Agenda

- Purpose of the Research IT Forum
- Using Velos and Epic
- Charge hold update
- Placing research protocol orders
- Updated IRB consent and confidentiality of research results
- Entering external results into Epic
Purpose of the Research IT Forum

- The implementation of Epic and Velos changes how research staff, PI’s and coordinators manage their studies and subjects.
- These systems and other non-IT initiatives require a more centralized and standardized approach for research workflows.
- The departmental liaisons are responsible for communication between Research IT and other research governing bodies and their department’s research staff:
  - New workflows
  - Policy updates
  - Required training
- The departmental liaisons should bring feedback from their research staff to this forum to ensure that the systems and policies are meeting their requirements.
- This meeting, while initially focused on IT systems, will be broadened to include a variety of research governance issues.
New IT Systems

Velos

• Montefiore-Einstein Clinical Trials/Research Management System.
• Single source of information re: institutional research.
• Centralizes research activities (administrative, investigational, clinical, financial and compliance).
• Integrates with relevant systems, e.g. IRB, Epic.
• Ultimately, a “one stop shop” for clinical research management.
• Functionality to support
  – Billing compliance
  – Financial management
  – Regulatory requirements
  – Automated processes for IRB, Recruitment, Study calendar, Invoicing
  – Data analytics
New IT Systems

Epic

• Montefiore Electronic Medical Record System.
• Enables scheduling, ordering, result reporting and charge capture for research associated encounters.
• Supports segregation of charges into separate accounts for standard of care and for research.
• Data analytics
• Decision support to facilitate recruitment
• Documentation tools
Updates to charge hold

- At present, all charges are held for patients enrolled in research studies.
- Research coordinators are required to review charges on a regular basis, confirm that they were appropriately assigned to research vs standard of care, update as needed and release.
- The justification for this back end review is to ensure that health plans do not get charged for services that are research associated.
- Recognizing the burden this additional work entails, we have been discussing applying charge hold to those studies where it makes most sense, i.e. trials where research and standard of care charges are highly intermixed.
- For studies that are all Standard of Care charges, we can update Epic to exclude those studies from charge hold.
- For studies that are all Research charges, we are considering updating Epic to exclude those studies from charge hold.
Updates to charge hold

- For studies that generate only Research charges
  - Exploring the capability of Epic to route these charges to the research account without the charge hold and review component
  - If this is enabled, PI’s and coordinators need to be diligent and mark all research visits and orders accordingly, else the health plan could be charged.
  - The proposal will need to be approved by MMC leadership, including Compliance.
- For studies that generate only Standard of Care charges, Epic can be updated now to eliminate the charge hold component.
Research associated lab and imaging orders

- “Standard of care” orders are subject to scope of practice, billing compliance and meaningful use requirements that limit their entry to “providers”—physicians, physician assistants and nurse practitioners.
- Many research studies have a standard set of lab/imaging orders that are placed at pre-determined times throughout the study.
- Pre-Epic, these orders were entered on paper requisitions by non-provider research staff.
- Given that these are research associated orders, can non-providers be enabled to enter these orders “as per research protocol”?
- If there are no regulatory barriers, these could be enabled in Epic
  - For research charge only studies
  - Limited to lab and imaging orders
  - Limited to only tests pre-specified by the study protocol
  - Using Order sets that include only those orders specified by the protocol
- If approved, timing is subject to availability of IT resources
Updated IRB consent form

- In May 2016, the IRB communicated with the research community re: an update to the consent form to be signed by study participants.

Montefiore recently adopted a new electronic medical record system, called Epic, and its related systems. Going forward, your study-related information (visits, test results, etc.) will be entered into Epic. This will allow your physician and other members of your care team to see the study-related information in your record, which may be useful in planning your care.
Addressing Confidential Results

- Some studies could be biased by the inclusion of certain results in the EMR used by the general clinical staff
- Some studies may have explicit requirements for confidentiality
- The current solution is outside of Epic, i.e. continue to use paper lab requests (contact Maria Cassese for details)
- Discussion is underway with Pathology to determine how to enable Epic ordering without returning the results to Epic.
High level Velos workflow

- Studies are interfaced to Velos from the MMC-Einstein IRB and the BRANY IRB
- For all studies--PI/regulatory coordinator must update Velos with
  - Summary: Complete study summary information
  - Study team: Verify staff and access roles
  - Attachments: Upload non-IRB generated documents
  - Study status: Activate the study

- For studies that recruit patients
  - Assign patients to the study
  - Update patient status (informed consent signed/screening/screen failure/enrolled/active on treatment/follow-up/off-study).
  - For OCT studies, mark visit completion in Velos.
  - For BRANY studies, mark visit completion in SMART.
  - For other studies ???
High level Epic workflow

- Study records and patient association from Velos
- Visits in Epic should be marked as “Research” during scheduling.
- Orders placed in Epic should be marked as “Research Associated”
- Patients enrolled in research have “all” charges held in a work queue review to confirm that research and standard of care charges were appropriately marked.
- Research fee schedule
- Invoice generation and payment posting
IRB-Epic-Velos interfaces

- IRB→Velos: Approved studies
- Epic→Velos: Patient records
- Velos→Epic: Study records, study staff and patient status

<table>
<thead>
<tr>
<th>IRB</th>
<th>Velos</th>
<th>Epic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study approval</td>
<td>Study management</td>
<td>Patient encounters</td>
</tr>
<tr>
<td>Patient recruitment</td>
<td>Financial management</td>
<td>Services/procedures</td>
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<tr>
<td>Regulatory compliance</td>
<td></td>
<td>Charge capture and routing</td>
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<tr>
<td>Internal/External reporting</td>
<td></td>
<td>Oncology protocols</td>
</tr>
</tbody>
</table>
Scheduled PatientEncounters

- Scheduled appointment is associated to the research study (either at time of scheduling or subsequently).
- The appointment displays the “lab flask” icon 🧲

![Image of appointment scheduling interface](image-url)
Associating an Order with the Study

- Tests, procedures, medications or referrals
- Associate the order to “research”.

[Image of a software interface showing unsigned orders with options to associate and review orders]
Marking research associated
Marking the diagnosis
<table>
<thead>
<tr>
<th>Order Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBC, Automated</td>
<td>Expected-10/13/2015, Expires-9/29/2016, Lab Collect</td>
</tr>
<tr>
<td>Lipid Profile</td>
<td>Expected-9/29/2015, Expires-9/29/2016, Lab Collect</td>
</tr>
<tr>
<td>Urine, Pregnancy</td>
<td>Order details</td>
</tr>
</tbody>
</table>

Last Reviewed by Naz Khan, MD on 9/29/2015 at 11:39 AM

Mark All Taking | Mark as Reviewed

Click here to select a pharmacy

Associate | Research Association | Edit Multiple | Providers

Order Entry | Sign | Pend
Charge Review

Charge review screen shows which charges were marked as research and which were not—update, confirm and mark as reviewed.
Updates to charge hold

- At present, all charges are held for patients enrolled in research studies.
- Allows for a final review to confirm that charges were appropriately assigned to research vs standard of care.
- Most of the $’s held in charge review are clinical, not research.
- Most of the studies that account for charge hold are Oncology.
- Plan to update charge hold to those studies where it makes most sense, i.e. trials where research and standard of care charges are highly intermixed.
- Therefore, plan to exclude the following types of studies:
  - All expected charges are standard of care (including studies where investigational drug is marked as “no charge”).
  - All expected charges are covered by the grant (coordinators/PIs must reliably mark visits and orders as research).
  - No clinical charges are generated as part of the study protocol.
- Charge hold would remain for:
  - Oncology studies
  - Studies that include hospital admission.
How to obtain training

Epic
- For coordinators and front desk staff request via EpicTrainingDept@montefiore.org
- For PI’s, contact Evelyn Koestenblatt at ekoesten@montefiore.org

Velos
- http://ephpublic.aecom.yu.edu/velos_ctms
Velos CTMS

Documents

TRAINING MATERIALS
TRAINING VIDEOS
Velos User System Access Request
Report an Issue

Documents
Recent

VELOS POLICIES AND PROCEDURES CERTIFICATION FORM
VELOS USER SYSTEM ACCESS REQUEST - Authorization Form

Data Entry Date: 1/30/2017

Requester Full Name: ____________________________ Email: ____________________________ Phone: ____________________________

Requested Action: Select from Drop Down List

If Other: Specify Reason Or New Organization

Create New User Account: [ ]

I. General Information: Please provide information about the user for whom you are requesting access

First Name: ____________________________ Last Name: ____________________________ Phone Number: ____________________________ Department: ____________________________

New User Access Request (Check all that apply)

☐ MNC employee
☐ Einstein employee
☐ Vendor
☐ Consultant
☐ Temp or Non Monte Personnel
☐ Medical student
☐ Volunteer or under 18 years of age
☐ Observer/Auditor
☐ Regulatory Coordinator on a Research Study
☐ Study coordinator on a Research Study
☐ Pharmacy Staff for a Research Study
☐ PI of a Research Study
☐ Co-Investigator of a Research Study
☐ Physician Associated with a Research Study
☐ Other Staff with a Research Study
☐ Other

If Consultant/Vendor/Temp/External Personnel, please provide the company name and an expiration date

Company: ____________________________ Date: ____________________________

If Other, Please specify:

If Other: ____________________________

II. Application Access

Does this person currently have access to an EMR data system (EPIC, Carecast etc)?: [ ]

EZID (if known): ____________________________

III. Infrastructure - IS VPN Access Required?

[ ] Yes

Does this person have a Montefiore AD username and password?: [ ]

IV. Form Must Be Signed by Manager or Director

(Do not sign if any of the information is incomplete)

To print this form, right click mouse and select "Print"

Please Sign Name: ____________________________ Date: / / 

Print Name: ____________________________

Once completed, please fax to 718-430-2521 or scan it and email to veloshelp@montefiore.org

All applicants will be contacted to schedule training.

Investigators Only: You may complete online training. Click here to view online Investigator Training Materials and sign the certification box below. You will be notified when your account has been created.

Certification: To Be Signed Only After Applicant Completes Applicable Training:

APPLICANT HAS READ THE VELOS POLICIES/PROCEDURES CERTIFICATION FORM & AGREES TO ABIDE BY ALL STATED & APPLICABLE POLICIES

Signature of Person for Whom Access Is Required: ____________________________ Date: / / 

To print this form, right click mouse and select "Print".

Once completed, please fax to 718-430-2521 or scan it and email to veloshelp@montefiore.org
Between now and next meeting

- Share information with the researchers in your department.
- Identify studies that should be exempt from charge review and send to Evelyn Koestenblatt ekoesten@montefiore.org.
- Ensure that research staff in the department have attended training and are using Velos and Epic.
- Send questions to
  - Epic: Evelyn Koestenblatt ekoesten@montefiore.org
  - Velos: Mindy Ginsberg Mindy.Ginsberg@einstein.yu.edu
- Provider agenda items for next meeting(s) to Matt Berger maberger@montefiore.org
Future agenda items

• Continue to define studies for charge hold/review
• Invoicing process Epic vs Velos
• Full research revenue cycle
• Confidential results
• Collaboration with MMC revenue cycle
Meeting Schedule

First Wednesday of each month 8a to 9a alternating between Price Center and Tishman Learning Center.

Next meeting
   Wednesday, March 1, 2017  TLC room 5, Moses