

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



**STANDARD OPERATING PROCEDURE**

**Clinical Research Office**



**Title: VELOS DISASTER RECOVERY PLAN**

**SOP No.: 5.1**

**Version No.: 3**

**Effective Date: 9/15/17**

**Owner: Velos Database 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

3/20/2018  
Date

## **INTRODUCTION AND PURPOSE**

This standard operating procedure (SOP) describes the processes followed at the University of New Mexico Comprehensive Cancer Center (UNMCCC) in the event of a system failure or shut down of Velos. The Velos Clinical Trials Management Software (CTMS) runs on a server administered by the UNMCCC Information Technology Department and uses an Oracle database interface. A server runs applications and stores/distributes data to computers that connect to it. When users connect to a server, they can access programs, files, and other information from it. If the Velos server fails or becomes inaccessible, steps must be taken by Velos administrators (mainly the Database Administrator) and IT staff to pursue resolution. Clinical research office staff also have to take steps to keep clinical research activities operational until Velos can be restored.

## **SCOPE**

This SOP applies to procedures which are executed by various members of the UNMCCC IT team and research staff at UNMCCC and NMCCA sites if and when Velos fails or is inaccessible for a length of time that affects clinical study operations.

## **APPLICABLE REGULATIONS AND GUIDELINES**

None.

## **REFERENCES TO OTHER APPLICABLE SOPs**

N/A

## **RESPONSIBILITY**

- UNMCCC Data Manager (DM)
- Velos Database Administrator (DBA)
- UNMCCC Server Administrator
- UNMCCC System Analyst
- UNMCCC Clinical Operations Manager (CROM)
- UNMCCC IT Manager
- CRO Administrative Office
- NMCCA Clinical Research Supervisor (NMCCA CRS)
- NMCCA Clinical Research Manager (NMCCA CRM)
- Regulatory Coordinators (Reg Coord)
- Data Coordinator (DC)

## **PROCEDURES**

Appendix A provides the list of information technology contacts for technical issues with the system. The Appendix will be updated as required.

**In the event of a complete system failure, the following plan will be initiated:**

UNMCCC Server Administrator and/or UNMCCC System Analyst	Contacts the Velos DBA, DM, CROM and UNMCCC IT Manager with information regarding the system failure.
DBA	or  Contacts the UNMCCC System Analyst/Administrator, CROM and UNMCCC IT Manager to inform them that Velos has failed. Opens a HEAT Ticket in the Cancer Center HELP system at <a href="https://help.health.unm.edu/CherwellPortal/CancerCenter#0">https://help.health.unm.edu/CherwellPortal/CancerCenter#0</a>  Forwards the ticket via email to the UNMCCC IT team.
DBA	Alerts all Velos users via email of the system failure and provides information including the anticipated time to restore the Velos system.
DBA	Assess the situation in terms of the data and productivity loss.
DBA	Updates UNMCCC CRO Administrative Office every two hours. The contact number is 505-272-5490.
CRO Administrative Office	Will communicate information to the NMCCA CRS, NMCCA CRM, and UNMCCC CROM with updates every two hours
NMCCA CRS	Will email all non-UNM affiliate user sites of the situation and will communicate with all UNM and non-UNM users every two hours.
Reg Coord	Upon request, will make current consents and protocols available to all Research Coordinators by email or fax to ensure protocol compliance. They will also document on paper any study updates that are finalized during the down time to ensure all is entered once the system is back on line.
DC	Will document on paper all subjects' material that will need to be entered into Velos once the system is back on line.
DBA	If the system failure extends for more than 7 hours, the DBA will request a view to the Velos backup file. This will enable UNMCCC CRO personnel to see the data but it will not allow new data entry.
DBA	Establishes a view of the most current Velos data backup.
UNMCCC Server Administrator and/or UNMCCC System Analyst	Contacts the Velos DBA when the system recovery is completed and Velos is online.
DBA, DM	Tests the Velos database and assesses what, if any, data has been lost.
DBA	Informs all Velos users via email that Velos is online and what data, if any, has been lost.

## Appendix A: Velos and Information Technology Resources

### September 2017

Robert Gagnon and Siri Khalsa are the UNMCC IT systems analysts and system administrators for servers entitled HSC-Velos3HSC- VelosDB2, HSC-Velos2, HSC-VelosTestApp, HSC-VelosTestDB, HSC-VelosApp, and HSC-VelosDB#.

- Robert Gagnon: 505-272-1411, [rgagnon@salud.unm.edu](mailto:rgagnon@salud.unm.edu)
- Siri Khalsa: 505-272-6201 [skhalsa10@salud.unm.edu](mailto:skhalsa10@salud.unm.edu)

Velos database administrator (currently unfilled position) is responsible for backing up the Velos data.

Eddy Archibeque is the UNMCCC IT manager. 505-925-0444; [earchibeque@salud.unm.edu](mailto:earchibeque@salud.unm.edu)

Jean DeMarte is the UNMCCC Velos Data Manager. 505-925-0384; [jmaurice@salud.unm.edu](mailto:jmaurice@salud.unm.edu)