
Velos eResearch Rules of Use

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Effective Date: September 17, 2008

Revision History (list dates of amendments):

Responsible University Officer: Vice Provost for Research

Responsible Office: Office of the Vice Provost for Research,
Office of Research Information Management

Policy Statement

Velos eResearch is the University of Miami's enterprise clinical research management system. This system tracks patients, studies, calendars, events, data collection, milestones, & provides a interface for standard and ad hoc reporting. Using this web-based tool, permits the University and key stakeholders controlled access to study-related information to track study progress, safety, and financials. To operate this tool in a consistent way across the institution, this document describes a list of rules for using the system. These rules are mandated and enforceable for any study using the Velos eResearch system.

Rules of Use

1. No social security numbers are to be stored in Velos.
2. Patients are registered to the site at which they are enrolled/consented. No patients will be enrolled to the University of Miami organization. They will only be registered at a UM child organization such as UMMG, UMHC, Jackson, or ABLEH among others.
3. Velos defers to IDX as the data authority for enrolled patient demographics. If a patient is in IDX, that MRN (Medical Record Number) must be in Velos. If the patient's information needs to be updated, do it in IDX first.
4. Duplicate patients are not permitted. Velos allows a patient to be connected to multiple studies and for that patient to have multiple facility IDs (MRNs).
5. An MRN can not be used as a Patient Study ID. This voids our ability to use Patient Study ID as a more secure replacement for protected health information.
6. Study title follows this naming configuration: EPROSTNUMBER – Funding Sponsor – PI

7. If your study is being managed in Velos and the study involves any chance of providing a clinical service that could generate a bill, complete names and demographics for those patients must be in Velos along with consent, enrollment, and treatment-related dates. If patients are not entered into Velos in a timely fashion per UM CRRC policy, the issue may be reported to ORCA for audit consideration.
8. If you are recruiting at Jackson or other affiliate facility, complete patient names and facility IDs (MRNs) must be in Velos.
9. If you are tracking Severe or other Adverse Events (S/AEs) in Velos, you must still follow all reporting requirements to the IRB through eProst.
10. eProst is the data authority for protocol information. Velos will defer to eProst for the most up to date information regarding the protocol's contents, study team members, and protocol submission status.
11. Default system logout time is set to 60 minutes to allow for lengthy form completion. This will be reset to the 30 minute guideline once form functionality allows a reset.
12. Access rights to protected patient information on a study will mimic the roles that are described in the associated eProst protocol.
13. End-users must satisfy the Velos eResearch training requirement appropriate for their role & complete an authorization process prior to receiving their production log-in credential. This process requires potential users to acknowledge their responsibility in complying with applicable University policies.
14. No study-related consent forms or other study-related, scanned documents are to be uploaded and stored with a patient in Velos. Access to this specific information section in the product is not restricted to just study team members and could divulge PHI to those who do not need the information.
15. User accounts that have gone 120 days without being used will be deactivated. Users will be required to request reactivation via the Velos support team.
16. It is the responsibility of an investigator to satisfy copyright, permission of use, or other requirements for any applicable study form/data collection tool that is resident in or is being created for UM's Velos eResearch library. An existing, copyrighted form available in the eResearch library still requires the investigator to seek the appropriate permission to use it to support his or her research. The UM Velos eResearch system support team will not seek these permissions on behalf of an investigator. Any forms provided for development within the Velos eResearch system are assumed by the development team to have the proper permissions per the investigator's responsibilities.
17. If ORIM (Office of Research Information Management) is customizing applications within Velos for a department there will be extra charges for that department depending on the complexity of the customization and the amount of hours needed to complete the work. The charge will be \$150/hr, and a quote will be provided to the requester before work is started.

18. If department requires an interface with Velos, then it is are required to fill out an “Interface Request Form” and for reviewed by the Velos Team. Interfaces expire at the end of the UM fiscal year. They must be renewed prior to expiration, unless the interface was initiated within 6 months of the expiration date. Renewals can be submitted using the same Interface Request Form. Depending up the interface request, approval may also be contingent upon review by the University of Miami Privacy and Security office among others.
19. If a Study Team member is removed of a study, it is the responsibility of the study manager to remove and manage them. If the study manager elects to have the Velos team remove or edit rights of a Study Team member, the study manager needs to send a request via email to the Velos team with the details.
20. Patient Lookup Tool Rules –
 - Your searches will be tracked and available for reporting by those authorities that oversee enforcement of UM privacy policy. If you are conducting searches that are not applicable to your study, you may be subject to a privacy audit and associated consequences
 - When importing a patient from the clinical system, always set the patient’s organization equal to your enrolling site. This will ensure that you can view the patient once enrolled.
21. Naming Conventions Generic names for calendars and budgets should be used. Do not use study id’s etc for general templates. Libraries must be carefully monitored to assure that duplicate or similar templates are not being created. The libraries will have a strict access control to users who are trained in developing templates for re-use. Re-Use as much as possible!
 - **Study Number Naming Convention** - [eProstNumber FundingSponsor PILastName](#)
 - **Calendar Naming Convention** – [Study Number or Dept_ CalName VisitCount](#)
 - **Generic Follow-up calendar** - [FollowUp Interval VisitCount](#)
 - **Event Naming Convention** – First you will need to search through the Chargemasters loaded into Velos. For those events that are not listed in the library, and are study related; save the events in [Study Visits](#) category or [Study Visit Forms](#). Details for the Event naming convention will go as follows: [Event Name or Form Name](#)
 - **Forms Naming Convention** - will be the department the form belongs to. Neurology type forms, Oncology type forms etc. All forms should be associated with a “Type” to ease searching and classification of forms. Additional types for General Patient, General Account and General Study are also available for forms that are general across divisions. Form name can be any name however it should be indicative of the form function/objective. The official form name should be used if available. All forms should have a short description that indicates the purpose/objective of the form. Details the Form naming convention will go as follows: [Form Type - Neurology](#)

- **Field Naming Convention** - Any descriptive name indicative of field data capture objective. Field Id is currently migrated fields from Velos (i.e. Defaults) and they carry naming convention of NCI_shortFieldNameSeparatedByUnderscores. This must be unique within the system. Keep in mind that this may be reported on by statisticians who may just be receiving a data dump. New fields created for initial launch of SEPA study do not follow this naming convention. We should follow shortFieldNameSeparatedByUnderscores. All fields should have a full description of the type of data the field will be collecting along with being assigned to a category.

Type	Convention	Example
Migrated Data	mig_description	mig_patientDemographics
Calendar	Department_CalName_VisitCount	Neurology_Treatment_5
Calendar on study		
Follow Up Calendar	Follow Up_Interval_VisitCount	FollowUp_monthly_12
Event	ChargeDesc-ChargeCode-AbrevDept-FullCharge	Biofeedback by EMG-3060005-PSY-126
Form Types	Department. This can further be divided by Department – sub form type.	Nursing, Nursing-Survey
Form Name	Official form name	Concomitant Medications
Field Name	The actual question to be asked on the form	Data Entry Date
Field ID	The question in abbreviated form separated by underscores.	Data_Entry_Date
Study ID	eProstNumber_FundingSponsor_PILastName	2007001_112233
Reports	Rpt_description	Rpt_patientDate

Glossary

- **IDX** - Clinical registration and billing system for UMHC/SCCC, UMMG, & ABLEH.
- **eProst** – UM’s protocol human subjects protocol submission, review, & version tracking system.
- **PHI** – Protected Health Information – Patient information that is designated as protected by the University’s implementation of the Health Information Portability & Accountability Act.
- **PLT** – Patient Lookup Tool
- **IRB** – Institutional Review Board – Administered by the Human Subjects Research Organization and responsible for reviewing protocols to optimize patient safety.
- **MRN** – Medical Record Number – which is the patient’s clinical file that contains all the clinical data related to that patient. Along with billing information.
- **UMHC** – University of Miami Hospital Clinics
- **UMMG** – University of Miami Medical Group
- **JMH** – Jackson Memorial Hospital
- **ICF** – Informed Consent – this is the form