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, template 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:

1. Login to eProst and locate study
2. From Study workspace: Select ‘Create Site Modification’
3.

**Modification**

*What is the purpose of this submission?*

- Modification / Update

**Modification scope:**

- Study team member information
- Other parts of the study

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.

For Modifications that include 'Other Parts of the study/site' scope:

*This Modification includes changes to: (check all that apply). You will be required to provide more detail on the next page*

<table>
<thead>
<tr>
<th>Type of Change for MOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Principal investigator</td>
</tr>
<tr>
<td>☑ Funding source</td>
</tr>
<tr>
<td>☐ Research locations</td>
</tr>
<tr>
<td>☐ Study protocol (including changes to procedures, study calendar, treatment plan, changes to drug dosage-routing, etc.)</td>
</tr>
<tr>
<td>☐ Drug/Device information (including IND/IDE, investigator procedure)</td>
</tr>
<tr>
<td>☐ Inclusion/exclusion criteria</td>
</tr>
<tr>
<td>☐ Consent/assent documents and/or consent process, translations</td>
</tr>
<tr>
<td>☐ Recruitment materials, surveys, questionnaires</td>
</tr>
<tr>
<td>☐ Risks/benefits</td>
</tr>
<tr>
<td>☐ Data collection or data sharing</td>
</tr>
<tr>
<td>☐ Administrative changes</td>
</tr>
<tr>
<td>☐ Adding Personnel</td>
</tr>
<tr>
<td>☐ Removing Personnel</td>
</tr>
</tbody>
</table>
| ☐ 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)
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.
5.

**Basic Local Site Information**

1. *Local principal investigator:*
   
   [UMTest Princ Investigator (pi)]

2. *Brief description of activities this site will perform:* (enter "ALL" if this site will perform all procedures in the protocol)
   
   [Script ID: IRB-078 1.0 - External IRB – Modifications & Updates (Scenario 1) (UAT)]

   (NEW for v8.2.4)

3. Attach the protocol:

   ![Document Table]

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Protocol(0.01)</td>
<td>IRB Protocol</td>
<td>10/22/2019</td>
<td>History</td>
</tr>
</tbody>
</table>

**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.
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.

NOTE: This a non-UM team member who is conducting research activities under UM PI oversight. DO NOT include personnel from other relying sites.
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
8. **NOTE:** Consent forms, HIPAA Authorizations, recruitment materials, press releases, and data collection sheets will be finalized and sent to Velos D-Link.

### Local Site Documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miami ICF(0.01)</td>
<td>Consent Form</td>
<td>10/22/2019</td>
<td>History</td>
</tr>
<tr>
<td>ESCRO document(0.01)</td>
<td>ESCRO Form</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IBC Document(0.01)</td>
<td>IBC Supplemental Form</td>
<td></td>
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<tr>
<td></td>
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<td></td>
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</tbody>
</table>

**Suggested attachments:**
- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

### Local Site Documents

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

   - Miami ICF(0.01) - Consent Form - 10/22/2019

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

   - Miami ICF(0.01) - Consent Form - 10/22/2019

3. **Other attachments:**

   - ESCRO document(0.01) - ESCRO Form
   - IBC Document(0.01) - IBC Supplemental Form

**All additional documents should be uploaded here.**

For example:
- **HIPAA Authorization**
- **Ancillary Review Forms**
  - Biological Agents Registration Form
  - CTRS Service Request Form
  - ESCRO Form
  - IBC Supplemental Form
  - JHS CTO Application Form
  - UHT Application Form
  - Research Data Security Assessment Form
- **Genomic Data Sharing Plan**
- **NIH Institutional Certification**
- **Certificate of Confidentiality**
- **Data Use Agreement**
- **Patient Forms**
  - Data Collection Sheets
  - Questionnaire/Survey/Interview/Diary
- **Other**
- **Study Protocol**

**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.

**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

**1. Select the type of research:**

- Biomedical
- Social/Behavioral

**2. Will any data be shared outside of the University of Miami?**

- Yes
- No

**3. If you answered YES in question 1a, please indicate what data will be shared outside of the University of Miami.**

<table>
<thead>
<tr>
<th>Data Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Protected Health Information (PHI)</td>
</tr>
<tr>
<td>☐ Personally Identifiable Information (PI)</td>
</tr>
<tr>
<td>☐ Limited Data Set (LDS)</td>
</tr>
<tr>
<td>☐ De-identified Data</td>
</tr>
<tr>
<td>☐ Other</td>
</tr>
</tbody>
</table>

If other, please specify:  

If you selected YES in question 1a and “Protected Health Information” or “Other” in question 1b, then approval from the Data Security Ancillary Committee is required and the Research Data Security Assessment Form must be uploaded in the Local Site Documents section.

**C. 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.**

<table>
<thead>
<tr>
<th>Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Business Associate Agreement</td>
</tr>
<tr>
<td>☐ Data Use Agreement</td>
</tr>
<tr>
<td>☐ Registry Participation Agreement</td>
</tr>
<tr>
<td>☐ No Agreement</td>
</tr>
<tr>
<td>☐ Other</td>
</tr>
</tbody>
</table>

If other, please specify:  

Approval from the Data Security Ancillary Committee is required and the Research Data Security Assessment Form 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) you selected “No Agreement” or “Other” in question 1c and did not select “De-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 visits
   • Procedures, lab tests, or medical interventions that might be billed through UI Health or a commercial laboratory

   Yes  No  [Click]

If yes, you must enroll all participants into IRB. Please refer to the Clinical Research Participant Enrollment & Training Policy for more information.

This assists an online survey that facilitates the determination if your study meets the requirements for registration on Research.gov. If not, the study may not be submitted on Research.gov. If it requires specific language in the IIR regarding registration on Research.gov.

A. If your answers to question 1, please check all that apply:
   - Chart review
   - Interview or survey activities
   - Observational
   - Study-initiated research
   - Behavioral interventions, process of care changes, dietary changes, or physical therapy
   - Database or registry containing personally identifiable information
   - Repository involving biological specimens associated with personally identifiable information
   - Other

   [If other, please specify: ___________________________]

B. Please indicate where IDENTIFIABLE study data will be collected and stored.

   - Check all that apply:
     - UMI's Uniq ID
     - UMI's REDCap
     - Box Vital
     - UMI's Qualtrics
     - UMI's OneDrive
     - UMI's Google Drive
     - UMI's Secure Workbench
     - UMI's Microsoft Office
     - UMI's RDS, Research
     - LIChart Electronic Medical Records System
     - System provided and maintained by the Study’s sponsor
     - System provided and maintained by collaborating institution
     - UMI Center for Computational Sciences
     - Other mobile device (including smartphones, flash drives, smart devices)
     - Personally or sponsor owned laptop, computer or device
     - Study uses an electronic device (such as a tablet, watch or other extender) that collects and transmits PHI
     - Other

   [If other, please specify: ___________________________]

The first ten selections refer to the acceptable UII Data Storage Options within those systems.

If none or more of these options are selected, you must complete a [Research Data Security Assessment Form] and upload the completed form to the Local Site Documents section. Approval from the Data Security Advisory Committee will be required before this study can move forward.

C. Will study generate large-scale human or non-human genomic data?
   - Yes  No  [Click]

   When the [Genetic Data Sharing Plan] and [UMI Institutional Certification] are completed, please either upload them to this submission or submit them as a modification in a subsequent submission.
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:
   
   - University of Miami
   - Jackson Health Systems
   - Miami VA
   - JFKI Hospital
   - UI Sina Medical Center
   - Other

5. If you selected University of Miami in question 4, please indicate all UM sites where study activities will take place:

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design</td>
<td>University of Miami - Coral Gables Campus</td>
</tr>
<tr>
<td>UMMU</td>
<td>University of Miami Medical Campus</td>
</tr>
<tr>
<td>BPED</td>
<td>Bascom Palmer Eye Institute</td>
</tr>
<tr>
<td>ARLED</td>
<td>Anne Boleyn Leush Eye Hospital</td>
</tr>
<tr>
<td>BMPI</td>
<td>Bascom Palmer atMiami Beach</td>
</tr>
<tr>
<td>FNP</td>
<td>Bascom Palmer at Ft. Lauderdale</td>
</tr>
<tr>
<td>SPRI</td>
<td>Bascom Palmer Research Institute at Naples</td>
</tr>
<tr>
<td>SORI</td>
<td>Bascom Palmer Research Institute</td>
</tr>
<tr>
<td>UM</td>
<td>University of Miami - General Hospital</td>
</tr>
<tr>
<td>UMHC</td>
<td>University of Miami - Hospital Clinics</td>
</tr>
<tr>
<td>UMMHC Deerfield</td>
<td>University of Miami - Hospital Clinics at Deerfield</td>
</tr>
<tr>
<td>DRI</td>
<td>Dadebrow Research Institute</td>
</tr>
<tr>
<td>CTRR</td>
<td>Clinical Translational Research Site</td>
</tr>
<tr>
<td>AMI</td>
<td>Institute for Women's Health</td>
</tr>
<tr>
<td>WCCS</td>
<td>Miami Center for Child Development</td>
</tr>
<tr>
<td>Miami Project</td>
<td>Miami Project to Cure Parkinson</td>
</tr>
<tr>
<td>RMSAS</td>
<td>Rosenstiel School of Marine and Atmospheric fcience</td>
</tr>
<tr>
<td>SCCD</td>
<td>Sylvester Comprehensive Cancer Center</td>
</tr>
<tr>
<td>SCCD Coral Springs</td>
<td>Sylvester CCG at Coral Springs</td>
</tr>
<tr>
<td>SCCD Deerfield</td>
<td>Sylvester CCG at Deerfield Beach</td>
</tr>
<tr>
<td>SCCD Hollywood</td>
<td>Sylvester CCG at Hollywood</td>
</tr>
<tr>
<td>SCCD Kendal</td>
<td>Sylvester CCG at Kendal</td>
</tr>
<tr>
<td>SCCD Plantation</td>
<td>Sylvester CCG at Plantation</td>
</tr>
<tr>
<td>LMC</td>
<td>The Lenox Planation Medical Center</td>
</tr>
<tr>
<td>TTRI</td>
<td>Tuch Research Institute</td>
</tr>
<tr>
<td>UPLC</td>
<td>Lila Pope Life Center</td>
</tr>
<tr>
<td>UMMI</td>
<td>University of Miami - Kendal Clinic</td>
</tr>
<tr>
<td>CBBG</td>
<td>Clinical Research Building</td>
</tr>
<tr>
<td>DMBG</td>
<td>Discharge UM</td>
</tr>
<tr>
<td>PAC</td>
<td>Professional Arts Center</td>
</tr>
<tr>
<td>RMHMB</td>
<td>Rosenstiel Medical Science Building</td>
</tr>
<tr>
<td>Other UM Site</td>
<td>Other University of Miami Site</td>
</tr>
</tbody>
</table>

6. If Other UM Site was selected in question 4, please specify:
9. Additional Study Information cont’d

5. * Does this research involve facilities and/or support from the Clinical Translational Research Site (CTRS)?
   - Yes [ ] No [ ]
   
5.1. Yes. The CTRS Service Request Form must be submitted to the CTSI Site Documents section.

6. * Will any study-related activities be performed or possibly performed at a Jackson Health Systems (JHS) site?
   - Yes [ ] No [ ]
   
6.1. Yes. This includes recruitment of subjects, facilities use, retrospective analysis of chart records, subject interventions, such as tests, treatments, drug administration, or surgery, involving subjects, and tissue specimen collection.

7. * Will any study-related activities be performed or possibly performed at a UHealth Tower (UHT) site?
   - Yes [ ] No [ ]
   
7.1. Yes. This includes recruitment of subjects, facilities use, retrospective analysis of chart records, subject interventions, such as tests, treatments, drug administration, or surgery, involving subjects, and tissue specimen collection.

8. * Is this study cancer related (whether it includes a drug, biological, device, interventions, epidemiologic, behavioral other observations, ancillary, preventive, surveillance or formative studies)?
   - Yes [ ] No [ ]
   
8.1. Yes. Review and approval from the Cancer Research Review Committee (CRR) is required for all studies involving cancer patients, diagnosis, or therapy.

9. * Who initiated this study?
   - [ ] Appropriate group indicated

10. Please provide a brief (maximum 2 sentences) lay description of your study.
    Potential participants searching Clinical Research website will be provided this description and a link to the full details of your study.

11. * Does the study prospectively assign research subjects to one or more interventions?
    - Yes [ ] No [ ]

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.
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.
11. **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.

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12. **Pre-Submission**

MOD00031899: Modification / Update #4 for Script ID: IRB-078.1.0 - External IRB – Modifications & Updates (Scenario 1) (UAT)

**Last updated:** 10/29/2019 1:12 PM

**Principal investigator:** UMTest P Innoc of the investigation (p)

**Submission type:** Modification / Update

**Primary contact:** UMTest P Innoc of the investigation (p)

**Institution:** Western IRB (WIRB)

**IRB office:** HSRO

**IRB coordinator:**

**Regulatory authority:** 2018 Requirements

**Site:** 20190903

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**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.