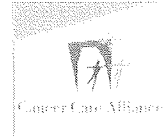


University of New Mexico Comprehensive Cancer Center/New Mexico Cancer Care Alliance



STANDARD OPERATING PROCEDURE

Clinical Research Office



Title: VELOS ACCOUNTS AND PASSWORDS

SOP No.: 5.2

Version No.: 3

Effective Date: 2/15/06

Owner: Velos Data Manager

Name: Jean DeMarte

Jean DeMarte
Signature

3/19/2018
Date

Authorized / Approved by:

Name: Olivier Rixe, MD, PhD

Title: NMCCA Medical Director

[Signature]
Signature

3/28/2018
Date

INTRODUCTION AND PURPOSE

This standard operating procedure (SOP) describes the processes followed at UNMCCC to attain access to view, edit, and change records as well as generate reports in the Clinical Trials Management Software (CTMS), Velos.

SCOPE

This SOP applies to access to clinical research data in Velos for all clinical studies subject to investigational new drug (IND) regulations for drugs and biologics or investigational device evaluation (IDE) regulations for devices during all investigational phases of development.

APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.50	General responsibilities of sponsors
21 CFR 312.56	Review of ongoing investigations
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
21 CFR 312.64	Investigator reports
21 CFR 312.68	Inspection of investigator's records and reports
21 CFR 312.70	Disqualification of a clinical investigator
FDA Information Sheets, October 1995	Recordkeeping in Clinical Investigations
January 1988	Guidelines for the Monitoring of Clinical Investigations
May 1997	International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline

REFERENCES TO OTHER APPLICABLE SOPs

N/A

RESPONSIBILITY

This SOP applies to those members of the clinical research team who need access to records housed in the Velos software system.

This includes the following:

- UNMCCC CRO Director / NMCCA Executive Director
- NMCCA Clinical Research Supervisor (NMCCA CRS)
- NMCCA Clinical Research Manager (NMCCA CRM)
- Clinical Research Operations Manager (CROM)
- UNMCCC Data Manager (DM)
- UNM HSLIC System Administrator

And any third party audit service or employee who needs access to clinical research data in Velos

PROCEDURES

Request for Password to access Velos CTMS

Owner	Criteria / Steps
NMCCA CRS, CROM, and/or NMCCA CRM	Request for new user is emailed to Velos Data Manager (DM).
UNMCCC CRO Director / NMCCA Executive Director	<p>Verifies/approves new user request.</p> <p>All new users must have completed UNMH/HSC HIPAA training prior to request.</p> <p>Any vendor or subcontractor who requests access will need a signed business agreement with UNMH/HSC.</p>
DM	<p>If user is an affiliate member and outside the UNM system, they must complete the UNM affiliate-demographic-form.</p> <p>The DM completes the UNM-affiliate-data-entry-request form to acquire a Banner ID from UNM Human Resources.</p> <p>Once the Banner ID is received, a HSC net ID is requested from HSLIC by opening a HELP Ticket at the HSC Help desk. https://help.health.unm.edu/CherwellPortal/home#9</p> <p>Affiliate member and non-UNM accounts are subject to an annual review. Forms are resubmitted on an annual basis for continued access.</p>
UNM HSLIC System Administrator	Affiliate member with HSC net ID is added to the CAG (CITRIX Access Gateway) in order to gain access to Velos eResearch application.
DM	<p>User account is created in Velos that requires three security levels.</p> <p>These are:</p> <ol style="list-style-type: none"> 1. Velos eResearch user login and password; 2. User is assigned to a specific group (role) that provides restricted database view or rights; 3. User is assigned to protocols/studies study team that allows for modifications to a specific study. <p>All initial Passwords and Digital e-signatures are automatically created by the Velos application and sent via encrypted e-mail. Users are prompted to change their Passwords and Digital e-signatures upon logging in.</p> <p>Velos Research is configured to require new Passwords and Digital e-signatures every 90 days.</p> <p>Passwords are to use the following formula: one capital letter, at least one number, and at least one special character (e.g. @, #, \$, %, &, etc.)</p>
DM	Upon terminating employment with UNMCCC and/or NMCCA affiliates, the user's account is deactivated in Velos. However, the user will remain on the study team list in Velos as a deactivated team member in order to preserve study history.

	<p>If the user is an affiliate member and outside the UNM system, a Help Ticket is created asking HSLIC to deactivate the HSCID.</p>
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