a status of 'Submitted'.

At the bottom of the interface, there are buttons for 'Exit', 'Save', and 'Continue'.

10) Once the pSite application is submitted, it will undergo IRB review. Upon review, the pSite application may be returned with issues that need to be addressed or it may be approved. If returned, the pSite study team will be required to address all review concerns.

11) *If there are oral consent/written consent/assent forms*, the consent form specialist (CFS) will build the appropriate documents for each pSite once the outcome for the pSite application has been recorded as Approved.

12) IRB staff will process the pSite approval letter and the approved site-specific consent form (and any additional documents) for each pSite, *if applicable*.

- The approval letter will include:
  - i. A list of documents approved with this pSite application [e.g., site-specific consent form]
  - ii. A list of currently-approved documents (e.g., protocol version date) that are relevant to the pSite approval
  - iii. Instructions to provide the pSite with a copy of the JHM IRB pSite approval letter

## Addition of Participating Site Process and Workflow [JHM SIRB]

### Access to Approved Study Documents

Site approval letters are accessible on the pSite workspace:

**Current Status**

Approved

**Project Editor**

[View](#)

[Print Friendly](#)

[View Differences](#)

**Current Activities**

Alert Parent Study PI

Contact sIRB

**Create Further Study Action**

Create...

**pSite Workspace**

**Title:**  
SITE FOR My Test Study - Post IRB

**Parent Study Title:**  
My Test Study - Post IRB

**Parent ID:** NA\_00091608

**Number:** SITE00000479

**Principal Investigator:** Janelle Maddox-Regis - jmaddox3@jhmi.edu  
**Site Lead Contact:** Reg User 1 Test -

**Institution Profile:** Anne Arundel Medical Center

**IRB Committee:**  
IRB-1

**Review Type:**  
Expedited

**RedCAP ID:**

**Date Submitted:** 2/18/2021  
**Last Scheduled Review:** 2/22/2021

**Study Expiration Date:**  
2/16/2022

**Initial Approval Date:**  
2/18/2021

**IRB Review Items:**

| Review Date | Review Type | Outcome  | Letter Sent | Response | Agenda Topic    |
|-------------|-------------|----------|-------------|----------|-----------------|
| 2/18/2021   | Expedited   | Approved | View Letter |          | New Application |

Current versions of study-wide documents [e.g., multisite protocol; recruitment materials] can be retrieved from the pSite application workspace, under “**Additional Documents**”.

History Log
Reviewer Notes
Further Study Actions
Additional Documents
...

**Additional Documents for pSite Use**

**Written Consent Forms:**

| Title   | Date Modified      | Version | Status    |
|---|--------------------|---------|-----------|
| <a href="#">View</a> Master CF Template(0.04)                                   | 1/16/2015 11:32 AM | 0.04    | Submitted |
| <a href="#">View</a> JH Site Specific Consent Information Template [SSCI](0.01) | 2/17/2021 12:53 PM | 0.01    | Submitted |

**Script/Text - Adults:**

| Title                         | Date Modified | Version | Status |
|-------------------------------|---------------|---------|--------|
| There are no items to display |               |         |        |

**Assent Forms:**

| Title                         | Date Modified | Category | Version | Status |
|-------------------------------|---------------|----------|---------|--------|
| There are no items to display |               |          |         |        |

**Supplemental Documents:**

| Title                         | Date Modified | Version | Status |
|-------------------------------|---------------|---------|--------|
| There are no items to display |               |         |        |

**Protocol:**

| Title                               | Date Modified    | Version | Status    |
|-------------------------------------|------------------|---------|-----------|
| <a href="#">View</a> Protocol V1(1) | 2/3/2014 9:38 AM | 1       | Submitted |

## Addition of Participating Site Process and Workflow [JHM SIRB]

Stamped documents can be retrieved from the pSite application workspace, under “**Stamped Documents**”. These documents will only be available on the pSite application workspace – not the parent application workspace.

| History Log  | Reviewer Notes | Further Study Actions | Additional Documents | Stamped Documents |
|--|----------------|-----------------------|----------------------|-------------------|
| <b>Written consent form(s):</b>  |                |                       |                      |                   |
| <b>Title</b>   |                |                       |                      |                   |
| <a href="#">View</a> Ball State University Site-Specific ICF_11.27.pdf(0.01) |                |                       |                      |                   |
| <b>Oral consent script(s):</b>   |                |                       |                      |                   |
| <b>Title</b>   |                |                       |                      |                   |
| <b>Date Modified</b>   |                |                       |                      |                   |
| <b>Versio</b>  |                |                       |                      |                   |
| There are no items to display  |                |                       |                      |                   |