

# eProst Update Study Details Process for External IRB Studies (IRB8.2.4)



This guide is for updating study-wide details for External IRB Studies

**NOTE: DO NOT USE \*UPDATE STUDY DETAILS FOR UM SPECIFIC MODIFICATIONS**

**Updates that will affect the University of Miami study site and its affiliate locations *MUST BE SUBMITTED AS A MODIFICATION* to be reviewed and acknowledged by the University of Miami IRB**

\*Update Study Details in IRB8.2.4 is reserved for any non-UM specific changes (i.e., New study wide PI, study funding, study scope (drugs or devices information), template ICF, study-wide documents). These will NOT go through to UM IRB for review and will not update to VELOS. Please see Update Study Details Guide for more information

# UPDATE STUDY DETAILS:

1. Login to eProst and locate the study
2. From Study workspace: Select Update Study Details

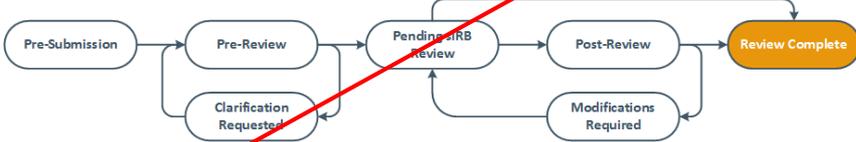
**Active**

Entered IRB: 10/22/2019 7:17 PM  
Initial approval: 10/2/2019  
Initial effective: 10/1/2019  
Effective: 10/2/2019  
Approval end: 9/30/2020  
Last updated: 10/23/2019 2:30 PM

**20190968: Script ID: IRB-078.1.0 - External IRB – Modifications & Updates (Scenario 1) (UAT)**

**Principal investigator:** UMTTest Princ Investigator (pi)  
**Submission type:** IRB Site  
**Primary contact:** UMTTest Princ Investigator (pi)  
**PI proxies:** UMTTest StudyStaff1 (ss1)  
**Institution:** Western IRB (WIRB)

**IRB office:** HSRO  
**IRB coordinator:** UMTTest IRBCoord1 (irbc)  
**Letter:** Correspondence\_for\_20190968.pdf(0.01)  
**Regulatory authority:** 2018 Requirements  
**External study ID:** 45646



**Next Steps**

- View Site
- Printer Version
- View Differences
- Create Site Modification
- Update Study Details**
- Report New Information
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Report Continuing Review Data
- Correspond with sIRB

History | Funding | Contacts | Documents | Follow-on Submissions | Reviews | Snapshots | Pending Contingencies

Filter by: Activity

Activity	Author	Activity Date
<b>i</b> Modification MOD00031891 review complete: Approved Modification: MOD00031891	IRBCoord1 (irbc), UMTTest	10/23/2019 2:30 PM
<b>i</b> Modification MOD00031891 Opened Modification: MOD00031891	Princ Investigator (pi), UMTTest	10/23/2019 1:45 PM
<b>i</b> Modification MOD00031884 Closed (Discarded) Modification: MOD00031884	Sakhrani, Kanchan M	10/22/2019 7:54 PM
<b>i</b> Modification MOD00031884 Opened Modification: MOD00031884	Sakhrani, Kanchan M	10/22/2019 7:42 PM
<b>i</b> Update MOD00031883 complete Study Update: MOD00031883	Sakhrani, Kanchan M	10/22/2019 7:35 PM

**NOTE:** The study must be in 'Active' state in order to use the 'Update Study Details' function.

### 3. Study Update Information

1. \* Summarize the updates:

1. Updates to Study Funding.
2. Updating new sponsor contact information
3. Uploading new sponsor info sheet.

**NOTE:** You must provide a complete summary of changes being made to the overall study. Please list all revised documents that will be uploaded here.

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Continue »

### 4.

#### Basic Study Information

1. \* Title of study:

Script ID: IRB-078.1.0 - External IRB – Modifications & Updates (Scenario 1) (UAT)

2. \* Short title:

Script ID: IRB-078.1.0 - External IRB – Modifications & Updates (Scen

3. \* Brief description:

Script ID: IRB-078.1.0 - External IRB – Modifications & Updates (Scenario 1) (UAT)

4. \* What kind of study is this?

- Multi-site or Collaborative study  
 Single-site study  
[Clear](#)

5. \* Will an IRB other than the University of Miami act as the IRB of record for this study at the UM Site?

- Yes  No

6. Lead principal investigator:

(NEW for v8.2.4  
Not a required field)

**Help**

**Short Title**

Select a short title for your study. You can use the sponsor's short title or any other unique name. As a guideline, keep it shorter than 50 characters.

The short title identifies the study throughout the IRB system, such as in your inbox and in the IRB's list of submissions to review.

**Help**

**Brief Description**

In a few words, summarize:

- The central question the research is intended to answer
- The primary objectives
- The methods used

For example:

This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine...

**Help**

**Kind of Study**

A multi-site or collaborative research study is one where two or more institutions collaborate to complete the research outlined in a specific protocol. (Note that a study that utilizes one or more Research Locations at your institution would likely not be considered a multi-site or collaborative research study in this system. Please contact the IRB office for any questions about your study scenario.)

A single-site study is one where all research activities occur at one institution.

**Help**

**External IRB of Record**

For a multi-site study (MSS):

Select Yes if an IRB outside your institution will review this study and decide whether to approve it with permission from the local (your institution's) IRB. For example, if you are a participating site in an MSS, select Yes.

If you are the sIRB of record for a multi-site or collaborative study, select No.

**Related Topics**

**\*\*NOTE:** For external studies, Multi-site Study should always be selected! Once External IRB has been confirmed Q. 3 and Q.4 are un-editable

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Hide/Show Errors

Continue »

## 5. External IRB

### 1. \* External IRB:

Western IRB (WIRB) ... ⊙

### 2. External study ID:

45646

### 3. Approval letter from external IRB:

WIRB Approval(0.01) Upload Revision ✕

### 4. Initial approval date by external IRB:

10/1/2019 📅

### 5. Last day of approval period:

9/30/2020 📅

### 6. \* Specify the reason(s) the study should be reviewed by an external IRB (check all that apply):

Required by regulation

Required by sponsor as a condition of conducting the trial

Other

### 7. If Other, specify the reason the study should be reviewed by an external IRB:

NEW Required field



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Hide/Show Errors

Print

Jump To

Continue »

**NOTE:** UM does not require continuing reports for external IRB studies. Therefore, the study team must monitor Q.5 the 'Last Day of Approval period' and update as appropriate.

6.

## Study Funding Sources ?

1. Identify each organization supplying funding for the study:

The screenshot shows the 'Add Funding Source' form with a table containing one entry: NIH Clinical Center (CC). A red dashed arrow points from the question mark icon in the section header to a 'Help' window. A red solid arrow points from the 'Add' button to the 'Add Funding Source' form below. The 'Help' window contains the following text:

**Funding Sources Page**  
Identify all external funding sources, such as industry sponsors and government agencies. The main purpose is to help the IRB identify all studies associated with particular grants.  
If funding comes from a specific internal funding program, also identify that funding source.

At the bottom of the page, there are navigation buttons: << Back, Save, Exit, Hide/Show Errors, Print, Jump To, and Continue >>.

The screenshot shows the 'Add Funding Source' form in a browser window. The form has the following fields and sections:

- 1. \* Funding organization: ? (text input field with a dropdown arrow)
- 2. Sponsor's funding ID: (assigned by external sponsor) (text input field)
- 3. Grants office ID: (assigned internally) (text input field)
- 4. Attach files: (include any grant applications) (button '+ Add' and a table)

The table under 'Attach files' has the following columns: Document, Category, Date Modified, Document History. Below the table, it says 'There are no items to display'. At the bottom of the form, there are buttons for 'OK', 'OK and Add Another', and 'Cancel'. A legend indicates '\* Required'.

**NOTE:** This page is for capture of general study funding source(s) information. This is NOT the same as Local Funding for UM

7.

## Study Scope

1. \* Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?   
 Yes  No [Clear](#)
2. \* Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?  
 Yes  No [Clear](#)

Help

### Study Scope Page

Identify factors involved in the study that may require review of additional details. Your answers determine whether you must provide additional information.

After answering these questions and clicking Continue, you can use the Jump To navigation element located at the top of the page to skip between any of the forms you need to fill out. You can also exit the form and return later to add information before submitting the study for review.

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[Save](#)

[Exit](#)

[Hide/Show Errors](#)

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[Jump To](#)

[Continue »](#)

### Drugs

1. \* List all drugs, biologics, foods, and dietary supplements to be used in the study:

[+ Add](#)

Generic Name	Brand Name	Attachment Name
<a href="#">Update</a> Acetaminophen	Tylenol	Drug attach

2. \* Will the study be conducted under any IND numbers? 

Yes  No [Clear](#)

3. \* Identify each IND: 

[+ Add](#)

IND Number	IND Holder	Other Holder
1234	Sponsor	

4. Attach files: (such as IND or other information that was not attached for a specific drug) 

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

### Devices

1. \* Select each device the study will use as an HUD or evaluate for safety or effectiveness:

[+ Add](#)

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. \* Device exemptions applicable to this study: 

- IDE number
  - HDE number
  - Claim of abbreviated IDE (non-significant risk device)
  - Exempt from IDE requirements
- [Clear](#)

3. Attach files: (such as IDE, HDE, or other information that was not attached for a specific device) 

[+ Add](#)

Document	Category	Date Modified	Document History
There are no items to display			

**NOTE:** Checking Yes to Q.1 will require further information on Drugs (see above). Checking yes to Q.2 will require further information on Devices (see right)

## 8. **ALERT:** Documents attached on this page do NOT get finalized and may not be visible on Velos D-Link

### Study-Related Documents

#### 1. **Consent form templates:** (include an HHS-approved sample consent document, if applicable)

Document	Category	Date Modified	Document History
There are no items to display			

#### 2. **Recruitment material templates:** (add templates for all material to be seen or heard by subjects, including ads)

Document	Category	Date Modified	Document History
There are no items to display			

#### 3. **Other attachments:**

Document	Category	Date Modified	Document History
There are no items to display			

#### Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

**NOTE:** Documents uploaded here should ONLY be the study-wide templates from which customized University of Miami documents are modeled. Documents and pertinent approvals that are specific to use at University of Miami MUST be submitted through a Modification.

## 9.

### Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:

1. Click **Finish** to exit the form.
2. **Important!** To send the submission for review, click **Submit** on the next page.



**NOTE:** It is helpful to use the Hide/Show Errors function before clicking Finish.

# 10.

## Updating Study

### MOD00031900: Update #2 for Script ID: IRB-078.1.0 - External IRB – Modifications & Updates (Scenario 1) (UAT)

**Principal investigator:** UMTTest Princ Investigator (pi)  
**Submission type:** Study Update  
**Primary contact:** UMTTest Princ Investigator (pi)

**IRB office:** HSRO  
**IRB coordinator:**  
**Regulatory authority:** 2018 Requirements



History | Documents | Reviews | Snapshots

Filter by <sup>?</sup> Activity

No data to display.

- Finalize Updates
- Manage Ancillary Reviews
- Add Comment
- Discard

Execute "Finalize Updates" on MOD00031900 - Google Chrome

irbstaging.med.miami.edu/Eproststaging/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.ent...

### Finalize Updates

By signing below you are verifying that:

- You have updated the study record only to reflect what the External IRB has approved.
- You assure the following:
  - The the information submitted in this application is true, complete, and accurate to the best of your knowledge, and
  - That you (as Principal Investigator) agree to conduct and to report this study in a responsible manner, free from fabrication, falsification, and/or plagiarism.
  - That you have taken into account appropriate security measures to protect data.

**NOTE:** Study Team members can enter details of the study update. However, only the PI and PI Proxy are able to execute 'Finalize Updates'.

**Updates Complete**

# MOD00031900: Update #2 for Script ID: IRB-078.1.0 - External IRB – Modifications & Updates (Scenario 1) (UAT)

Effective: 10/2/2019  
Last updated: 10/30/2019 12:37 PM

**Principal investigator:** UMTest Princ Investigator (pi)  
**Submission type:** Study Update  
**Primary contact:** UMTest Princ Investigator (pi)

**IRB office:** HSRO  
**IRB coordinator:**  
**Regulatory authority:** 2018 Requirements

**Next Steps**

View Study Details

Printer Version

View Differences

Manage Ancillary Reviews

Add Comment



History Documents Reviews Snapshots

Filter by ? Activity   + Add Filter ✕ Clear All

	Activity	Author	Activity Date
<input checked="" type="checkbox"/>	Updates Finalized	Princ Investigator (pi), UMTest	10/30/2019 12:37 PM

**NOTE:** The Study update is assigned a MODXXXXXXXX number, but is labeled as an Update # X, rather than a Modification.