eProst Submission Process for External IRB Modifications (IRB8.2.4)



This guide is for Modifications created for External IRB Studies

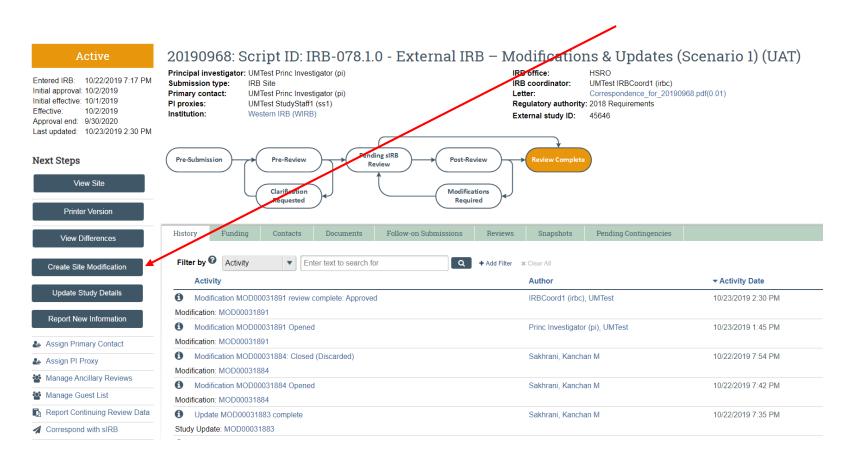
NOTE: DO NOT USE *UPDATE STUDY DETAILS FOR UM SPECIFIC MODIFICATIONS

Updates that will affect the University of Miami study sites must be submitted as a Modification in eProst, 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, general study funding, <u>template</u> ICF) These will NOT go through to UM IRB for review and will not update to VELOS D-Link. Please see Update Study Details Guide for more information.

CREATE A MODIFICATION:

- Login to eProst and locate study
- From Study workspace: Select 'Create Site Modification'



Modification

* What is the purpose of this submission?			
•	Modification / Update		
0	To change the PI, choose 'Other parts of the study/site' scope		
For	External IRB Submissions only, please select both 'Other parts of the site' AND 'Study team and research location information' options to make any changes to the submission.		
Mo	dification scope: Study team member information Other parts of the study Please select both		
For	Modifications that include 'Other Parts of the study/site' scope:		
* T	his Modification includes changes to: (check all that apply). You will be required to provide more detail on the next page		
	Type of Change for MOD		
	Principal Investigator		
~	Funding source		
	Research locations		
	Study protocol (including changes to procedures, study calendar, treatment plan, changes to drug dosage/routing, etc.)		
	Drug/Device information (including IND/IDE, investigator brochure)		
	Inclusion/exclusion criteria		
	Consent/assent documents and/or consent process, translations		
	Recruitment materials, surveys, questionnaires		
	Risks/benefits		
	Data collection or data sharing		
	Administrative changes		
	Adding Personnel		
	Removing Personnel		
	Other (please specify in summary on next page)		

NOTE: External studies do not need to submit continuing reviews to the University of Miami IRB. They are only required to be submitted to the IRB of record (sIRB)

Modification Information (NEW for v8.2.4)

1.3	. * Study enrollment status:	
	□ No subjects have been enrolled to date	
	✓ Subjects are currently enrolled	
	 Study is permanently closed to enrollment 	
	 All subjects have completed all study-related interventions 	
	☐ Collection of private identifiable information is complete	
	☐ Not applicable. Study does not enroll subjects (e.g. chart review)	
2.	. * Notification of subjects: (check all that apply)	
	Current subjects will be notified of these changes	
	☐ Former subjects will be notified of these changes	
	✓ Not Applicable	
	Attach files: If notifying subjects, add a description of how they will be notified	to the Other attachments section of the Local Site Documents page.
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NOTE: Please list all items included in the modification. If items have been included that are not mentioned in Q.3 above, they will be sent back to the study team for clarification.

Basic Local Site Information

1. * Local principal investigator:

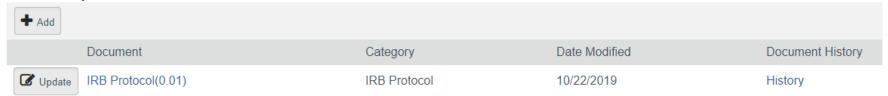
UMTest Princ Investigator (pi)		
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2. * Brief description of activities this site will perform: (enter "ALL" if this site will perform all procedures in the protocol)

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Script ID: IRB-078.1.0 - External IRB - Modifications & Updates (Scenario 1) (UAT)
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(NEW for v8.2.4)

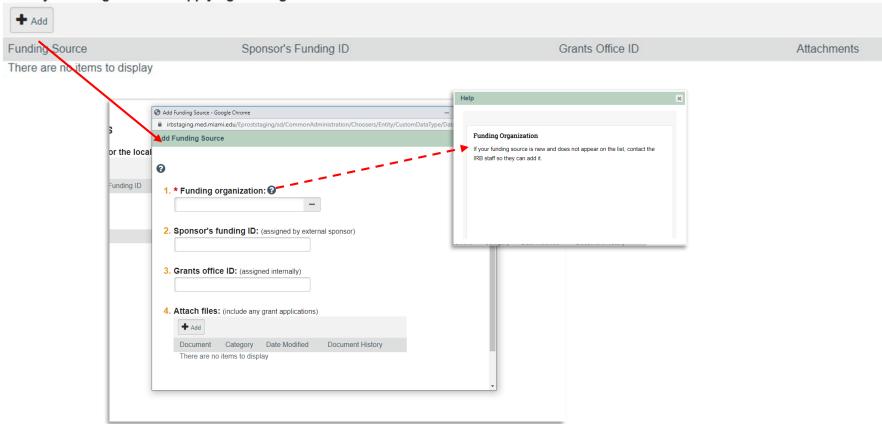
3. Attach the protocol:



NOTE: IRB Protocol Attachments (to be finalized in IRB8.2.4) submitted here will go to Velos D-Link

Additional Local Funding Sources

1. Identify each organization supplying funding for the local site:

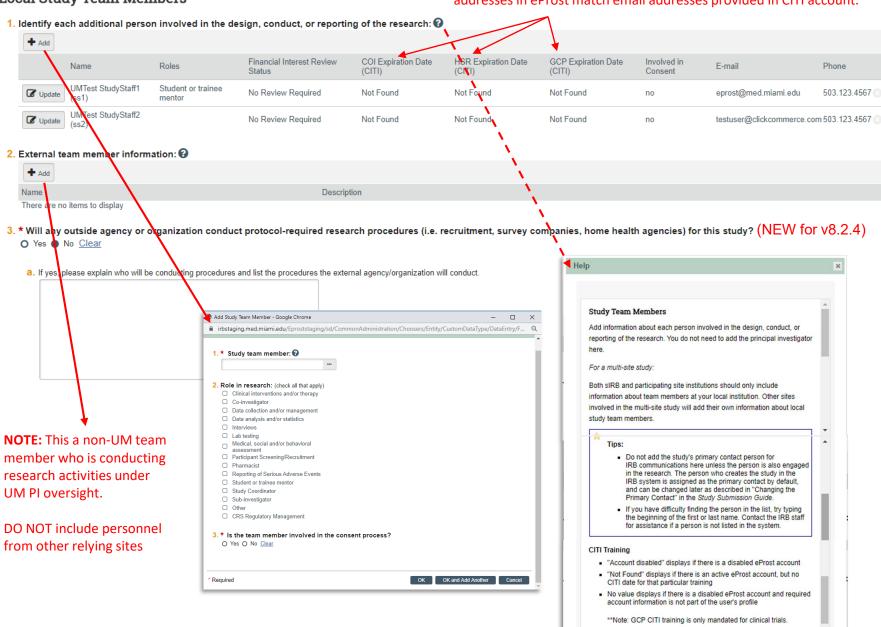


NOTE: This is NOT the same as the Study Funding Source. This section is reserved for funds that impact University of Miami and its affiliate locations only, not the entire study.

Local Study Team Members

NOTE: (New for v8.2.4)

Team member CITI compliance training will auto-populate provided email addresses in eProst match email addresses provided in CITI account.



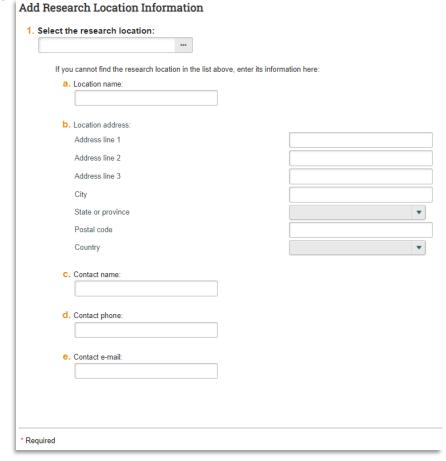
Local Research Locations @

1. Identify research locations where research activities will be conducted or overseen by the local investigator:



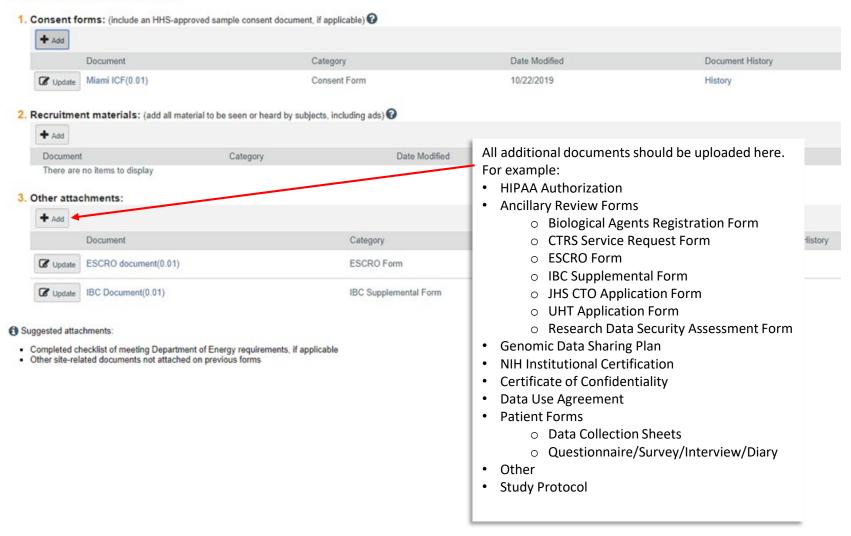
NOTE: This section is reserved for study sites that will conduct the research under the purview of the University of Miami study team

- This is NOT the same as UM Research Locations or Performance Sites (i.e., Jackson, CTRS, UHT, Cancer Center satellite sites, etc)
- This is NOT the same as participating sites in MSS studies



ALERT: Study protocol updates (and amendments) should be uploaded in Local Site Documents under 'Other Attachments' so that they will be finalized and uploaded to Velos D-Link.

Local Site Documents @



NOTE: Consent forms, HIPAA Authorizations, recruitment materials, press releases, and data collection sheets will be finalized and sent to Velos D-link

Additional Study Information

elect the type of research:
Type of Research
Blomedical
Social/Behavioral
Clear
* Will any data be shared outside of the University of Miami? O Yes No Clear
If you answered YES in question 1a, please indicate what data will be shared outside of the University of Miami.
Data Type
Protected Health Information (PHI)
Personally Identifiable Information (PII)
Limited Data Set (LDS)
□ De-identified Data
□ Other
If you selected YES in question 1a and "Protected Health Information" or "Other" in question 1b, then approval from the <u>Data Security Ancillary Committee</u> is required and the <u>Research Data Security Assessment Form</u> must be uploaded in the Local Site Documents section. If anything other than De-Identified Data is selected for 1b, please indicate the agreement(s) you currently have in place which allows the sharing of such data. Select all that apply.
Agreement
Business Associate Agreement
Data Use Agreement Registry Participation Agreement
□ No Agreement
□ Other
If other, please specify:
Approval from the <u>Data Security Ancillary Committee</u> is required and the <u>Research Data Security Assessment Form</u> must be uploaded in the Local Site Documents section if. (1) you selected "LDS" in question 1b and did not select "Data Use Agreement" in question 1c; OR (2) if you selected "No Agreement" or "Other" in question 1c and select "Da-identified Data" in question 1b.

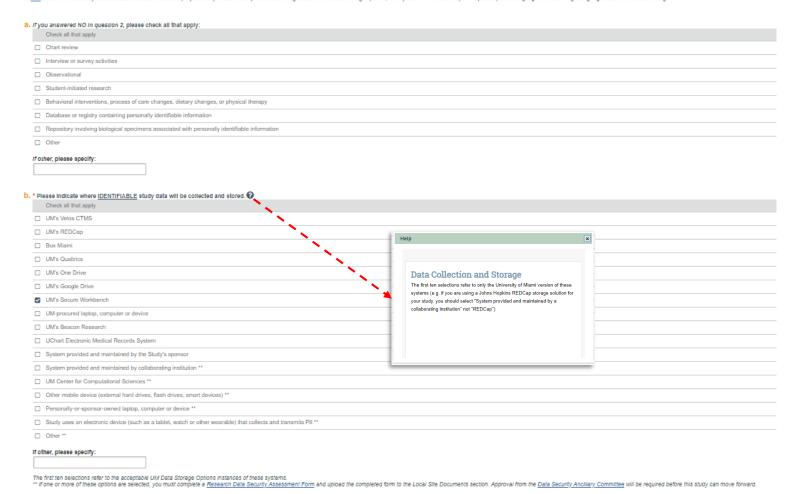
9. Additional Study Information cont'd

2. * Does this study involve ANY of the following?

- Testing a drug, device, or biologic
- Pharmacovigilance study
- · Interventional or surgical procedure
- Clinic vis
- · Procedures, lab tests, or medical interventions that might be billed through UHealth or a commercial laboratory
- Yes O No Clear

If yes, you must enroil all participants into Velos. Please refer to the Clinical Research Participant Enrollment & Tracking Policy for more Information.

This link is to an online survey that facilitates the determination 1) if your study meets the requirements for registration on ClinicalTrials gov per UM Policy HSR-P-101 and/or 2) if it requires specific language in the ICF regarding registration on ClinicalTrials gov.



C. * Will study generate large-scale human or non-human genomic data?

O Yes ● No Clear

9. Additional Study Information cont'd

3. * Please enter the expected number of subjects to be enrolled at this investigator's sites: If this is a chart review, please enter the expected number of charts to be reviewed: 4. * Study will take place at: Check all that apply University of Miami Jackson Health Systems ☐ Miami VA □ JFK Hospital ☐ Mt. Sinai Medical Center Other a. If you selected University of Miami in question 4, please Indicate all UM sites where study activities will take place: University of Miami: Coral Gables Campus Gables □ UMSM University of Miami Medical Campus □ BPEI Bascom Palmer Eye Institute □ ABLEH Anne Bates Leach Eye Hospital □ BPPB Bascom Palmer at Palm Beach □ BPIP Bascom Palmer at Plantation □ BPRC Bascom Palmer Retina Center in Naples □ BCRI Batchelor's Children Research Institute □ UHT UHealth Tower □ UMHC University of Miami Hospital & Clinics ☐ UMHC Deerfield University of Miami Hospital & Clinics at Deerfield Beach □ DRI Diabetes Research Institute □ CTRS Clinical Translational Research Site □ IWH Institute for Women's Health Mailman Center for Child Development ☐ MCCD Miami Project Miami Project to Cure Paralysis □ RSMAS Rosenstiel School of Marine and Atmospheric Sciences Sylvester Comprehensive Cancer Center Sylvester CCC at Coral Springs SCCC Coral Springs ☐ SCCC Deerfield Sylvester CCC at Deerfield Beach ☐ SCCC Hollywood Sylvester CCC at Hollywood ☐ SCCC Kendall Sylvester CCC at Kendall ☐ SCCC Plantation Sylvester CCC at Plantation The Lennar Foundation Medical Center □ TRI Touch Research Institute Lois Pope Life Center □ UMKM University of Miami Kendall Clinic □ CLRB Clinical Research Building □ DAYS Daystar UM □ PAC Professional Arts Center □ RMSB Rosenstiel Medical Science Building Other University of Miami Site

b. If Other UM Site was selected in question 4a, please specify:

9. Additional Study Information cont'd

11. * Does the study prospectively assign research subjects to one or more interventions?

a. Does the study have a health-related biomedical or behavioral outcome?

O Yes O No Clear

5. * Does this research involve facilities and/or support from the Clinical Translational Research Site (CTRS)? O Yes ● No Clear		
If yes, approval from the CTRS is required and the CTRS Service Request form must be uploaded in the Local Site Documents section.		
6. * Will any study-related activities be performed or possibly performed at a Jackson Health Systems (JHS) site? This includes recruitment of subjects, facilities use, retrospective analysis of charts/records, subject interventions, such as tests, measurements, drug administration, or s	surgery, consenting subjects, and tissue/specimen collection.	
○ Yes ● No <u>Clear</u>		
If yes, approval from the JHS Clinical Research Review Committee (JHS CRRC) is required, the JHS CTO Application Form and JHS Study Calendar must be uploaded	In the Local Site Documents section.	
7. * Will any study-related activities be performed or possibly performed at a UHealth Tower (UHT) site? This includes recruitment of subjects, facilities use, retrospective analysis of charts-records, subject interventions, such as tests, measurements, drug administration, or s	surgery, consenting subjects, and lissue/specimen collection.	
○ Yes ● No <u>Clear</u>		
If yes, approval from the <u>UHT Ancillary Committee</u> is required.		
8. * Is this study cancer related (whether it includes a drug, biologic, device, interventions, epidemiologic, behavioral other observation	ne ancillary preventive surveillance or correlative studies (20	
Check all that apply	Notes	
Protocol objectives/endpoints are cancer-related or have implications for cancer prevention or control		
Protocol will predominantly recruit/accrue within a population of patients being treated, followed, or evaluated for cancer	This includes cancer patients, cancer survivors, or individuals at risk for cancer within the University of Miami or in the	e community
☐ Protocol requires use of Sylvester Comprehensive Cancer Center (SCCC) resources	This includes SCCC patient records/specimens (retrospective or prospective), SCCC personnel (investigators, nurse	s, research staff), and/or SCCC facilities (SCCC clinics, units, shared resources, laboratories), or financial or research administrative supp
○ None of the above Approved from the <u>Cancer Protocol Review Committee</u> is required for all studies involving cancer patients, diagnosis, or therapy. 3. Which service will you require?		
Check all that apply	1	lotes
SCCC Clinical Research Services (CRS)	1	his includes CRS coordinator, regulatory, informatics, or data support
☐ Behavioral and Community-Based Shared Resource (BCSR)	1	his includes protocol management, regulatory, informatics, or data support
SCCC Data Safety Monitoring Committee (DSMC)	ı	nvestigator Initiated Studies (IISs)
☐ IND/IDE Support Services	3	CCC IND/IDE submission and maintenance support
☐ Monitoring Services - Clinical Research Operations and Regulatory Support (CRORS)	1	his includes the monitoring of SCCC cancer related trials
☐ Compliance Review Services	1	his includes pre and post audit assessments and response assistance
□ No SCCC services required		
9. * Who initiated this study? Cooperative group initiated ▼		
 Please provide a brief (maximum 2 sentences) lay description of your study. Potential participants searching UM's clinical research website will be provided this description and a link to the full details of your study. 		
Not Applicable for this study		

NOTE: Answers here will determine if any ancillary committee reviews will be required for the study. Reviews by IBC, PRC, HRSC and ESCRO must be completed and approved before a modification can be acknowledged by the IRB.

10 Clinical/Medical/Biomedical Research Only

This information is NOT required for social/behavioral research.

1. * Does this study involve patient specimen collection at any UM patient care facility, archived tissues or slides, and/or Department of Pathology expertise or facilities? This does not include chart reviews or review of laboratory results in the electronic medical record.

O Yes No Clear

2. * Does this research involve blood, handling blood or other material?

O Yes No Clear

If yes, approval from the Environmental Health & Safety Committee, Biosafety Officer, is required. See EHS website for the Biological Agents Registration Form which must be uploaded in the Supporting Documents section,

3. * Does this study involve radioactive materials, radioisotopes, and/or radiation producing equipment?

O Yes No Clear

If yes, approval from the Human Use Radiation Safety Committee may be required. See the HSRO website for additional information

4. * Does this study involve recombinant DNA and/or gene transfer?

● Yes O No Clear

If yes, approval from the Institutional Biosafety Committee is required. See IBC website for additional information and forms.

5. * Does this research involve human embryonic stem cells and/or their derivatives?

Yes O No Clear

If yes, approval from the ESCRO committee is required. See ESCRO website for additional information and forms

6. * Select drug study phase:

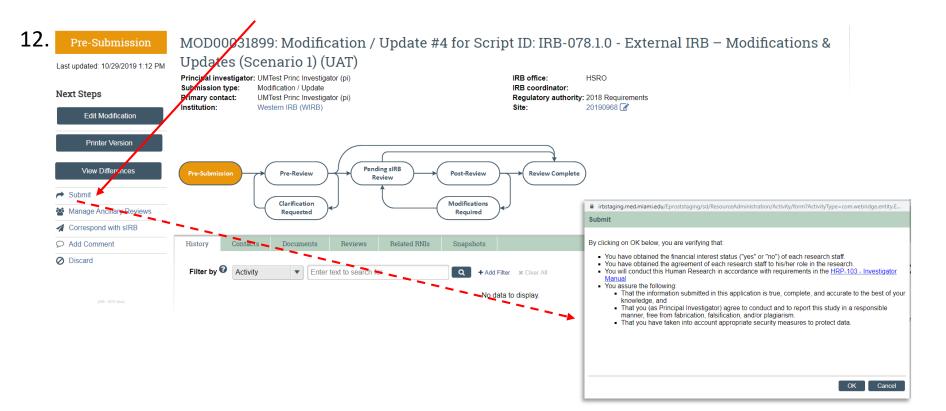
Clear

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Phase	Description				
 Not Applicable 	For trials without phases				
O Pilot/Phase 0	Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory IND studies for more information.				
O Phase I	Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients				
O Phase I/II	For trials that are a combination of Phases I and II				
O Phase II	Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks				
O Phase II/III	For trials that are a combination of Phases II and III				
O Phase III	Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling				
O Phase IV	Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use				
O Approved Drug/off- label use					
O Other					

NOTE: Answers here will determine if any ancillary committee reviews will be required for the study. Reviews by IBC, PRC, HRSC and ESCRO must be completed and approved before a modification can be acknowledged by the IRB.

Final Page ②





NOTE: Study team members can enter details of the Modification. However, only the PI and PI Proxy are authorized to execute 'Submit' Modification.

If your modification submission is successful, study status will have advanced to Pre-Review.

