Velos eResearch Governing Policies

Revision History

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Revision Date</th>
<th>Author</th>
<th>Description</th>
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<tbody>
<tr>
<td>4 Dec 2012</td>
<td>12 Nov 2012</td>
<td>HMAnfrediz</td>
<td>Added policy #20.</td>
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<td>Removed &quot;COMMENT&quot; statement on policy #11, as it was intended as an internal use notation. Not for our end-users. Also, added policies #17, #18, #19.</td>
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<tr>
<td>10 Nov 2011</td>
<td>10 Nov 2011</td>
<td>EPonce</td>
<td>Removed &quot;COMMENT&quot; statement on policy #13, as it was intended as an internal use notation. Not for our end-users.</td>
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<tr>
<td>19 Sep 2011</td>
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<td>E Ponce</td>
<td>Significant modifications to terms of use. Updated language. Removed reference to IDX, replaced with UChart.</td>
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<td>2008</td>
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Signatures / Approvals

Prepared by (Signature): [Signature]
Name: HMAnfrediz
Title: Project Manager
Date: 11/4/2013

Approved by (Signature): [Signature]
Name: SDeGennaro
Title: Director
Date: 4/26/2013

Approved by (Signature): [Signature]
Name: Ravi DSingh
Title: Executive Director, UMIT, & C
Date: 06/May/2013
Purpose

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 or user using the Velos eResearch system.

Definitions

- **eProst** – UM’s protocol human subjects protocol submission, review, & version tracking system.
- **IRB** – Institutional Review Board – Administered by the Human Subjects Research Organization and responsible for reviewing protocols to optimize patient safety.
- **ORIM** – Office of Research Information Management oversees the implementation and support of Velos eResearch.
- **PHI** – Protected Health Information – Patient information that is designated as protected by the University’s implementation of the Health Information Portability & Accountability Act.
- **UChart** - Clinical registration and billing system for UMHC/SCCC, UMMG, & ABLEH.
- **Velos eResearch** – University’s clinical trials management system used for tracking research subjects, their schedules, and related data collections for human subjects studies.
- **Medical Record Number (MRN)** – A number used to link patients with their medical history information across time within the health care provider’s jurisdiction.

Responsibility

Administrators supporting the Velos eResearch system and authorized end-users.

Procedure

N/A

Policy

1. No social security numbers are to be stored in Velos eResearch.

2. Patients are registered to the site at which they are enrolled/consented. No patients will be enrolled to the “University of Miami” or “Non-University of Miami” root organizations. The former is reserved for regulatory responsibility only. Patients will only be registered at a “University of Miami or “Non University of Miami” child organization such as UMMG, UMHC, Jackson, or ABLEH among others.
3. Velos eResearch defers to UChart system as the data authority for patient demographics when the enrolling site is a child organization to the University of Miami. This is done to minimize double data entry as well as facilitate institutional interfaces that support research billing compliance processes. The UChart system and Velos eResearch patient demographics are aligned via a common MRN (medical record number). If a patient’s demographic information needs to be updated, it is to be updated in UChart. Such changes will be reflected in Velos via its UChart interface.

4. Duplicate patients to a University of Miami related organization are to be minimized as much as possible. Duplicated patients create end-user confusion regarding which patient to attach to a study, hinders the billing compliance process, and could expose participants to avoidable safety risks. Velos eResearch allows a single instance of a patient to be connected to multiple studies and for that patient to have multiple facility IDs (MRNs) and Study IDs.

5. Study numbers follow this naming configuration: eProst Number – Funding Sponsor – PI Last name. This enables improved reporting throughout the system.

6. If Jackson is an enrolling site on your study, study teams must enter accurate patient names and an accurate Jackson facility ID (MRN) for those subjects into Velos eResearch.

7. 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.

8. eProst is the data authority for protocol information. In general Velos will defer to eProst for the most up to date information regarding the protocol’s content, study team members, and protocol submission or approval state.

9. Default Velos eResearch logout time is set to 60 minutes. This means that the user can remain inactive for 60 minutes before the system logs him or her out.

10. System Access rights to PHI in Velos eResearch will mimic the roles that are described in the associated eProst protocol as closely as possible or as authorized via an Access Request Form.

11. End-users must satisfy the Velos eResearch training requirement appropriate for their role & complete an Account Request Form (ARF) prior to receiving their production log-in credential. This process requires potential users to acknowledge their responsibility in complying with applicable University policies and system terms of use.

12. No signed study-related consent forms, or study related scanned documents are to be uploaded and stored anywhere in Velos eResearch. This is to limit PHI access to only those users that have a need to know it.

13. User accounts that have gone 90 days without being used will be eligible for deactivation. Deactivated users will be required to request reactivation using the Access Request Form. If they have been
reactivated for more than 90 days, they will be required to re-fulfill the respective training requirements for their role.

14. 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 Velos eResearch library still requires the investigator to seek the appropriate permission to use it to support his or her research if not available under Copyright Act Section 107: Limitations on exclusive rights: Fair use (http://www.library.miami.edu/about/copyright/fairuse.html). 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.

15. The Office of Research Information Management (ORIM) reserves the right to charge study teams for creating, changing, customizing and supporting case report forms, creating or modifying calendars, creating or modifying milestones, migrating data into Velos, generating custom data exports (reports), and other special services within the University’s policy B020 for Recharge or Cost Centers.

16. PI and Study Team are responsible for the accuracy and timeliness of the data collected, entered, disseminated, as well as all calculations/algorithms provided for inclusion on CRF’s and/or data extraction for reporting.

17. All Velos users must use a University of Miami or affiliate institution email address for system communications. No personal emails are to be used for this purpose.

18. As per HR/Faculty Affairs and University leadership, all Medical campus staff and faculty are required to take the baseline "HIPAA Privacy & Security Awareness" training. This is a minimum HIPAA training requirement for Velos access, and equivalent training (such as the training provided by Citiprogram.org) will be confirmed for non-medical campus users.

19. Blinded studies must be managed by the research study team in accordance to the specifications outlined in their respective study protocol, as well as Good Clinical Practice guidelines. In Velos, blinded studies must not identify the treatment arm of each patient, and patient study IDs must not be assigned in any way that will identify each patient’s treatment arm.

20. Electronic signatures used in Velos are intended to be the legally binding equivalent of traditional handwritten signatures captured in the Velos Access Request Form or equivalent training form.

Documentation & References

N/A

Templates/Forms

Velos eResearch Access Request Form (ARF)
# | Name            | Desired e-signature (4 digits) | Date | Signature | E-mail Address | Campus: Coral Gables - CG Medical - M RSMAS - R | HIPAA Trained? (y/n) if yes, where? | Faculty | Staff | Other |
---|-----------------|-------------------------------|------|-----------|----------------|-----------------------------------------------|----------------------------------|---------|-------|-------|
1  | Jun Antigas    |                               | 5/31/13 |           |                |                                               |                                  |         |       |       |
2  | Daniel Auguste |                               | 5-31-13 | Daniel       |                |                                               |                                  |         |       |       |
3  | Madhu Damarthi |                               | 5/31/13 |            |                |                                               |                                  |         |       |       |
4  | Ravi Engle     |                               | 5/31/203 |           |                |                                               |                                  |         |       |       |
5  | Huntington Lam |                               | 5/31/13 |           |                |                                               |                                  |         |       |       |
6  | Stephen Delgrosso |                           | 5/31/13 |           |                |                                               | M Y                             |         |       |       |
7  | Raquel Zamaro Alfonso |                         | 5/31/13 |           |                |                                               | M Y                             |         |       |       |
8  |                |                               |        |            |                |                                               |                                  |         |       |       |

Trained by/date: _______________________________

ORIM-100-03