MMC-Einstein Research IT Forum

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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

- Review Velos and Epic workflows
- Velos study audit
- Training
- Proposed Epic billing rules
- Research unit with HSR
- IT resources
- Epic upgrade
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 Approval Required
    - OCT managed
      - OCT not managed
        - No Action Required in Velos
    - OCT not managed
      - Study Documentation in Velos
        - Study Summary
        - Study Team Verification
        - Study Status Activation
      - No need to enter study subjects in Velos
        - If not a Cancer study
        - Subjects do not need to be tracked in Velos

Do Not Send to Epic if:
- IRB non exempt
  - Procedures/consent performed at MMC/Einstein
  - Procedures/consent performed only at another institution
  - Study Documentation in Velos
    - Study Summary
    - Study Team Verification
    - No Epic Submission
- IRB exempt*
  - Procedures/consent performed at MMC/Einstein
  - Procedures/consent performed only at another institution
  - Study Documentation in Velos
    - Study Summary
    - Study Team Verification
    - No Epic Submission

Enter study subjects in Velos
- Send to Epic if:
  - Interventional (drug/device/treatment) or
  - Epic Orders or
  - Epic Research Visits or
  - Study Participation Flag or
  - All Cancer studies
  - Other studies where Velos is needed to track subjects
When entering subjects into Velos include all status updates:
  - Initial Consent Signed
  - Screening
  - Enrolled
  - Active on Tx
  - Active off Tx
  - Off study

*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 45 CFR 46.101(b) for more information
Velos-Epic Processes for Different Types of Clinical Research

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

Enter study subjects in Velos
Document Initial Consent Signed status and then document ALL Status updates
(Screening->Enrolled->Active on Tx->Off Tx->Off Study)

No research associated charges
Study flag only
NO charge hold & review

SOC charges only
Epic orders**
Epic visits
Study flag
Charge hold & review at present
Automate process with new Epic charge handling rules

Mixed SOC and Research charges
Epic orders**
Epic visits
Study flag
Charge hold & review & assignment
This could be facilitated through creation of billing calendars to pre-assign SOC vs Research charges

Research charges only
Epic orders**
Epic visits
Study flag
Charge hold & review at present
Automate process with new Epic charge handling rules.

**Studies with confidential results
Use paper orders/requisitions outside of Epic
Follow ancillary department workflow to keep results from filing to Epic
Training

• Epic and Velos teams will be creating a refresher training for coordinators and PIs to review current workflows.
• New user training will be redesigned to cover Velos and Epic components.
• Consider adding a series to cover relevant elements of research billing, e.g. coverage analysis, research modifiers, etc.
Dollars held for research review
Proposed Epic research charge flow rules

Four categories for research charge handling are being created within Epic:

1. No research associated charges, e.g. survey studies
   - No charge hold applied

2. “Standard of care only” research charges, i.e. all research charges are paid by health plan
   - Coordinator/PI must mark visits and orders as research associated
   - Those charges will have research associated modifiers applied automatically and billed to health plan
   - No charge hold applied

3. “Research only” research charges, i.e. all research charges are paid by sponsor
   - Coordinator/PI must mark visits and orders as research associated
   - Those charges will flow to the research account to be invoiced
   - No charge hold applied

4. “Mixed SOC and Research charges, e.g. Oncology, CT surgery
   - All charges held for review and assignment to appropriate account
New Epic research charge flow rules

- Which charge rules apply to which study should be driven by the coverage analysis.
- Coordinators/PIs must reliably mark visits and orders as research associated.
- Creation and testing of the rules are underway.
- In the meantime, we should start identifying in VELOS studies that are candidate for the different categories. (STUDY SUMMARY tab)
Research unit within HSR

- Up and running.
- Working with PIs, coordinators, OCT, Epic, Velos teams.

Research IT resources

- Evelyn Koestenblatt is returning on September 18
- Crystal Branch has been extended for an additional 6 months

Epic Upgrade

- Scheduled for October 6-7
- New “look and feel”, new features and functions
- Consult the Epic@Montefiore link on the Montefiore Intranet
Next Meeting

Monday October 2, 8a to 9a
Einstein-Price Center, conf rm 351