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

**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 (NEW for v8.2.4 Not a required field).

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 (Scenario 1)

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)

**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.
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.
NOTE: This page is for capture of general study funding source(s) information. This is NOT the same as Local Funding for UM.
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).
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**.
NOTE: Study Team members can enter details of the study update. However, only the PI and PI Proxy are able to execute ‘Finalize Updates’.
NOTE: The Study update is assigned a MODXXXXXXXX number, but is labeled as an Update # X, rather than a Modification.