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

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

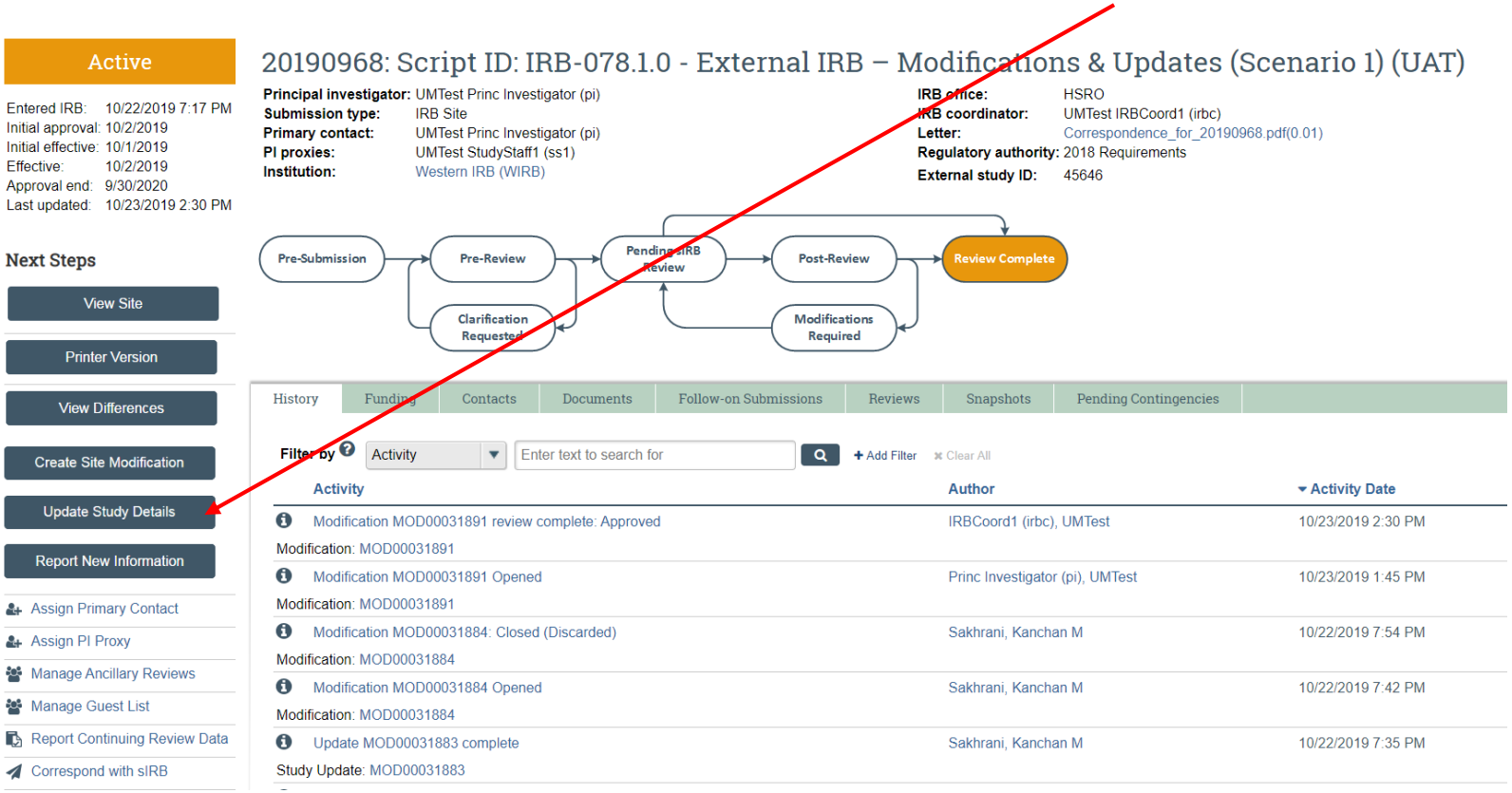
NOTE: DO NOT USE *UPDATE STUDY DETAILS FOR UM SPECIFIC MODIFICATIONS

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



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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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 (Scena

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)

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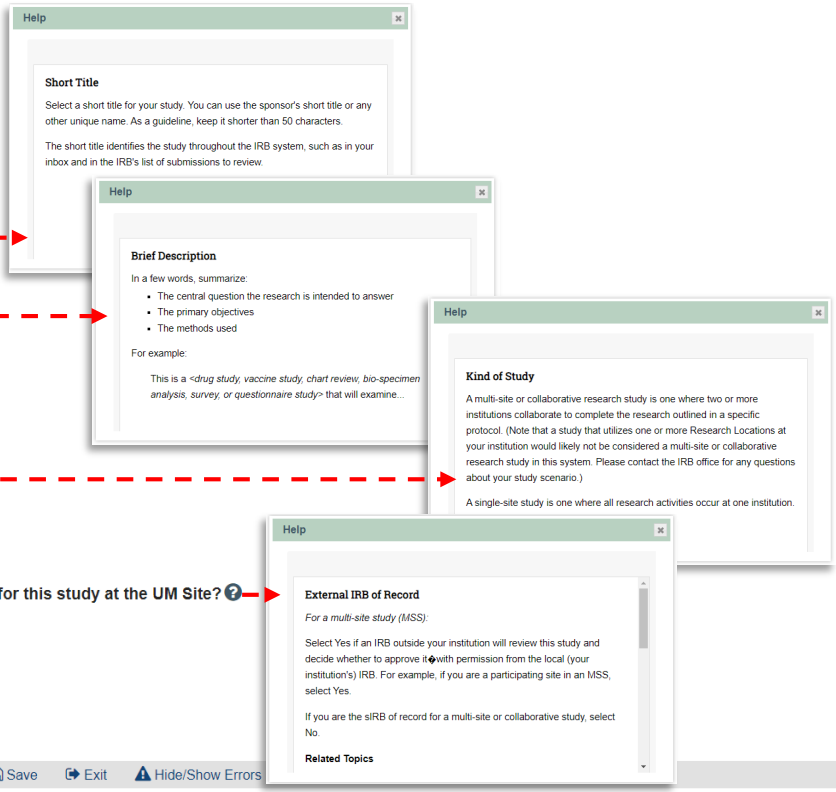
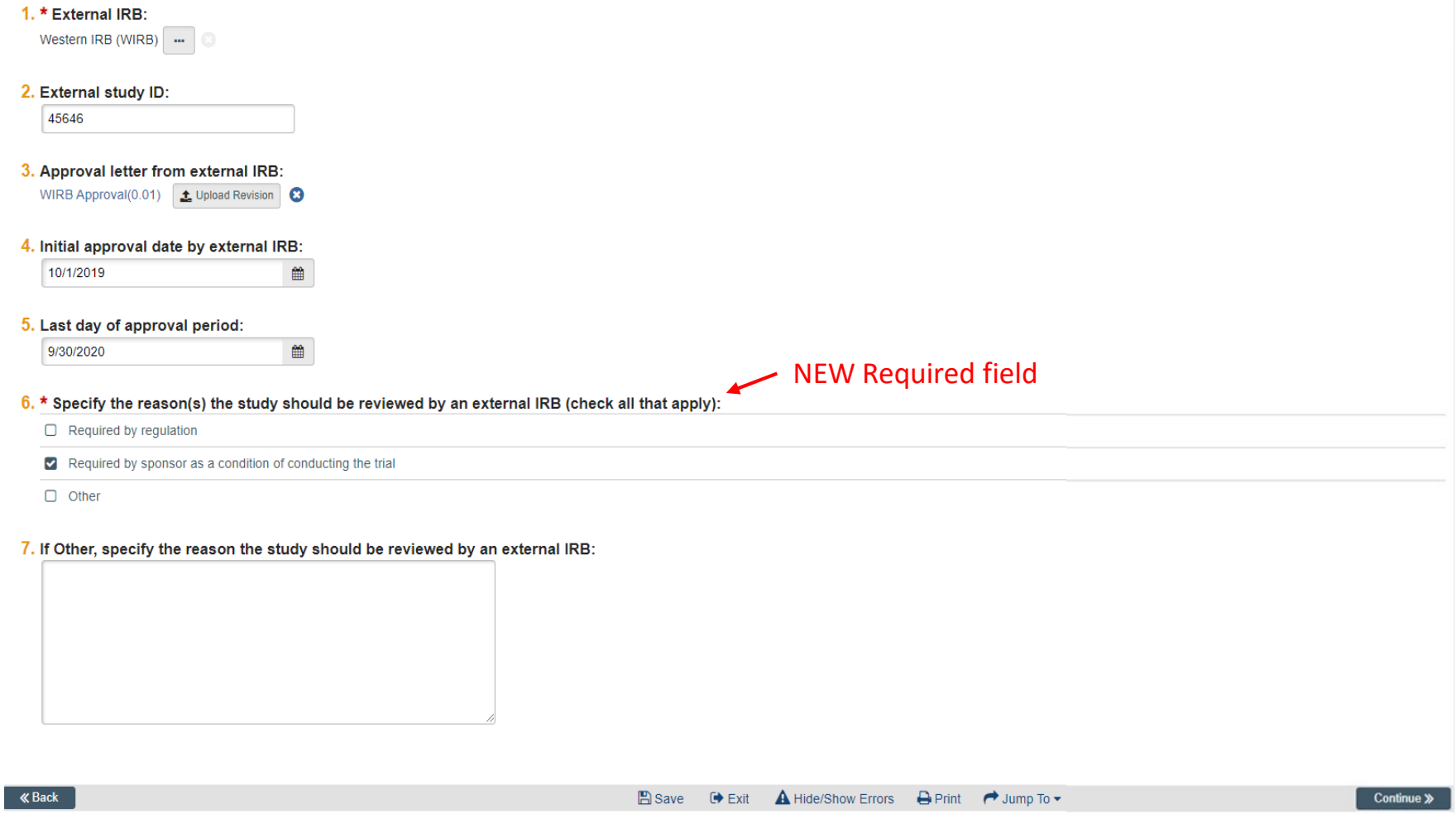


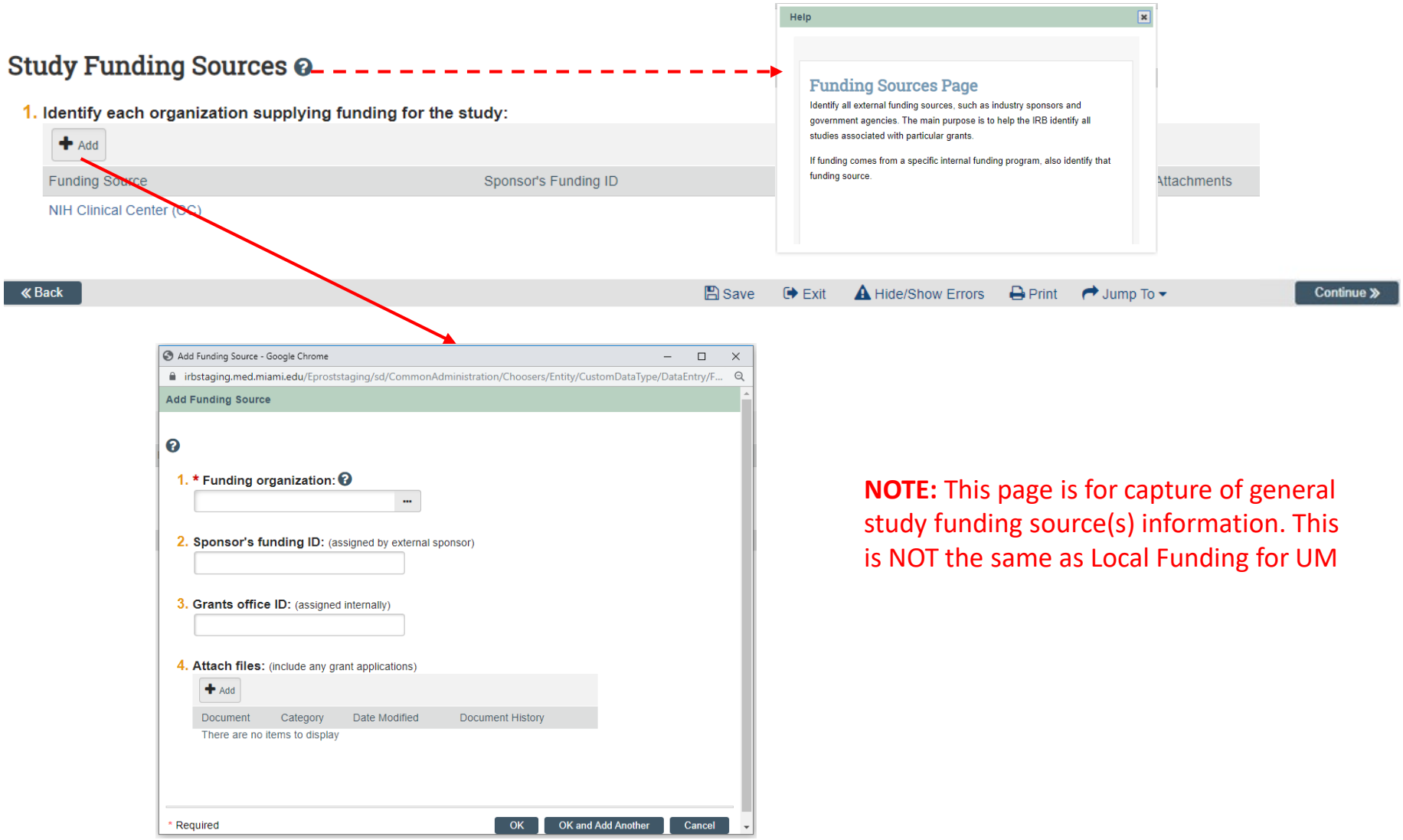
****NOTE:** For external studies, Multi-site Study should always be selected! Once External IRB has been confirmed Q. 3 and Q.4 are un-editable

5. External IRB



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.



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

« Back | Save | Exit | Hide/Show Errors | Print | Jump To | Continue »

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.

Drugs

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

+ Add

	Generic Name	Brand Name	Attachment Name
Update	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 (nonsignificant 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)

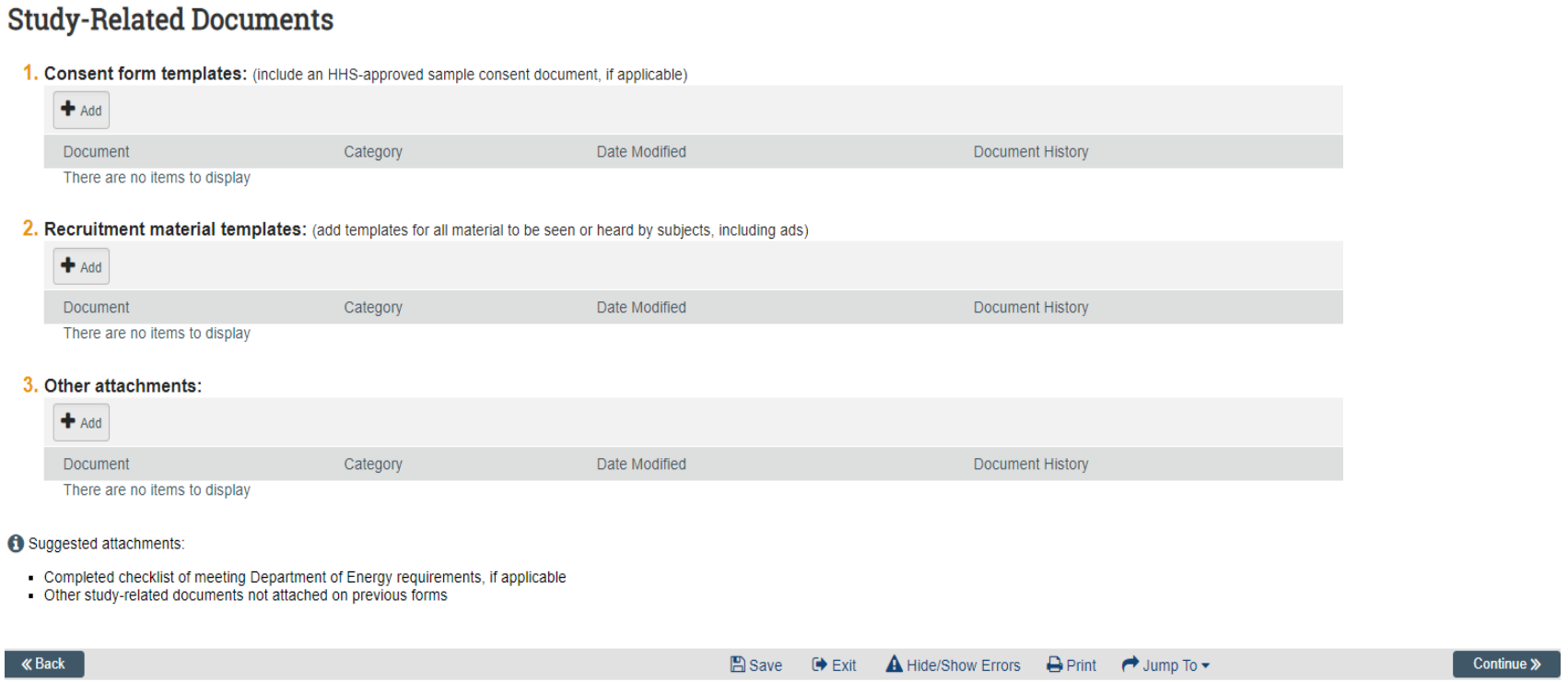
+ Add

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

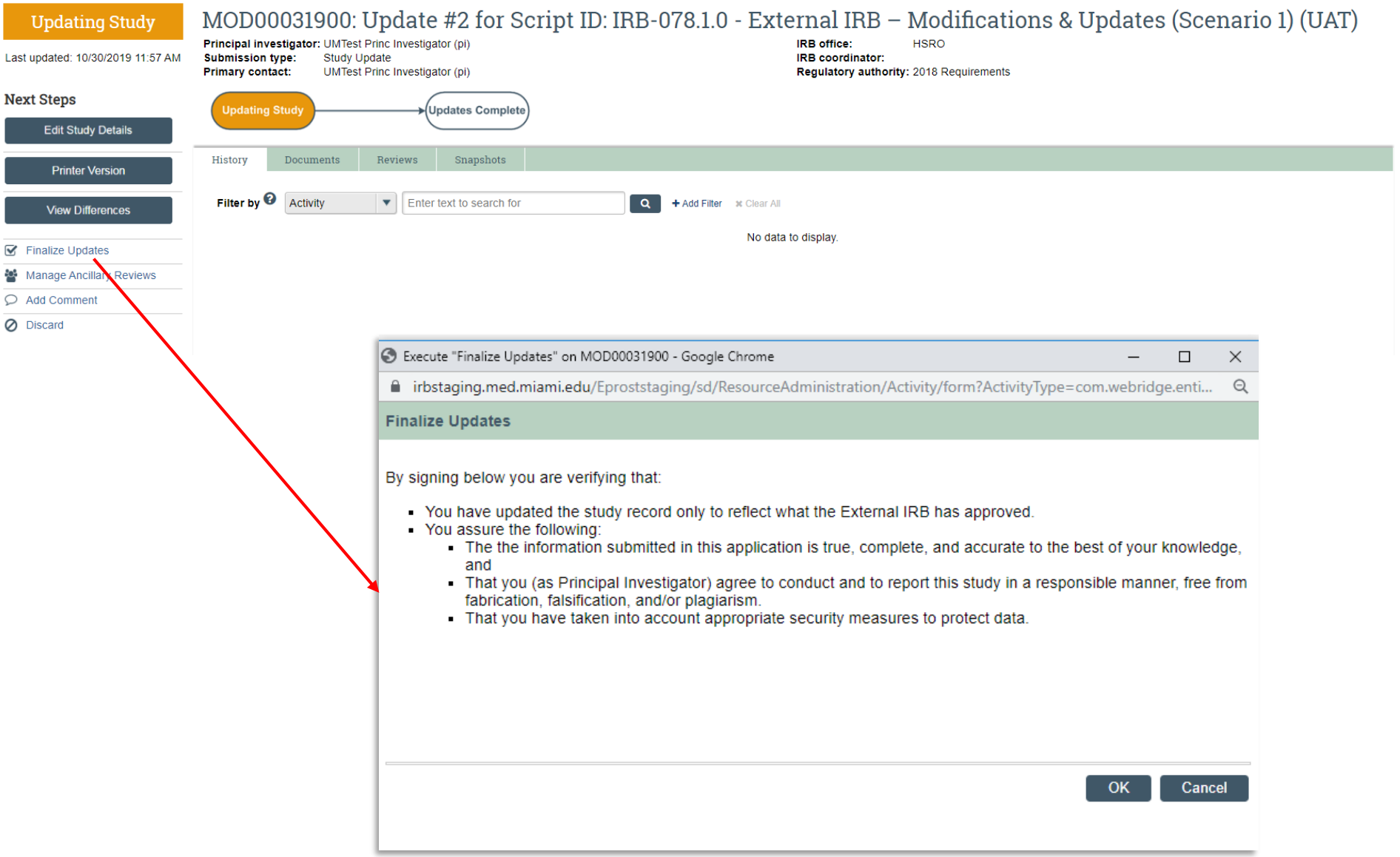


NOTE: Documents uploaded here should *ONLY* be the study-wide templates from which customized University of Miami documents are modeled. Documents and pertinent approvals that are specific to use at University of Miami *MUST* be submitted through a Modification.

9.

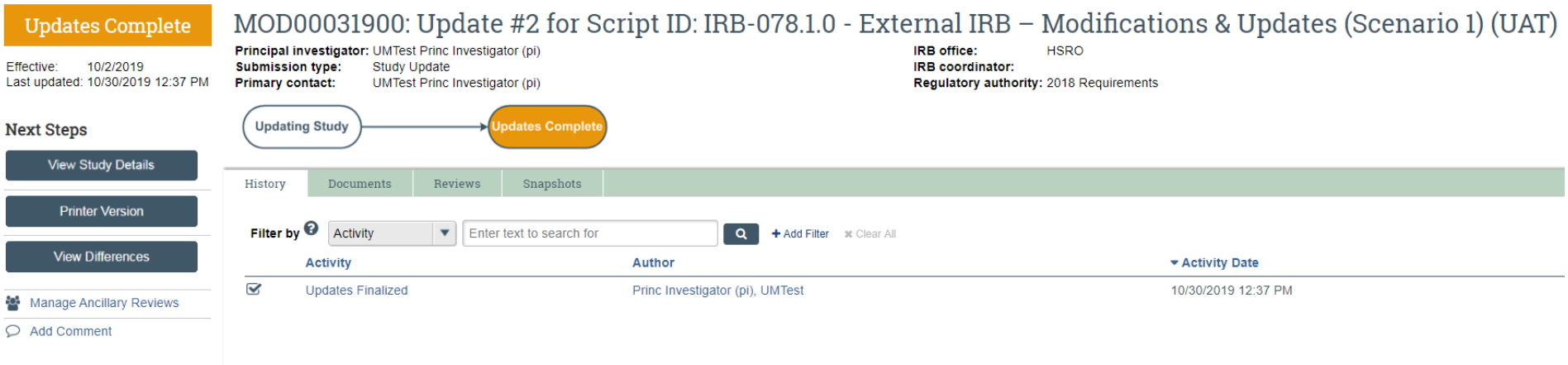
NOTE: It is helpful to use the Hide/Show Errors function before clicking Finish.

10.



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

11.



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