

Velos eResearch: Patient Quick Reference

Quick Reference Sections

- Patient Quick Reference
- Tips for Saving Time & Avoiding Headaches
- Adding Patient into Velos (Patient Lookup Tool)
- Adding Patient into Velos (Add Patient)
- Adding Patient into Velos (Select Patient)
- Adding Patient into Velos (Manually)
- Adding the Study ID for a patient (Manually)
- Glossary

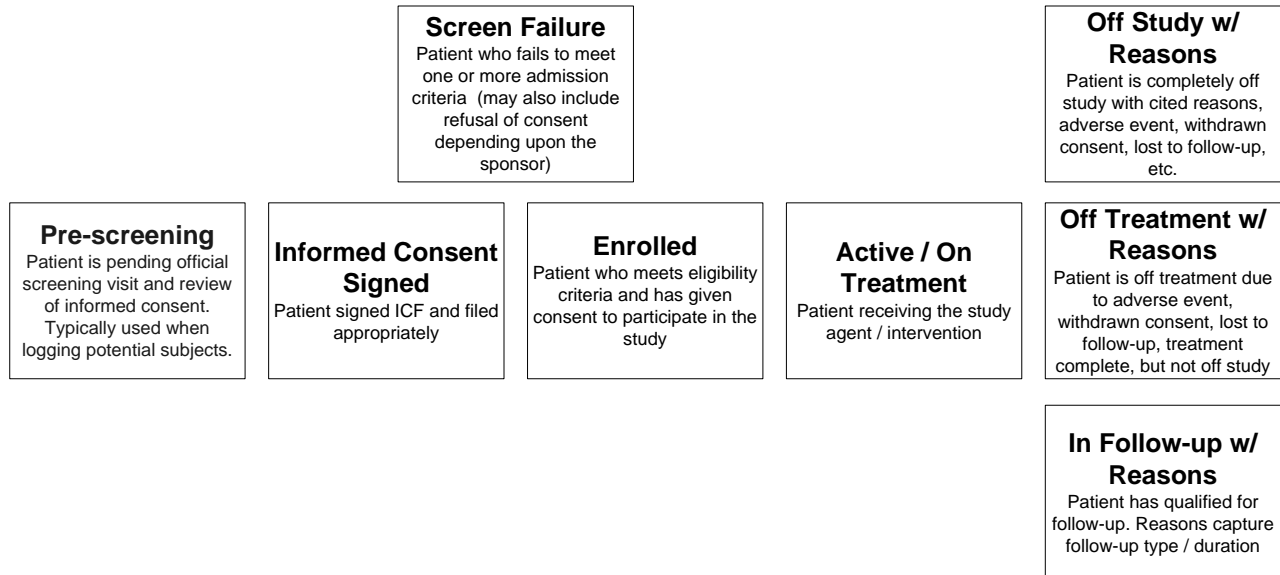
Effective Date: September 11, 2008

Responsible University Officer: Vice Provost for Research



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

Patient Quick Reference

Patient Status Definitions



Tips for Saving Time & Avoiding Headaches

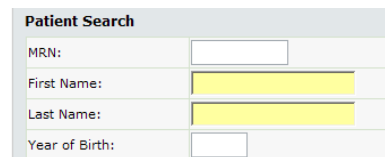
- Log patient statuses immediately whenever there is a change 
- Use the notes field when adding a status to help remind you of important things regarding a status change. These notes show up on the Screening information screen and are easy to track.
- Be very careful when changing statuses. A status change can trigger a milestone and an invoice. If you change a status by accident, inform your financial administrator of any issues.
- Do not store any social security numbers or documents (signed consent forms, etc) in Velos 

Status	What to enter	Why it is important
Pre-screening	Date, Screening Outcome, Person who screened the subject	Tracks total number of subjects whose eligibility was considered for the study. This is typically for an initial conversation and preliminary eligibility review. This is not used after a consent has been signed or any procedures have been done.
Informed Consent Signed	Date, ICF version number (be consistent in how you log versions). Also enter the Patient MRN in the Facility ID of the enrollee's organization.	Tracking consents signed makes it easier to re-consent later if needed. The ICF version signed is summarized in the Patient Dump report, making it easy to identify which patients are on what consent. The MRN/Facility ID entered will automatically be sent to the research billing team and is part of UM's subject enrollment and tracking policy
Screen Failure	Date, Reasons from pick-list, Notes	Many sponsors will reimburse for screen failures. It is important to only use this when a consent wasn't signed or the patient's lab results disqualified them for the study. This status does not follow a Pre-screening status.
Enrolled	Date, Notes, (Edit status when needed to include Randomization Number)	Typically, this is only used when a patient is consented AND has met all eligibility requirements. Many milestones are set to track enrolled statuses. Entering the randomization number helps to identify if the pharmacy dispensed the correct drug to the subject.
Active / On Treatment	Date, Notes	Helps track number of subjects currently receiving intervention
Off Treatment (w / Reasons)	Date, Reasons from pick-list, Notes	Helps track why a patient is not currently receiving intervention / therapy
Off Study (w/ Reasons)	Date, Reasons from pick-list, Notes	Helps track why a patient is not currently participating in the study after being enrolled
In Follow Up (w / Reasons)	Date, Reasons from pick-list, Notes	Helps track the nature of follow-up for a study subject


Adding Patient into Velos (Patient Lookup Tool)


Per University policy, the MRN is required to be entered into Velos for a patient immediately when you enter a status of Informed Consent Signed. Once you enter the MRN, Velos will receive nightly updates to the patient’s demographic information from our clinical system. If a patient’s information changes, the clinical system will have to be updated. This can be done by contacting crcc@med.miami.edu.

1. On the left-hand menu bar, click on **Manage Patients** tab and select “**New**”, to search
2. The “**PLT**” search screen will appear
3. Enter the information related to patient in the search fields













Patient Search	
MRN:	<input type="text"/>
First Name:	<input type="text"/>
Last Name:	<input type="text"/>
Year of Birth:	<input type="text"/>



 *Note: you may enter one or all of the details in the search fields, but we recommend to enter at least three fields to optimize your search results. This tool also accepts partial string searches.*

 *Note: 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.*


4. Click **Search** and the PLT will initiate the search for the patient. The PLT will look for patients in IDX. This includes MRNs from JMHC, UMHC, UMMG, ABLEH, and UMH.
5. Depending on the information entered into the search field it may return either none or many patients

UMMG:V699	Guerrero	Angelica	09/04/1980	
UMHC:7896541	Jaffer	Amir	05/19/1979	
School of Nursing:V719	L	A	06/01/1970	
UMHC:212	Loor	Angel	02/26/2008	
ABLEH:54840,JMH:14812,UMHC:784569,UMMG:207512	ROBIN	AMY	12/25/1979	
School of Nursing:0022	V	A	01/01/1980	
ABLEH:54818,JMH:14790,UMHC:784547,UMMG:207490	VINCENT	ANDREW	12/25/1979	
School of Nursing:0026	W	A	07/07/1970	
UMHC:8298-003	Waterfall	Aprilyn	05/06/1979	
School of Nursing:00008	v	a	02/04/1965	


Your search returned 27 records. 27 records displayed.

- a. If patients are returned from the search. Then icons will appear on the right hand side of their name. If there were no patients returned then either change your search or proceed to “**Adding Patient into Velos (Manually)**” section of this document.
 - i.  **“Add Patient”** – means that you will import the patient into the Velos from IDX and then connect the patient with your study.
 - ii.  **“Select Patient”** – means that the patient is already in the Velos System. Just click this icon to connect the patient with your study.
 - iii. **“Manually Add”** a Patient to Velos

Adding Patient into Velos (Add Patient)

- If the patient is already in Velos then click on the **Select Patient** icon,  and you will be prompted to a dropdown that will allow you to select your study to connect to the patient
- Once study is selected, a screen will come up where you will enter the following information: **“Patient Status”**, **“Status Date”**, & **“Patient Study ID”** select **submit** and your patient is officially enrolled into your Velos Study

Adding Patient into Velos (Select Patient)

- If the patient is not in Velos then click on the **Add Patient** icon,  and you will be prompted to the patient’s demographics. Verify that the information is correct, and also on the dropdown select your study to connect to the patient
- Once study is selected, a screen will come up where **you will** enter the following information: **“Patient Status”**, **“Status Date”**, & **“Patient Study ID”** select **submit** and your patient is officially enrolled into your Velos Study

My Homepage


Personalize Account

Manage Account

Manage Protocols

Library

Manage Patients

New Open  1

Budget

Milestones

Report Central

Ad-Hoc Queries

Help

Logout

Current User:
Eric Ponce

System Timezone:
Eastern Standard Time

Manage Patients >> Demographics

Patient Search 2

MRN:











First Name: 3

Last Name:

Year of Birth:

- Please enter at least the patients name and/or the MRN to search on. Year of birth is optional.
- MRN can be either the patients UMMG, UMHC, ABLEH, or JMH number.

4

UMMG:V699	Guerrero	Angelica	09/04/1980	
UMHC:7896541	Jaffer	Amir	05/19/1979	
School of Nursing:V719	L	A	06/01/1970	
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UMHC:8298-003	Waterfall	Aprilyn	05/06/1979	
School of Nursing:00008	v	a	02/04/1965	

5

Your search returned 27 records. 27 records displayed.

If the patient is in Velos already, this is the next step

My Homepage	Manage Patients >> Protocols					
Personalize Account	Demographics Patient Profile Protocols Reports Appendix					
Manage Account	Pat.ID: V880 Age: 8 years Gender: Male Pat.Name: Barney Rubble Org: UMMG					
Manage Protocols						
Library						
Manage Patients	To enter screening/enrollment details for this patient, select the study from the following pulldown:					
Budget	Select Study	Select an Option	6			<input type="button" value="Submit"/>
Milestones	This patient has been associated to the following study protocols					
Report Central						
Ad-Hoc Queries	Enrolled On	Last Visit	Done On	Next Visit	Patient Status	
Help	08/06/2008	-	-	-	Enrolled	AE Forms
Logout						

Patient Study Status

Patient ID: V697 **Study Number:** 20081234 - Castro - Tanner

Please enter Status details

Status * 7/9

Reason 7/9

Status Date * [Select Date](#)

This is patient's current status in this study

Notes

Additional Information

Patient Study ID * 7/9

Assigned To [Select User](#)

Physician [Select User](#)

Treatment Location

Treating Organization

Evaluable Status

Evaluable Flag

Evaluable Status


Inevaluable Status

Patient Status

Survival Status


Date of Death [Select Date](#)








Cause of Death



Adding Patient into Velos (Manually)

10. If no patients returned on the search, then close out the PLT tool, by clicking on the button on the right hand side.
11. Enter the **Mandatory Fields** (i.e. red asterisk) for the patient entry screen.
12. Enter the Patients Primary Organization, Patient Facility ID for the patient as well as the Study on the Drop Down
13. Enter your **e-Signature** and select **submit**

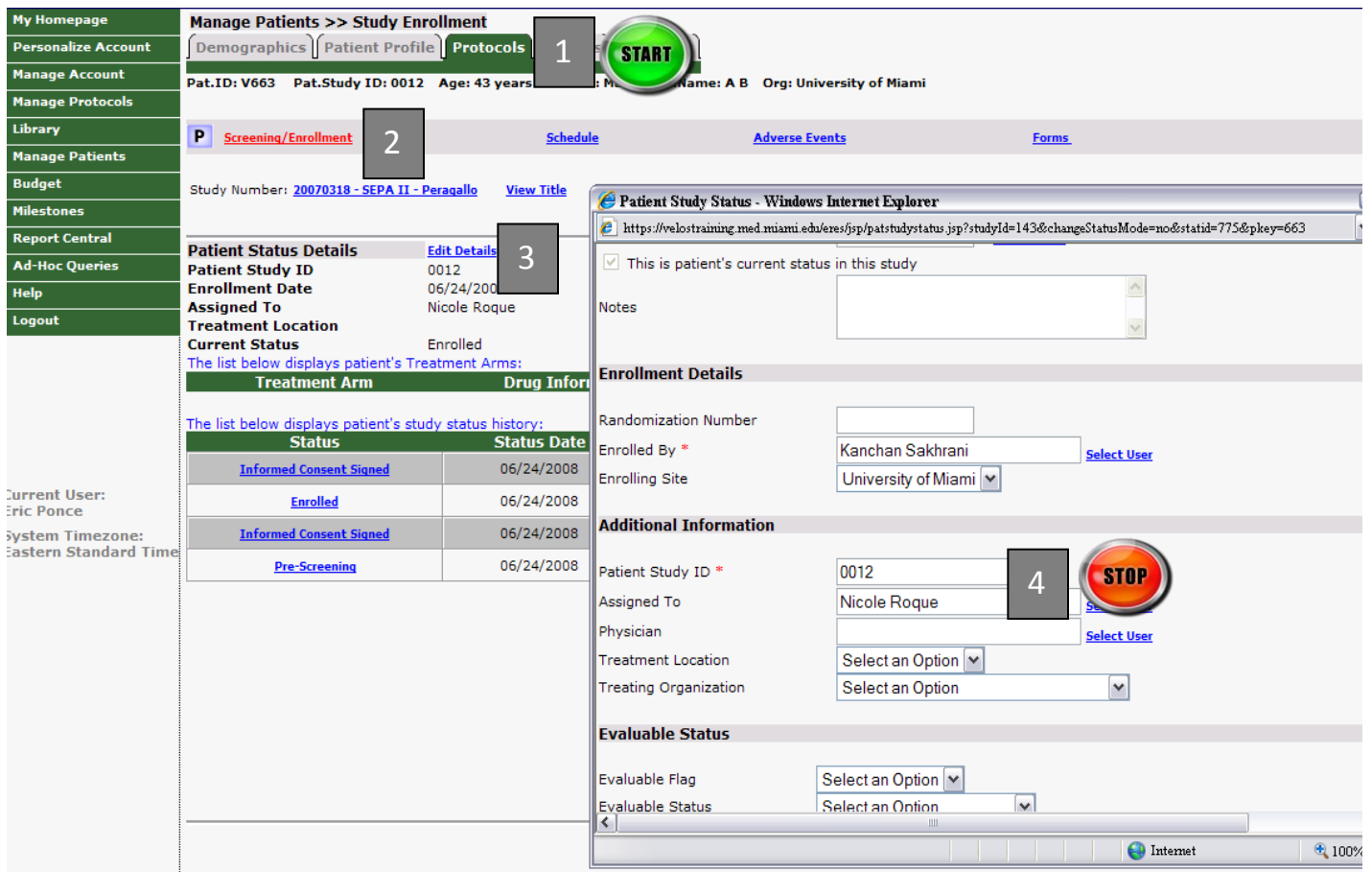
 *Note: It is extremely important to ensure that the patient's primary organization and study to be enrolled are selected, otherwise you will be unable to see the patient.*

My Homepage	Manage Patients >> Demographics																															
Personalize Account																																
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System Timezone: Eastern Standard Time																																
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Adding the Study ID for a Patient (Manually)

Per Protocol, the Study ID is required to be entered into Velos for a patient when you enter a status of Active/Enrolled. Once you enter the Study ID, you will be able to track your patients according to the protocol or sponsor instructions.

1. Find the patient, click on his/her **Protocols** tab
2. Select the Screening/Enrollment link
3. Adjacent to “**Patient Study Details**” select the link “**Edit Details**”
4. Under the Additional Information section, you may enter the **Patient Study ID** for that Study, enter your e-Signature, click Submit



The screenshot displays the Velos system interface. On the left is a sidebar with navigation options: My Homepage, Personalize Account, Manage Account, Manage Protocols, Library, Manage Patients, Budget, Milestones, Report Central, Ad-Hoc Queries, Help, and Logout. The main content area is titled "Manage Patients >> Study Enrollment" and includes tabs for Demographics, Patient Profile, and Protocols. A "START" button is visible. Below the tabs, patient information is shown: Pat.ID: V663, Pat.Study ID: 0012, Age: 43 years, Name: A B, Org: University of Miami. A "Screening/Enrollment" link is highlighted. The "Patient Status Details" section shows "Enrolled" status and includes an "Edit Details" link. The "Additional Information" section contains input fields for Patient Study ID (0012), Assigned To (Nicole Roque), and other details. A "STOP" button is located at the bottom right of the form. A "Treatment Arm" table is also visible, showing "Informed Consent Signed" and "Enrolled" statuses with dates of 06/24/2008.

Treatment Arm	Drug Inform
Informed Consent Signed	06/24/2008
Enrolled	06/24/2008
Informed Consent Signed	06/24/2008
Pre-Screening	06/24/2008

Glossary

- **PLT** – Patient Lookup Tool
- **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.
- **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