MMC-Einstein Research IT Forum
June 7, 2017

Harry Shamoon, Associate Dean for Clinical & Translational Research
Barrett Katz, Executive Director, Office of Clinical Trials
Vic Hatcher, Associate Dean for CME and Research Administration
Parsa Mirhaji, Director, Clinical Research Informatics
Matt Berger, Medical Director, MIT and Epic
Agenda

• Crystal Branch covering Epic research
• Updated proposal for Velos/Epic workflows
• Epic charge hold updates
• Request to senior MMC/Einstein leadership to confirm institutional objectives, processes and policies to govern use of Velos and Epic
Covering Epic Research Analyst

- Epic related research issues are being managed by Crystal Branch, a consultant hired to cover Evelyn Koestenblatt who is on leave of absence.
- Crystal has clinical and research background including clinical trial regulation, billing practices, charge review and Epic research functionality.
- Current activities
  - Audit of our processes
  - Ensuring synchronization between Epic and Velos
  - QA’ing billing reports
- For Epic research related activities, be sure to call in a Service Ticket.
- Crystal can be reached at crybranc@montefiore.org.
Velos-Epic Processes for Different Types of Clinical Research

- **All IRB Reviewed Studies (Monte/Einstein and BRANY)**
  - Non MMC/Einstein PI (e.g. Ferkauf) and non MMC patient
    - **No Action Required in Velos**
  - MMC/Einstein PI or MMC patients
    - IRB non exempt
      - **Study Documentation in Velos**
        - Study Summary
        - Study Team Verification
        - No Epic Submission
    - IRB exempt*
      - OCT managed
      - **No Action Required in Velos**
      - OCT not managed

- **Participants consented**
  - Procedures/consent performed at MMC/Einstein
    - **Full Study Activation in Velos**
      - Study Summary
      - Study Team Verification
      - Study Status Activation
  - Procedures/consent performed only at another institution
    - **Do Not Send to Epic if**
      - No Epic Orders (meds/tests/services) and
      - No Epic Research Visits and
      - No Study Participation Flag (confidential study)

- **Consent waived**
  - **Send to Epic if**
    - Interventional (drug/device/treatment) or
    - Epic Orders or
    - Epic Research Visits or
    - Study Participation Flag or
  - **Enter study subjects in Velos**
    - All Cancer studies
    - NIH sponsored studies (excluding survey studies)

*IRB exempt studies may include:
- Educational practices
- Cognitive testing, Surveys, Interviews
- Study of existing de-identified data, pathological specimens or diagnostic specimens

Contact the IRB Exempt Categories Common Rule 45CFR 46.101(b) for more information.
Velos-Epic Processes for Different Types of Clinical Research

Send to Epic
- Epic Orders (Meds/Tests/Services)
- Epic Research Visits
- Study Participation Flag

Enter study subjects in Velos

**SOC charges only**
- Epic orders**
- Epic visits
- Study flag
- **No charge hold (PI to provide attestation)**

**Mixed SOC and Research charges**
- Epic orders**
- Epic visits
- Study flag
- Charge hold & review

**Research charges only**
- Epic orders**
- Epic visits
- Study flag
- **No charge hold (PI to provide attestation)**

**Studies with confidential results**
Use paper orders/requisitions outside of Epic
Follow ancillary department workflow to keep results from filing to Epic
Global Charge Hold, Review and Release

- Will be limited to Mixed SOC and Research charges AND
- Drug/device studies billed to insurance (the required Q1 or Q0 modifier is needed to mark association to a clinical trial—done within charge review).

- Observation/Survey studies should continue to be identified and released from charge hold.
- Research only will require some updates in Epic to enable.
- Billing compliance has requested that PI’s provide a brief description of their study to confirm that there is not a mix of standard of care and research charges and therefore is appropriate to forego global charge hold.
Determining Institutional Objectives, Policy and Process

- Senior MMC and Einstein leadership are being engaged to address concerns raised by new IT systems and to provide institutional guidance and milestones.
Crystal Branch was introduced as the consultant covering Epic research while Evelyn Koestenblatt is out on medical leave.

The Velos workflow diagram was re-presented based upon input from IRB, Dean’s office, Legal, Office of Clinical Trials, Velos and Epic teams (slide 4). Attendees reflected general consensus with the updates to the workflow.

The Epic workflow diagram was presented (slide 5). Consensus was reflected in limiting charge hold and review to studies in Epic that were SOC only/observational as well as Research only.

Departmental liaisons were asked to identify active studies in Epic that are SOC only/Observational, yet currently mischaracterized as subject to charge hold. This will facilitate the Epic team’s effort to reverse the charge hold setting.

Research only studies relief from charge hold will require additional Epic build, the progress of which will be reported to the IT Forum at the next meeting in July.

Further study by study clarification as to Velos and Epic workflow will be needed for those that do not clearly fit into the current categorization.

The addition of billing calendars in Epic for Oncology trials will be addressed as additional resources are made available to build research cancer protocols. This will likely facilitate charge review procedures, though not eliminate them.

The Epic and Velos teams will continue to update the respective systems to reflect these updates to process.