
Velos eResearch: IRB Protocol Submissions

Quick Reference Sections

- Text for Protocol Submissions
- Glossary

Effective Date: September 8, 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

Text for: Velos eResearch Usage Description for Protocol Submissions

This study will be managed using the University of Miami's enterprise Velos eResearch system. At a minimum, patients associated with this study will have their ongoing study-related status tracked using this system. Patient schedules and visit activities may be tracked using an electronic version of the study calendar. Study team access to patient details (PHI) will be restricted to those as applicable per the approved IRB protocol. As needed, Velos eResearch will have electronic CRFs that will be used to collect data. Lab results may be received electronically from other UM systems when available or permitted.

More on Velos eResearch

Velos eResearch is a web-based application, backed-up and supported on site at UM. It supports UM's enterprise clinical research billing practices for study patient enrollment and tracking. It was acquired by the University of Miami in late 2007 as an enterprise solution for tracking clinical research studies and support of their compliant billing activities. Velos eResearch acts as a central database for facilitating processes for study and patient management, including scheduling/calendaring, data collection via electronic CRF, data & safety monitoring, study reporting, and milestone tracking.

To support and simplify compliance with the UM patient enrollment and tracking process, Velos eResearch strictly controls access to protected health information (PHI). This allows patient identifiable information to be stored safely in an electronic format. Access to the system is limited only to authorized users. Each user has his or her own individual username and password managed by the University CaneID single sign-on system. Only authorized members of a study team have the ability to identify a patient associated with their study. Key personnel and their roles on IRB approved protocols are used by the UM Velos support team when establishing access rights. The Velos access model has been reviewed by the UM Privacy Office for compliance with University directives for managing PHI. Every end-user click, change, or view within the application is tracked and available for audit. Changes to study or patient information require an end-user e-signature for validation as an extra precaution. UM research billing Clinical Research Revenue Cycle Office

and the UM Velos support team have access to patient information as part of their support of the research process and infrastructure. ORCA has patient record access as needed on an audit-driven basis.

Glossary

- **IP** – Internet Protocol
- **PHI** – Protected health information
- **ORIM** – the Office of Research Information Management
- **eProst** – UM’s protocol human subjects protocol submission, review, & version tracking system.
- **Department/Division** – The hierarchal breakdown of Department within the school of medicine, and under the department there are specific Divisions.
- **CRF** – Case Report forms