

UNIVERSITY  
OF MIAMI



# HSRO Monthly Office Hours

---

## Understanding Reliance

Presented by: HSRO Staff

---

# Topics to Cover



Basics of reliance



UM as the single IRB for other sites



Site onboarding/IBIS walkthrough



Tips to strengthen your application

# The basics

## Single IRB (sIRB)

- IRB of one site provides IRB oversight for all relying sites

## Reviewing IRB (IRB of record)

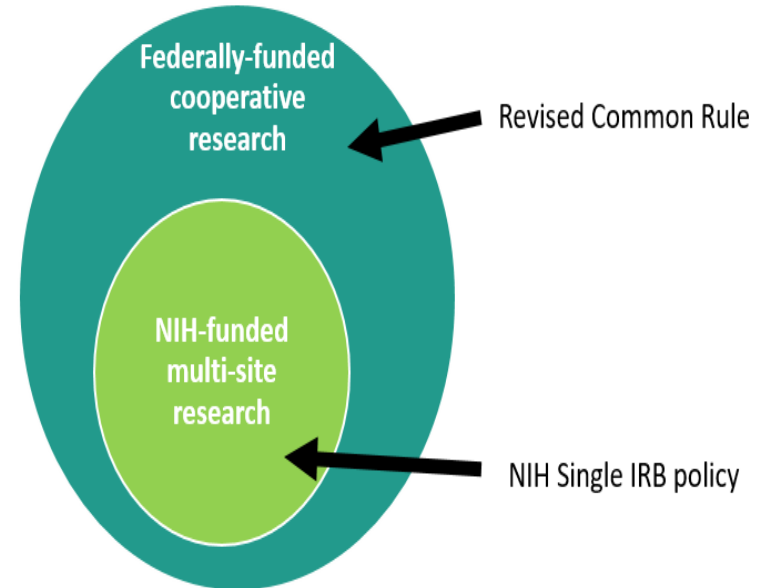
- Accepts the responsibility of research oversight
- Usually identified by the federal department supporting the research

## Relying IRB

- An IRB that agrees to rely on the Reviewing IRB and comply with their requirements

## Reliance agreement (IRB Authorization Agreement-IAA)

- Allows an IRB to rely on another IRB as the IRB of record
- Outlines specific provisions and responsibilities for each of the parties entering the agreement



<https://www.washington.edu>

---

# Responsibilities of Each Institution

## Relying Institution (Cedes review to another IRB)

- Provide local context (applicable state or local laws, regulations, institutional policies, local factors, etc.)
- Provide study documents with the local/institutionally required language (compensation for injury, payment, etc.)
- Perform ancillary reviews such as conflict of interest review.
- Review study personnel's education, training and qualifications.
- Comply with the determinations of the Reviewing IRB.
- Notify the Reviewing IRB of unanticipated problems, potential noncompliance, suspension or restriction, significant subject complaints.
- Submit any change in research in a timely manner

## Reviewing Institution (Serves as IRB of record)

- Making IRB determinations for all types of review (initial, amendments, continuing, reportable events, etc.)
- Review of findings and actions related to reportable issues (unanticipated problems, serious or continuing noncompliance, suspension or termination, subjects' complaints)
- Report to federal, state or funding agencies.
- Audits (Investigating and determining potential corrective and preventive actions in the event of non-compliance)

## Shared Responsibilities

- Sign an IRB Authorization Agreement (IAA).
- Establish a plan for sharing of information between the site and the IRB. A crucial one is as establishing a **Coordinating Center** or **Coordinating Center Liaison**.

---

# UM as the Single IRB

## Requirements

- Study is federally funded
- Relying site must be engaged in the human subject research
- The Lead PI is a UM PI or study is conducted in collaboration with a UM PI.
- The engaged site does not have an IRB.
- The relying site must be domestic.

## Exemptions

- International sites
- Exempt studies
- The federal department supporting the research determines that sIRB review is not appropriate.
- Prohibited by tribal or state laws so some sites may not be required to comply.

## Coordinating Center

- The UM PI will serve as the Coordinating Center for the research or designate a Coordinating Center Liaison.
- The Coordinating Center will be responsible for coordinating the submissions from each site and submitting information into the UM HSRO's electronic system, IBISResearch.

# UM as the sIRB

- Set up a reliance consultation with the HSRO to discuss the study plan, expectations, how many sites site eligibility, coordinating center responsibilities, etc...
- Submit the study through IBIS.
  - UM site must always be approved first
  - Submit as multi-site where all sites are relying on the UM IRB
- Include an external site application form **HRP-217:**
  - UM's role in the research
  - Relying site's role in the research
- A reliance agreement must be in place with each of the relying sites
- Each relying site must complete the Relying site Information Questionnaire form **HRP-218:**
  - Research personnel involved in the research at the site
  - Role of the site in the research
  - Confirmation that all ancillary reviews, training and financial disclosures have been completed
  - Local context/site's requirements for consent

## Documents

[Required Language for Consent Documents](#)

[UM Local Context Information](#)

[IRB Authorization Agreement](#)

[Individual Investigator Agreement](#)

[Request for Waiver of Authorization](#)

[SMART IRB Letter of Acknowledgement Template](#)

[HRP-216 \(External IRB Reliance Application\)](#)

[HRP-217 \(Reliance Questionnaire for Internal IRB Review\)](#)

[HRP-218 \(Relying Site Information Questionnaire\)](#)

[Interests Disclosure Form \(IDF\) for Investigators Not Affiliated with UM](#)

[Single IRB plan](#)

# UM as the sIRB

## Basic Study Information

**1. \* Title of study:**

[REDACTED]

**2. \* Short title:**

[REDACTED]

**3. \* Study purpose/objective (2-3 sentences):**

*The study purpose/objective should be at the same 6-8 grade reading level as the Informed Consent Form. This field will be exported and used by other UM systems/tools, which potential research participants will access to learn about the different research studies at the University of Miami.*

This Phase 2 study is a 2-arm, multi-center, double-masked, placebo-controlled, 2:1 randomized sequential trial design in new onset T1D participants (within 100 days of diagnosis). Participants will be administered [REDACTED] once every 14 days over 26 weeks with an additional 6-month follow-up period.

**4. \* What kind of study is this?**

Multi-site or Collaborative study

**5. \* Will an external IRB act as the IRB of record for this study?**

Yes  No

**6. \* Will your IRB act as the single IRB of record for other participating sites?**

Yes  No

# Study Funding Sources

## 1. \* Identify each organization supplying funding for the study:

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments
----------------	----------------------	------------------	-------------

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

History	Funding	Contacts	COI	Documents	Sites	Follow-on Submissions	Reviews	Snapshots	CITI Inform
---------	---------	----------	-----	-----------	-------	-----------------------	---------	-----------	-------------

### Study Related Documents

Draft	Category	Final
-------	----------	-------

**Study-Related Documents:** add templates for consent forms, recruitment materials, and other documents that are required study-wide and that participating sites will need to access.

### Site Related Documents

Draft	Category	Final
-------	----------	-------

**Local Site Documents:** add consent forms, recruitment materials and other documents specific to your site.



---

# Local Study Team Members

- List all UM staff who will be “engaged” in the study.

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/determining-when-institutions-are-engaged-in-research/index.html>

- It is the PI’s responsibility to ensure that all study team members are CITI Certified and keep a record of expiration dates. The HSRO no longer reviews training.
- If a member does not appear in IBIS, they do not have an IBIS account. Study team must contact [OVPRShelpdesk@miami.edu](mailto:OVPRShelpdesk@miami.edu) to troubleshoot any issues.
- Any individual added in this section will be required to also complete the COI Disclosure through [udisclose@miami.edu](mailto:udisclose@miami.edu).

# Parent study (UM) is approved first

Approved

Entered IRB: 11/27/2024 3:47 PM  
 Initial approval: 12/10/2024  
 Initial effective: 1/14/2025  
 Effective: 11/25/2025  
 Approval end: 11/24/2026  
 Last updated: 3/31/2026 1:36 PM

2024 [Redacted]  
 Principal investigator: [Redacted]  
 Submission type: Initial Study  
 Primary contact: [Redacted]  
 PI proxies: [Redacted]

IRB office: HSR0  
 IRB coordinator: Mabel Algeciras  
 Letter: Correspondence\_for\_2024 [Redacted]  
 Regulatory authority: 2018 Requirements + FDA



## Next Steps

- [View Study](#)
- [Printer Version](#)
- [Create Modification/CR](#)
- [Report New Information](#)

- [Manage Relationships](#)
- [Send Letter](#)
- [Prepare Letter](#)
- [Submit Committee Review](#)
- [Add Participating Sites](#)
- [Assign Coordinator](#)
- [Assign Primary Contact](#)

- History
- Funding
- Contacts
- COI
- Documents
- Sites**
- Follow-on Submissions
- Reviews
- Snapshots
- CITI Information
- ...

## Study Related Documents

Draft	Category	Final	Last Finalized
[Redacted]	IRB Protocol	[Redacted]	9/25/2025 1:24 PM
[Redacted]	Other	[Redacted]	
[Redacted]	Consent Form	[Redacted]	5/12/2025 12:11 PM
[Redacted]	Consent Form	[Redacted]	4/8/2025 3:25 PM
[Redacted]	Other	[Redacted]	
[Redacted]	Other	[Redacted]	
[Redacted]	Other	[Redacted]	
[Redacted]	Other	[Redacted]	
[Redacted]	Other	[Redacted]	

## Site Related Documents

Draft	Category	Final	Last Finalized	Document History
-------	----------	-------	----------------	------------------



# Process for Onboarding Relying Sites

#1

- Complete HRP-217 (External site application)
- Obtain reliance decision from Reliance Analyst (signed HRP-217)
- Complete HRP-218 (Relying site information questionnaire)

#2

Reliance agreement is executed



#3

IRB Submission

- The HSRO reliance coordinator will create the site submission for the relying site in the IBIS system upon completion of the reliance agreement.
- The Coordinating Center will submit all site materials including signed HRP-217, completed HRP-218 and relying site's local language documentation.
- The relying site must provide a version of the consent document(s) that includes the relying site's institutionally required language and meets their institutional and local requirements.
- The Coordinating Center will act as liaison to ensure any pending items are addressed to secure IRB approval for the relying site.
- IRB will conduct its review and provide approval letter for each onboarded site.
- Coordinating Center will distribute IRB approval letter and documents to the relying site.

**FORM: External Site Application for UM IRB Review**

NUMBER	DATE	VERSION	AUTHOR	APPROVED BY	PAGE
HRP-217	11/05/2019	2	C.GATES	C.GATES	1 of 3

The purpose of this application is to see if the proposed research qualifies for an IRB Reliance with the University of Miami serving as the IRB of record for the research. Please answer all of the questions and submit the application in eProst or via email.

1. If you have an eProst number, enter it here. (Please note, an eProst application is not required until the HSRO has determined whether the reliance can move forward)

2. UM Investigator

3. Name of Relying Site:

4. Study Title:

5. Name of Relying Site Investigator and credentials:

6. Relying Site Investigator phone number and email address:

Phone

Email

7. Who is primary contact for UM site:

8. UM Primary Contact phone number and email address:

Name

Phone

Email

9. Person Completing this Form, if different from Primary Contact

10. Will UM serve as the single IRB for all participating sites?

Yes

Maybe

NO

11. Please choose the applicable boxes below

Study is NIH funded – single IRB review is required

Study is industry sponsored – single IRB review is requested

Grantor is requiring single IRB as condition of the grant

Other

**FORM: External Site Application for UM IRB Review**

NUMBER	DATE	VERSION	AUTHOR	APPROVED BY	PAGE
HRP-217	11/05/2019	2	C.GATES	C.GATES	2 of 3

12. Before an institution can rely on an external IRB, a "Reliance Agreement" is required. Please indicate which "Reliance Agreement" will be used for this reliance.

SMART IRB Agreement. See <https://smartirb.org/agreement> for information

University of Miami HSRO Template Agreement located on the HSRO website

Other

13. Describe your plan for overseeing the study sites

A UM Investigator will be the Lead PI and will oversee all research activities

A researcher at another institution will be the Lead PI and will oversee all research activities

Each research site will have its own PI to oversee the study activities at that site

None of the above

14. Describe UM's role in this research. Checklist all that apply

UM is the grant recipient

UM is the data coordinating center

UM Faculty and staff will be interacting or intervening with subjects to obtain data or specimens (this response includes administering a test article)

UM Faculty and staff will be collecting information from subjects through surveys or interviews

UM Faculty and staff will obtain private, identifiable data about subjects through review of records or other information that were collected for another purpose (e.g. EMR, student records, records from another study.) Note: Do not check this box if the data received are coded and linked to the subjects' identity and the researchers will not have access to the subjects' identities.

UM Faculty and staff will obtain anonymous or de-identified data about subjects that were collected for other purposes (e.g. a different research study, or a di-identified data base) Note: Check the box if the data you are receiving are in a Limited Data Set with a Data Use Agreement or when the data are coded and linked to the subjects' identity and the UM researchers will not have access to that link.

UM Faculty and staff will obtain identifiable human biospecimens that were collected for another purpose. Note: Do not check the box if the biospecimens are coded and linked to the subjects' identity when UM will not have access to that link.

None of the above (additional information required)

Please provide a description of the procedures UM will be conducting for this research:

15. Select the procedures the relying site will conduct for this research (check answer that applies):

The relying site is the grant recipient

Relying site is the data coordinating center

Relying site will be interacting or intervening with subjects to obtain data or specimens (this response includes administering a test article)

Relying site will be collecting information from subjects through surveys or interviews

Relying site will obtain private, identifiable data about subjects through review of records or other information that were collected for another purpose (e.g. EMR, student records, records from another study.) Note: Do not check this box if the data received are coded and linked to the subjects' identity when the relying site researchers will not have access to the subjects' identities.

A member of the HSRO Reliance Team will review the application and contact you with a decision.

**Institutional Sign-Off From HSRO**

<i>Signature</i>	<i>Printed Name</i>	<i>Title</i>	<i>Date</i>



# Reliance agreement

## Single IRB and Reliances

Does My Project Need Review  
by the IRB

Types of IRB Review

How to Submit to the IRB

Forms & Templates

Single IRB and Reliances

Introduction

Definitions

Documents

[Required Language for Consent Documents](#)

[UM Local Context Information](#)

[IRB Authorization Agreement](#)

[Individual Investigator Agreement](#)

[Request for Waiver of Authorization](#)

[SMART IRB Letter of Acknowledgement Template](#)

[HRP-216 \(External IRB Reliance Application\)](#)

[HRP-217 \(Reliance Questionnaire for Internal IRB Review\)](#)

[HRP-218 \(Relying Site Information Questionnaire\)](#)

[Interests Disclosure Form \(IDF\) for Investigators Not Affiliated with UM](#)

UNIVERSITY  
OF MIAMI



<https://hsro.uresearch.miami.edu/submit-to-the-irb/single-irb-and-reliances/index.html>



# After parent study is approved- how to create site pages (HSRO only)

**Approved**

Entered IRB: 1/15/2026 5:03 PM  
Initial approval: 2/10/2026  
Initial effective: 2/10/2026  
Effective: 4/21/2026  
Last updated: 4/21/2026 3:31 PM

**Next Steps**

- View Study
- Printer Version
- Create Modification/CR
- Report New Information
- Manage Relationships
- Send Letter
- Prepare Letter
- Submit Committee Review
- Add Participating Sites**
- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy

20250 [REDACTED]

Principal investigator: [REDACTED]  
Submission type: Initial Study  
Primary contact: [REDACTED]  
PI proxies: [REDACTED]

IRB office: HSRO  
IRB coordinator: Mabel Algeciras  
Letter: Correspondence\_for  
Regulatory authority: 2018 Requirements

```
graph LR; A([Pre-Submission]) --> B([Pre-Review]); B --> C([IRB Review]); C --> D([Post-Review]); D --> E([Review Complete]); B --> B1([Clarification Requested]); B1 --> B; C --> C1([Clarification Requested]); C1 --> C; D --> D1([Modifications Required]); D1 --> D;
```

History Funding Contacts COI Documents Sites Follow-on Submissions Reviews Snapshots CITI Information

Filter by

Activity	Author
Modi	[REDACTED]
Modi	[REDACTED]
Modi	[REDACTED]
Modi	[REDACTED]

**STUDY TEAM DOES NOT EXECUTE THE “ADD PARTICIPATING SITES” ACTIVITY- ONLY THE HSRO WILL PERFORM THIS FUNCTION**

# HSRO Analyst creates site page

## Pre-Review

Entered IRB: 4/28/2026 9:47 AM  
Last updated: 4/28/2026 9:47 AM

### Next Steps

- Edit Site
- Printer Version

- Assign Designated Reviewer
- Assign to Meeting
- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy
- Clinical Trials
- Manage Guest List
- Correspond with Site
- Add Comment
- Add Private Comment
- Withdraw
- Discard
- Manage Tags

(IRB - SITE)

SITE000003

Principal investigator: [REDACTED]  
Submission type: IRB Site  
Primary contact: [REDACTED]  
PI proxies:  
Institution: University of Mississippi Medical Center

IRB office: HSRO  
IRB coordinator: Mabel Algeciras  
Regulatory authority: 2018 Requirements  
Study: [REDACTED]



- History
- Funding
- Documents
- IRB Assignment Details
- Reviews
- Snapshots
- CITI Information
- Related Projects

Filter by Activity  + Add Filter X Clear All

Activity	Author
<input checked="" type="checkbox"/> Site Materials Submitted	[REDACTED]
Dear IRB	
Please review site documentation	
<input type="checkbox"/> Comment Added	Algeciras, Mabel
Dear study team,	
The site page for the University of Mississippi has been created. Please ensure the following steps are followed: 1) Submit all site specific documents that this relying site will use: <ul style="list-style-type: none"><li>• HRP-217 (signed)</li><li>• HRP-218 (completed collaboratively with the local PI)</li><li>• Consent/Assent Documents (if applicable)</li><li>• Relying Institution's Consent/Assent Template language/requirements document(s) (if applicable)</li><li>• Other site-specific documents (ex. Flyer with local contact information)</li></ul> 2) Answer question #3 in the IBIS application: "Brief description of activities this site will perform". NOTE: The creation of the site page in IBIS does NOT constitute approval of the site. You must submit all the site-specific documents for IRB review in order to obtain site approval.	
Thank you and feel free to contact me if you have any questions. Mabel read less	
<input checked="" type="checkbox"/> Invitation Decision Submitted	Algeciras, Mabel
Reliance agreement attached	



**Pre-Review**

Entered IRB: 4/28/2026 9:47 AM  
 Last updated: 4/28/2026 9:47 AM

**SITE000003** [REDACTED]

**Principal investigator:** [REDACTED]  
**Submission type:** IRB Site  
**Primary contact:** [REDACTED]  
**PI proxies:**  
**Institution:** University of Mississippi Medical Center

**IRB office:** HSR0  
**IRB coordinator:** Mabel Algeciras  
**Regulatory authority:** 2018 Requirements  
**Study:** [REDACTED]

**Next Steps**

- Edit Site
- Printer Version

- Assign Designated Reviewer
- Assign to Meeting
- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy
- Clinical Trials
- Manage Guest List
- Correspond with Site
- Add Comment
- Add Private Comment
- Withdraw
- Discard
- Manage Tags



- History
- Funding
- Documents**
- IRB Assignment Details
- Reviews
- Snapshots
- CITI Information
- Related Projects

Filter by: Activity [v] Enter text to search [ ] + Add Filter X Clear All

**Activity** **Author**

- Site Materials Submitted [REDACTED]

Dear IRB

Please review site documentation

Comment Added Algeciras, Mabel

Dear study team,

The site page for the University of Mississippi has been created. Please ensure the following steps are followed:

- Submit all site specific documents that this relying site will use:
  - HRP-217 (signed)
  - HRP-218 (completed collaboratively with the local PI)
  - Consent/Assent Documents (if applicable)
  - Relying Institution's Consent/Assent Template language/requirements document(s) (if applicable)
  - Other site-specific documents (ex. Flyer with local contact information)
- Answer question #3 in the IBIS application: "Brief description of activities this site will perform".

NOTE: The creation of the site page in IBIS does NOT constitute approval of the site. You must submit all the site-specific documents for IRB review in order to obtain site approval.

Thank you and feel free to contact me if you have any questions.  
 Mabel read less

- Invitation Decision Submitted Algeciras, Mabel

Reliance agreement attached

**Site Related Documents**

Draft	Category
UMMC - [REDACTED] HIPAA Authorization for Research Subjects	Other
UMMC - [REDACTED] Relying Site Information Questionnaire (HRP-218)	Other
UMMC - [REDACTED] External Site Application for UM Review (HRP-217) Signed 03.03.2026	Other
UMMC - [REDACTED] Institutional Authorization Agreement (Executed 04.06.2026)	Other
UMMC - [REDACTED] Prescreening Script v04.13.2026	Recruitment Materials
UMMC - [REDACTED] Website and Twitter Flyer v04.17.2026	Recruitment Materials
UMMC - [REDACTED] Recruitment Flyer v04.17.2026	Recruitment Materials
UMMC - [REDACTED] Participating Site Informed Consent v04.13.2026	Consent Form







# Continuing Reviews

Approved

CR000042 [REDACTED]

Entered IRB: 11/3/2025 9:48 AM  
Approval: 11/25/2025  
Initial effective: 11/25/2025  
Effective: 11/25/2025  
Last updated: 11/25/2025 2:08 PM

Principal investigator: [REDACTED]  
Submission type: Continuing Review  
Primary contact: [REDACTED]

IRB office: HSRO  
IRB coordinator: Mabel Algeciras  
Letter:  Correspondence\_for\_CR00 [REDACTED]  
Regulatory authority: 2018 Requirements + FDA

## Next Steps

[View Modification/CR](#)

 Send Letter

 Prepare Letter



 Assign Coordinator

 Manage Ancillary Reviews

 Add Comment

 Add Private Comment



History	Contacts	COI	Documents	Sites	Reviews	Snapshots	CITI Information	Related Projects
Filter by  Activity <input type="text" value="Enter text to search"/>  <a href="#">+ Add Filter</a> <a href="#">X Clear All</a>								
Activity							Author	Activity Date


## Continuing Review / Study Closure Information

1. \* Specify enrollment totals at this investigator's sites: 

0

2. \* Specify enrollment totals at this investigator's sites since last approval:

13

3. \* Specify enrollment totals study-wide: 

13

 (Confirmed sites: 5 of 5. Total enrollment for pSites with completed reports: 13)

# Continuing Reviews

Approved

CR000042 [REDACTED]

Entered IRB: 11/3/2025 9:48 AM  
 Approval: 11/25/2025  
 Initial effective: 11/25/2025  
 Effective: 11/25/2025  
 Last updated: 11/25/2025 2:08 PM

Principal investigator: [REDACTED]  
 Submission type: Continuing Review  
 Primary contact: [REDACTED]

IRB office: HSRO  
 IRB coordinator: Mabel Algeiras  
 Letter: [Correspondence\\_for\\_CR000042 \[REDACTED\]](#) ...  
 Regulatory authority: 2018 Requirements + FDA

## Next Steps

[View Modification/CR](#)

- [Send Letter](#)
- [Prepare Letter](#)
- [Assign Coordinator](#)
- [Manage Ancillary Reviews](#)
- [Add Comment](#)
- [Add Private Comment](#)
- [Manage Tags](#)

(IRB - MOD/CR - Review Complete)



History	Contacts	COI	Documents	<b>Sites</b>	Reviews	Snapshots	CITI Information	Related Projects
---------	----------	-----	-----------	--------------	---------	-----------	------------------	------------------

## Active Participating Sites

Filter by ? Institution  + Add Filter × Clear All

Execute Activity	Institution	Report Date	Total Enrollment	Enrollment Since Last Approval	Potential Concerns	Documents	Report Completed?
<a href="#">▶</a>	Barbara Davis Center (UC Denver)	11/3/2025	0	0	None	BDC DXT1D Continuing Review Form 06OCT2025.docx	<input checked="" type="checkbox"/> yes
<a href="#">▶</a>	Indiana University	11/3/2025	10	10	None	Indiana Deviation_Log_AO.doc Indiana DXT1D Continuing Review 2025.docx	<input checked="" type="checkbox"/> yes
<a href="#">▶</a>	UNIVERSITY OF FLORIDA (UF)	11/10/2025	0	0	None	UF DXT1D Continuing Review Form 2025.docx	<input checked="" type="checkbox"/> yes





# CR site activity reporting

## Summary of Continuing Review Data Reported

### Continuing Review Data Reported

Submit enrollment information to the sIRB for continuing review purposes

#### Summary

<b>Nov</b>	Author: [REDACTED] (Default)
<b>3</b>	Logged For (IRB Submission): Barbara Davis Center (UC Denver) Participating Site for [REDACTED]
<b>2025</b>	Activity Date: 11/3/2025 9:47 AM

#### Form

**1. Specify enrollment totals at this investigator's sites:**

0


**2. Specify enrollment totals at this investigator's sites since last approval:**

0

**3. Check the items that are true for this site since the last IRB approval:** (initial review or last continuing review)

- NO subjects experienced unexpected harm
- Anticipated adverse events have NOT taken place with greater frequency or severity than expected
- NO subjects withdrew from the study
- NO unanticipated problems involving risks to subjects or others
- NO complaints about the study
- NO publications in the literature relevant to risks or potential benefits
- NO interim findings
- NO multi-center trial reports
- NO data safety monitoring reports
- NO regulatory actions that could affect safety and risk assessments
- NO other relevant information regarding this study, especially information about risks
- In the opinion of the PI, the risks and potential benefits are unchanged
- All modifications to the protocol have been submitted to the IRB
- All problems that require prompt reporting to the IRB have been submitted

**4. Supporting documents:** (include an explanation of each item left unchecked above)

Name
 BDC [REDACTED] Continuing Review Form 06OCT2025.docx(0.01)

**5. Comments:**

# Site RNIs

**Active**

Entered IRB: 8/25/2022 10:19 AM  
Initial approval: 8/25/2022  
Initial effective: 8/25/2022  
Effective: 4/9/2024  
Approval end: 4/27/2027  
Last updated: 4/1/2026 1:13 PM

**Next Steps**

- View Site
- Printer Version
- Create Site Modification
- Report New Information**
- Send Letter
- Prepare Letter
- Return to Post-Review
- Update Site Status
- Assign Coordinator
- Assign Primary Contact
- Assign PI Proxy

## IRBSITE000001 [REDACTED]

**Principal investigator:** [REDACTED]  
**Submission type:** IRB Site  
**Primary contact:** [REDACTED]  
**PI proxies:**  
**Institution:** University of California - Los Angeles

**IRB office:** HSR0  
**IRB coordinator:** Mabel Algeciras  
**Letter:** Correspondence\_for\_IRBS [REDACTED]  
**Regulatory authority:** Pre-2018 Requirements  
**Study:** [REDACTED]

```
graph LR; A(Invitation Pending) --> B(Awaiting Site Materials); B --> C(Pre-Review); C --> D(IRB Review); D --> E(Post-Review); E --> F(Review Complete); E --> G(Modifications Required); G --> D;
```

History | Funding | Documents | Follow-on Submissions | Reviews | Snapshots | CITI Information | Related Projects

Filter by Activity  [+ Add Filter](#) [X Clear All](#)

Activity	Author
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]



---

# Reducing Your Burden for Onboarding Relying Sites

**Develop a protocol that clearly defines the responsibilities of each participating institution including data collection, subject recruitment, adverse event reporting, and communication with the reviewing IRB.**

- Ensure that the core elements in the study protocol are included as they pertain the UM **and** the relying sites in general or specific terms as applicable.
- This will reduce the need for revision, and, after study approval, this will help ensure that review of site submissions and modifications are not delayed until the protocol can be adequately revised.

**Develop Template versions of Consent Documents and Recruitment Materials.**

- Templates for these essential documents will help streamline the review process for the relying sites by significantly simplifying the document localization process.

**Ensure that the relying site completes the HRP-218 Relying site Information Questionnaire in coordination with their local IRB.**

- This document lists research personnel involved in the research at the site, the role of the site in the research, confirmation that all ancillary reviews, training and financial disclosures have been completed, and important local context.
- The local study team **alone** will likely not be able to complete this without assistance from their local IRB.

**Ensure that the relying site(s) provides a documentation of their institutionally required language and local requirements before submitting to the IRB for review.**

- This documentation from the relying site must be provided to validate that the revisions made to the consent documents are consistent with their institutional requirements.
- If the documents submitted deviate from the relying site's language requirements, we will send the submission back for confirmation.

---

# Reducing Your Burden for Onboarding Community Centers as Relying Sites

## Consider if they have an administrative body to identify and manage conflicts of interest.

- The HRP-218 will indicate if the Community Partner does or does not have an administrative body to identify and manage conflicts of interest.
- If the relying site does **not** have an administrative body to identify and manage conflicts of interest, the UM's office of Disclosures & Scholarly Activities Management (DSAM) will need to conduct these reviews on their behalf.
- This is a manual process where each individual team member will need to disclose to DSAM via Qualtrics.

## Consider the community partner's access to CITI training.

- If the community center does not have access to CITI training, the relying study team will need to complete Miami CTSI's Community Involvement in Research Training course. (CIRTification)
- <https://miamictsi.org/community/cirtification/>

---

# Tips for efficient reliance/review

- Plan ahead and initiate discussions early
- Engage with collaborating institutions and with the UM reliance team
- Be aware of the extra responsibilities on the UM PI/Coordinating Center liaison
- Develop a protocol that clearly defines the responsibilities of each participating institution, including data collection, subject recruitment, adverse event reporting, and communication with the reviewing IRB
- Develop template consent documents
- Provide training to all research team members involved in the reliance process, including investigators, coordinators, and IRB staff at each site
- Maintain regular communication with sIRB

# HSRO Helpful Links & Resources

- **FAQs**

<https://hsro.uresearch.miami.edu/resources-and-guidance/hsro-education-exchange/index.html>

- **Investigator's Manual & SOPs**

*Chapter 4*

*Reliances and Cooperative Research for IRB Oversight*

<https://hsro.uresearch.miami.edu/resources-and-guidance/policies-procedures-and-regulations/index.html>

- **Single IRB and Reliances**

<https://hsro.uresearch.miami.edu/submit-to-the-irb/single-irb-and-reliances/index.html>

- **Committee review dates**

<https://hsro.uresearch.miami.edu/institutional-review-boards/irb-meeting-dates/index.html>