MMC-Einstein Research IT Forum
August 2, 2017

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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

• Research IT Forum moves to Mondays starting next month
• New Epic Charge Hold billing rules
• QA audit #2
• Where are consent to research forms stored?
• Application of standard research fee schedules
• Research invoices
• Updating missing patient start dates
• More Epic enhancements to support research
Research IT Forum schedule

Moving to Mondays 8a to 9a

September 11    Price
October 2       Price
November 6      TLC
December 4      Price

Updates to Outlook invite will be sent
New 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 should be completed within 4 to 6 weeks.
• In the meantime, we should start identifying in VELOS studies that are candidate for the different categories. (STUDY SUMMARY tab)

• For mixed SOC and research studies, could use billing calendars to facilitate charge assignment in advance based upon the coverage analysis—this will require additional IT resources
• Charges held for review have reduced from peak of $20M one year ago to between $3M and $7M reflecting much improved throughput in performing charge review.
Clinical Trial QA Audit

Peds Heme-Onc study
• Visits not linked to the research study
• Charges billed to insurance instead of research
• Research codes not applied
• Informed consents not scanned into Epic

*While charge review is being performed more reliably, the accuracy of that review and other parts of the workflow remain problematic.*

• This underscores the importance of
  – Initiating the research billing unit
  – Soliciting reeducation of research staff in use of Velos, Epic and other systems/processes
  – Securing additional IT resources in the creation of billing calendars, relevant reports, etc.
At present, there are 2323 research consents scanned into Epic. Are some stored in Velos? Elsewhere?

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Additional activities

• Application of a uniform research fee schedule to Epic
• Generating research invoices
• Updating patients missing start dates
  – PI will receive a spreadsheet with a list of patients missing start dates
  – These can be updated on the spreadsheet and Epic/Velos team will update
• Additional Epic R&D enhancements to research, e.g. new status for active vs follow-up
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
  - IRB exempt*: No Action Required in Velos

**Participants consented**
- Procedures/consent performed at MMC/Einstein: No need to enter study subjects in Velos
- Procedures/consent performed only at another institution: Enter study subjects in Velos

**Consent waived**
- IRB Approval Required
  - OCT managed: Study Documentation in Velos
  - OCT not managed: No Action Required in Velos

**Study Documentation in Velos**
- Study Summary
- Study Team Verification
- No Epic Submission

**Do Not Send to Epic if:**
- No Epic Orders (meds/tests/services) and
- No Epic Research Visits and
- No Study Participation Flag (confidential study)

**Enter study subjects in Velos**
- 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

**Send to Epic if:**
- Interventional (drug/device/treatment) or
- Epic Orders or
- Epic Research Visits or
- Study Participation Flag or

**No need to enter study subjects in Velos**
- If not a Cancer study
- Subjects do not need to be tracked in Velos

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

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