EMR Systems and the Conduct of Clinical Research

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Clinical Research Environment

- Research protocols are becoming more complex
- In response to “precision medicine” paradigm, research teams support a greater number of protocols
- Multicenter protocols are increasing in comparison to single center protocols

Current Environment

- Greater focus on safety for clinical care
- Adverse events in clinical research frequently result from care that deviates from the approved protocol
- EMRs are becoming a favored method for providing decision support to enhance quality and safety of care

Clinical Research Environment

- Clinical research protocols do not scale well
  - Complex protocols that apply to a small number of research participants
  - IT cost per patient in clinical research protocol generally higher than average clinical patient
  - Estimated around 40 hours of programming time to create all the IT support per protocol

EHRs and Research in Academic Medical Centers

- Academic Medical Centers are making substantial investments in integrated EHRs
- Decisions about functionality of EHRs are driven by clinical, not research, needs
- Integrated EHRs provide unprecedented opportunities for supporting medical discovery

CRF IT Roundtable

- Need for research leaders in AMCs to provide road map for how to best leverage the EHR
- Progress will require cooperation of AMC IT leadership, clinical and research faculty, vendor community and regulatory offices (new focus on adding patients as well)
- With help from IT Roundtable Advisory Committee we organized 2 day conference to address these issues held October 2013

Conference Organization

- Goal was to provide a set of recommendations from the AHC Researcher Perspective for how to best leverage the EHR for research
- Attendees included:
  - 75 clinical researchers and IT professionals from 38 AHCs
  - 11 representatives from EHR and CTMS vendors
  - 5 representatives from PHARMA

Conference Organization

- 3 use cases
  - Randomized clinical trial
  - Clinical research registries
  - Secondary data analyses
- Small groups worked through the most important EHR functions needed to support each type of study (2 facilitators per group)
- Scrambled small groups to address overlying issues such as governance
- Complete group convened at end to make sense of recommendations and discuss next steps

Conference Output

- Extensive reports generated at time of conference and posted online for use by members
- White paper written by Co-leaders of conference
  - Peter Embi (Ohio State)
  - Daniel Ford (Johns Hopkins)
  - Peter Winkelstein (SUNY Buffalo)
- http://www.clinicalresearchforum.org/vertical/sites/%7B97FFC4B0-AA89-45B2-8F74-9693F47D3CB0%7D/uploads/4-23-14_IT_RT_paper_Draft.pdf

Recommendations

- Identification of Eligible Research Participants
- Enable Data Collection for Research Case Report Forms and Registries
- Engage Patients in Research
- Enhance Reuse of Clinical Data for Research
- Manage Data Access for Research

Recommendations

- Integrate Data from Multiple Sources (ex, EHR, Echocardiography, MRI, Research data)
- Create Governance Model
- Make the Case for the Value of EHRs and Research
- Facilitate Registration of Research Participant Consent and Preferences
- Create Metadata Surrounding Research Data

Deeper Dive on Recommendations

- *Recommendation A1*: Develop a standardized process for requesting patients' authorization to be contacted about participating in clinical research.
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- *Recommendation A2*: Ensure that all patients understand that their entry into a given health care system constitutes consent to allow their de-identified data to be used for observational studies in a way that protects their confidentiality while advancing new medical discovery

Deeper Dive on Recommendations

- *Recommendation A3*: Make EHRs useful for screening patients for clinical studies by enabling researchers to integrate information from several resources, such as:
  - Biorepositories
  - Laboratory tests
  - Clinical Trial Management Systems
  - Patient Self-reported Outcomes

Deeper Dive on Recommendations

- *Recommendation A4*: Include the following minimal dataset in EHRs to help researchers identify and screen potential study participants:
- Basic patient characteristics, such as age, sex, and race
  - Metadata (such as who determined a patient's ethnicity) to assess the data's validity
  - Diagnoses with date of onset (ideal)
  - Accurate smoking status
  - Patient authorizations to be contacted about participating in research and ability to track changes in this authorization
  - As use of a standard dataset for eligibility increases, study sponsors would be encouraged to match eligibility criteria to this common dataset

Deeper Dive on Recommendations

- *Recommendation A7*: Create efficient EHR alerts at time of visit reminding clinicians to ask patients meeting preliminary eligibility criteria about willingness to be contacted by research staff about participating in a study.
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- *Recommendation A8*: Create a governance structure within the AHC that manages the use of EHR research reminders that is respectful of clinician's time and ability to attend to multiple messages, the patient's primary focus on addressing clinical issues, and the public needs to complete research studies and advance medical knowledge.

Deeper Dive on Recommendations

- *Recommendation A5*: Create systems to store computable consent forms that can be queried to determine whether patients have agreed to be contacted about clinical research participation, might be willing to participate in such research, and have agreed to allow their biospecimens and/or data to be used in research
- *Recommendation A6*: Create systems and redesign workflow to efficiently manage communications with patients who have agreed to be contacted about participation in a study

Deeper Dive on Recommendations

- *Recommendation F1*: Provide substantial flexibility in EHR data entry but standardize mechanisms for integrating EHR data with data from other sources.
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- *Recommendation F2*: Create standards for integrating data from several sources.
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- *Recommendation F3*: Develop site-based, project-based, and source-specific security mechanisms, including audit trails, encryption, and de-identification, and enable non-employees (such as representatives of sponsors and regulatory agencies) to monitor these systems.

Deeper Dive on Recommendations

- *Recommendation G1*: Operationalize research IT governance structures that enable an evidence-generated medicine paradigm alongside one that values evidence-based medicine
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- *Recommendation G2* Create best practices for governance structures that bring together relevant stakeholders to enable appropriate and efficient policies for data access, stewardship and security, in order to facilitate rather than hinder data-driven research activities.
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- *Recommendation G3*: Assign a senior staff member (e.g., research IT director, chief research information officer, etc.) as a counterpart to the chief information officer or chief medical information officer to be responsible for all research IT strategy at the institution.
- Embi P, Payne PRO. Evidence Generating Medicine: Redefining the research-practice relationship to complete the evidence cycle. Medical Care 2013; August; 51:S87-S91.

Conclusions

- IT technical capacity in EHRs is rapidly progressing
- Next phase is discipline to focus on standards and managing interfaces to link data
- New focus on using EHRs to engage patients in research
- Academic centers will be challenged to manage resources and culture to leverage EHR for research

Simple, Easy, Nearly FREE!

Utilizing EHR for Research at Johns Hopkins

What are the main IT tasks?

- Prompt indicator that patient is in a research study
- Recruitment and registration
- Ordering clinical and research tests
- Open scheduling to create convenient visits with multiple components
- Ordering research medications
- Documentation of research visits

Decision Support

- Information about research study for the clinical team
- Investigational drug – assess for drug interactions and duplicate drugs
- Best practice advisories
  - "Do not start an antibiotic without checking with the research team."
- Research team pushed data if research participant admitted or seen in ER

Promise of EMRs

- Improve recruitment through smart point of service identification and referral
- Improve coordination of care between research and clinical team
- Improve adherence to protocol
- Improve safety

What is needed to realize the promise of EMRs?

- Research team (PIs, research coordinators, schedulers, investigational pharmacy) that meet regularly to develop agenda for research
- Someone with research perspective on all of the clinical teams working on EMR implementation
- A universal Clinical Trial Management System (CTMS) adds considerable value

What is needed to realize the promise of EMRs?

- Address perception that clinical care needs require fast turn around and research is on a slower timeline
  - Cohort discovery needs to be fast
  - Research teams cannot wait months to get their investigational drugs entered into pharmacy and order sets
- Research teams need to be willing to standardize work flows

Research and Epic @ Johns Hopkins

Johns Hopkins Health System includes:

- 5 hospitals in Baltimore-Washington Region
- 150 employed physicians in largest primary care network in Maryland
- 350,000 patients enrolled in the Johns Hopkins Health Plan
- An Accountable Care Organization

Epic deployment in progress, in use today at:

- 3 community hospitals (enterprise)
- 2 academic medical center outpatient areas
- State-wide primary care network

Research activity at John Hopkins:

- $650M sponsored research
- 5000 active protocols, 1300 protocols using investigational medications
- 1500 unique Principal Investigators

Guiding Principles

For the safety of our study participants, clinical research data relevant to patient care should be in Epic and viewable by the care team, just like other clinical data

Research data which are not needed for patient care are not required to be in Epic

There are a few special cases of sensitive research data that are needed for patient care – decide on approach with guidance from governance bodies

Good Governance is Critical

Epic Executive Council – C-band leadership. The buck stops here

Epic Coordinating Council – Addresses **cross-application, cross-institutional issues**, reports to Executive Council

Epic Research Task Force – Provide **high level vision for research use** of Epic. Reports to Coordinating Council

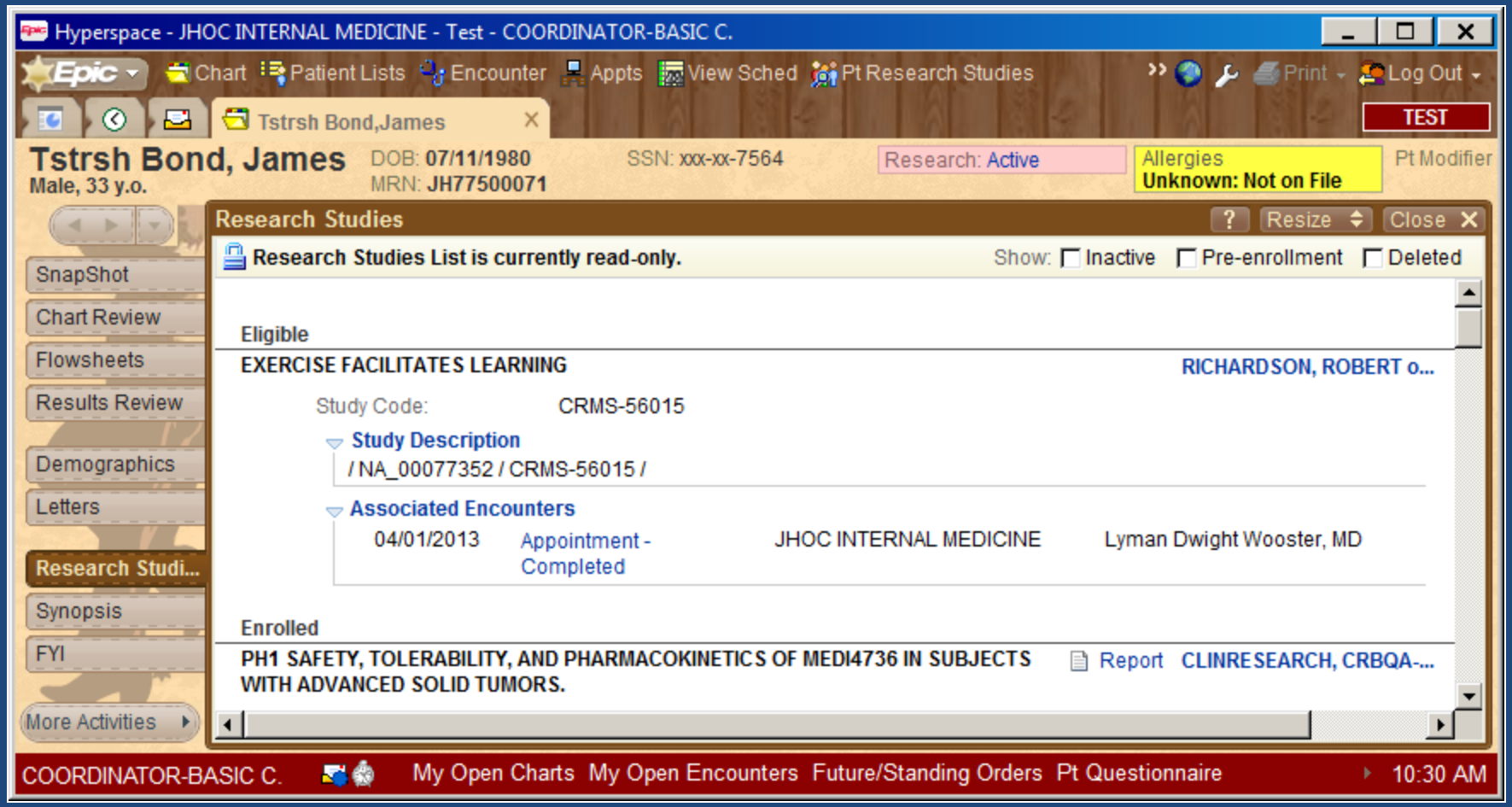
Epic Research Request Review (R-cubed) Committee – **reviews & prioritizes** enhancement requests. Reports to Research Task Force

Institutional Review Boards (IRBs)

Johns Hopkins Data Trust – access to clinical data for research and other purposes

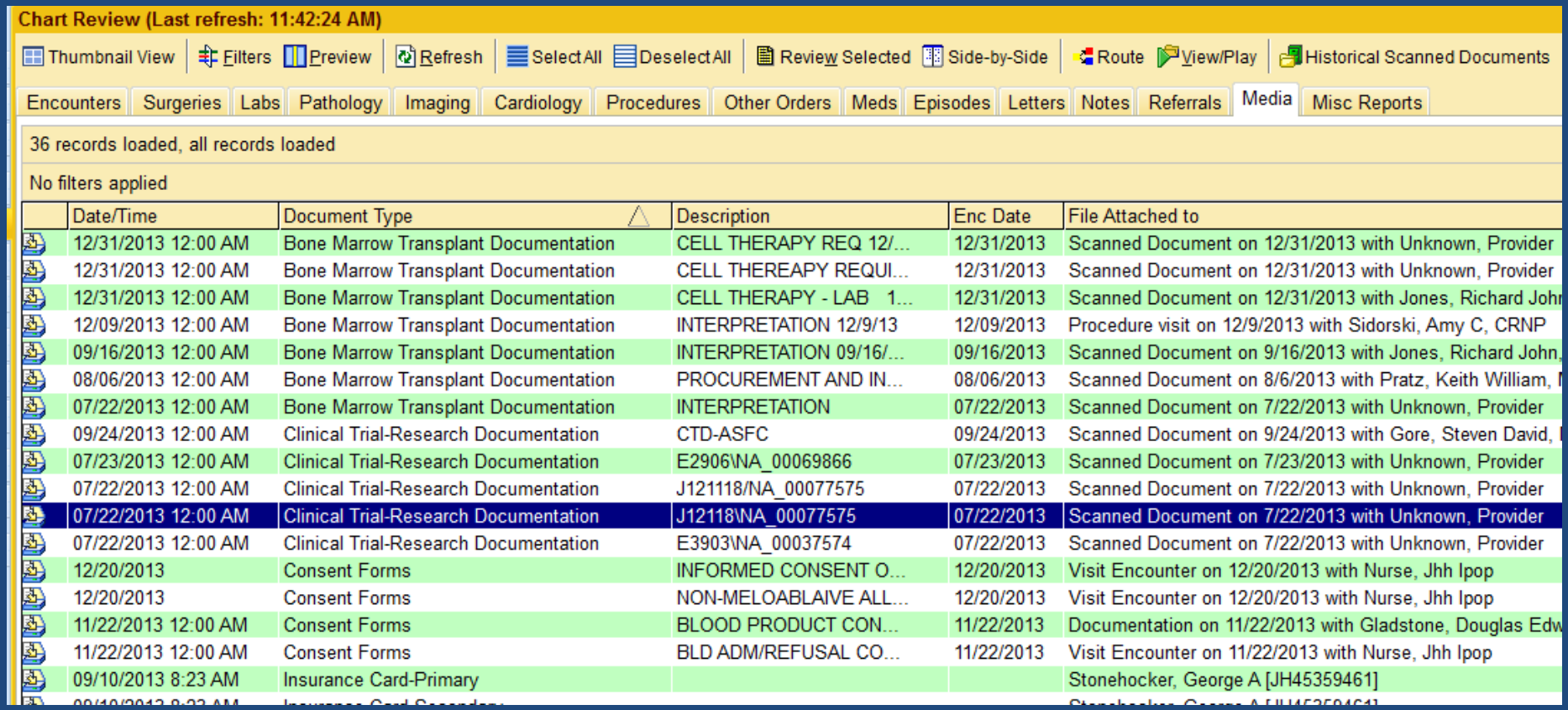
Research Data
Which We've Decided
SHOULD be in the Epic EMR

Patient on a Study



- For patient safety, clinicians need to know about research studies
- The study title can be modified by the investigator (in the CTMS)
- We do not display study association for retrospective data studies

Scanned Research Consent



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12/31/2013 12:00 AM	Bone Marrow Transplant Documentation	CELL THEREAPY REQUI...	12/31/2013	Scanned Document on 12/31/2013 with Unknown, Provider
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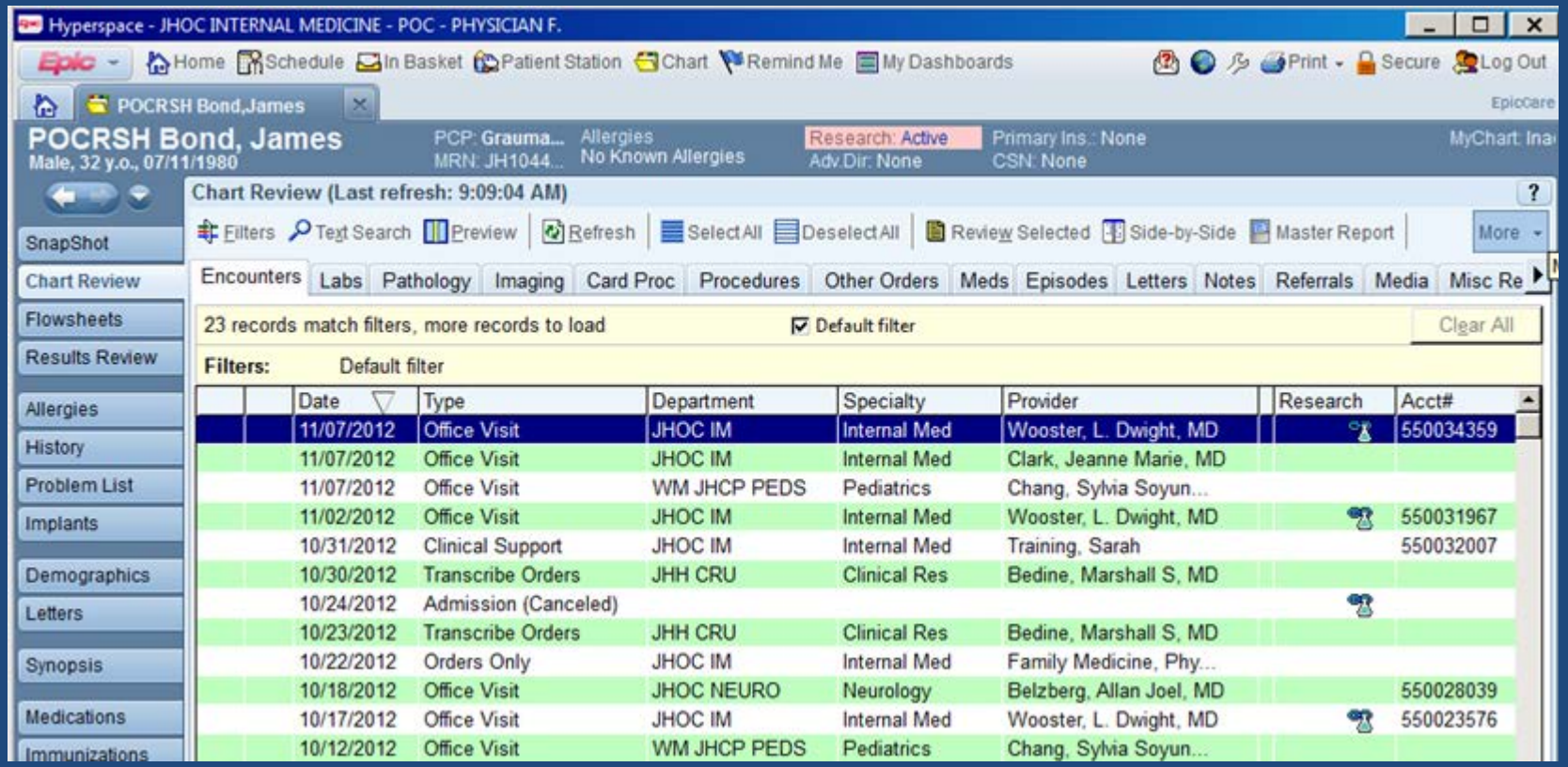
11/22/2013 12:00 AM	Consent Forms	BLD ADM/REFUSAL CO...	11/22/2013	Visit Encounter on 11/22/2013 with Nurse, Jhh Ipop
09/10/2013 8:23 AM	Insurance Card-Primary			Stonehocker, George A [JH45359461]

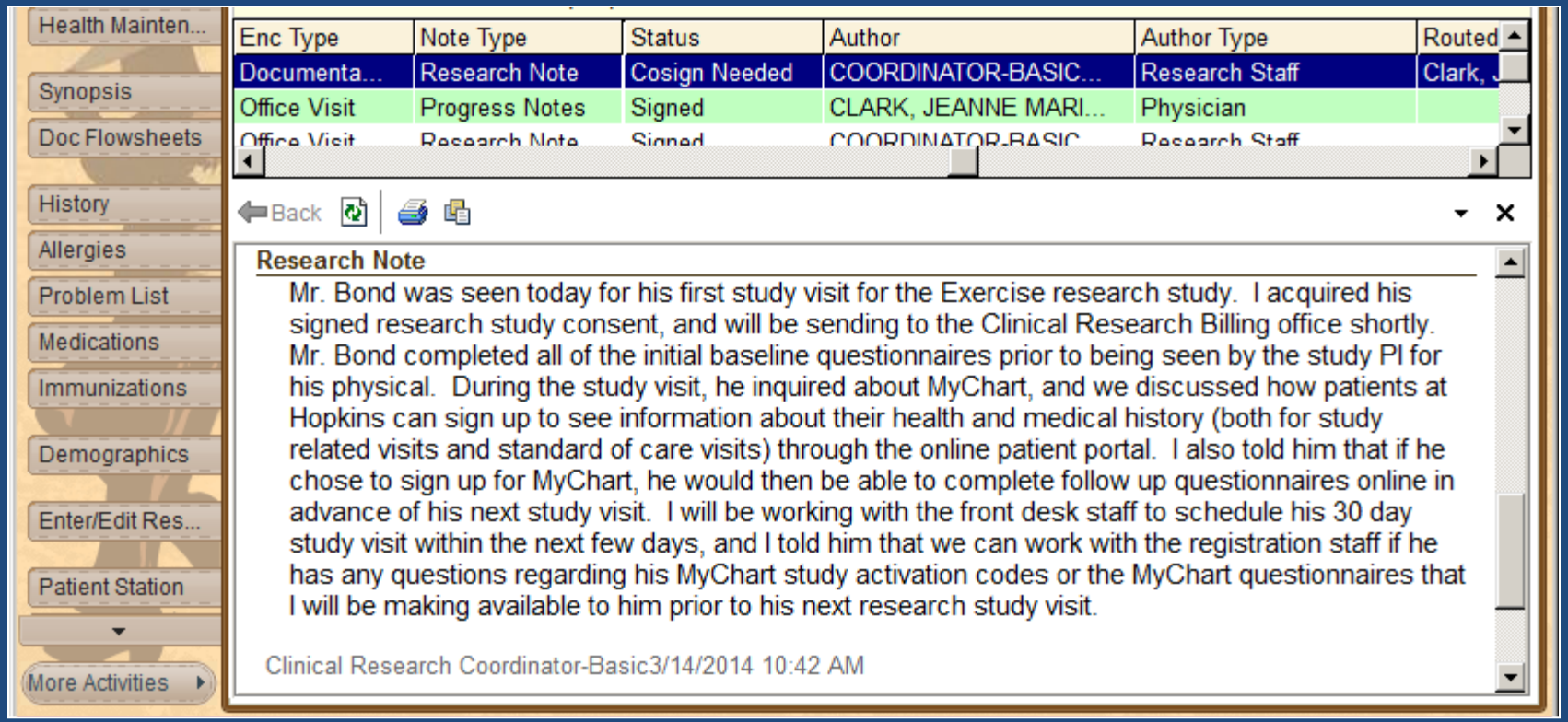
- Joint Commission requires consent forms for all treatment be in medical record
- A centralized service scans the research consent form into Epic
- If Certificate of Confidentiality, then flag is set which causes a review prior to release of medical record

Research-Linked Encounter



- All research visits must be scheduled using Epic
- Link encounters to a study to assist with billing

Clinical Research Documentation



Progress Note (part of legal medical record)

- Should contain standard clinical documentation

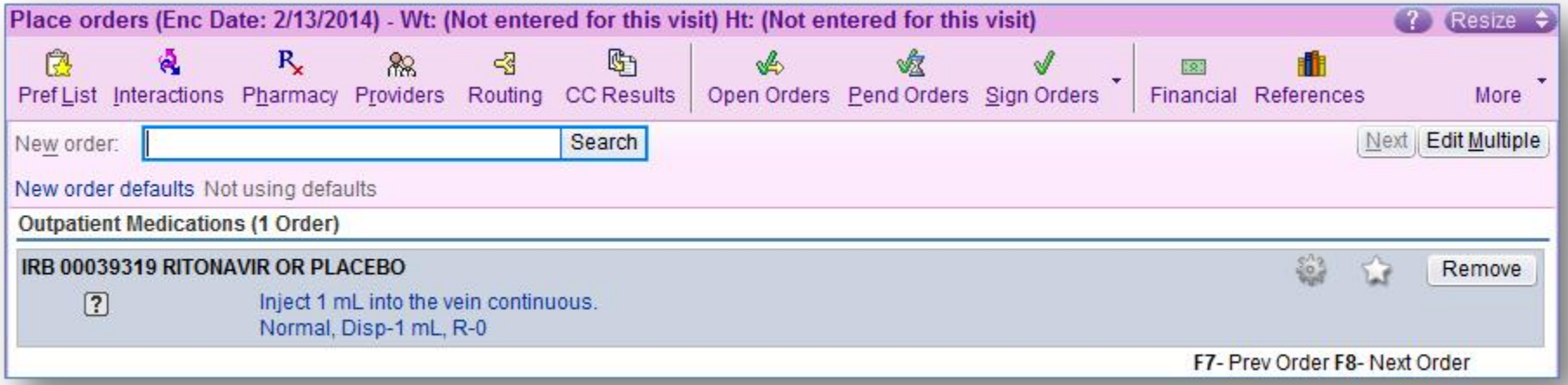
Research Note (NOT part of legal medical record)

- Created & edited by Research Coordinator. Must be cosigned by clinical user

Both notes are “discoverable”

Both notes are viewable by anyone with permission to see clinical docs

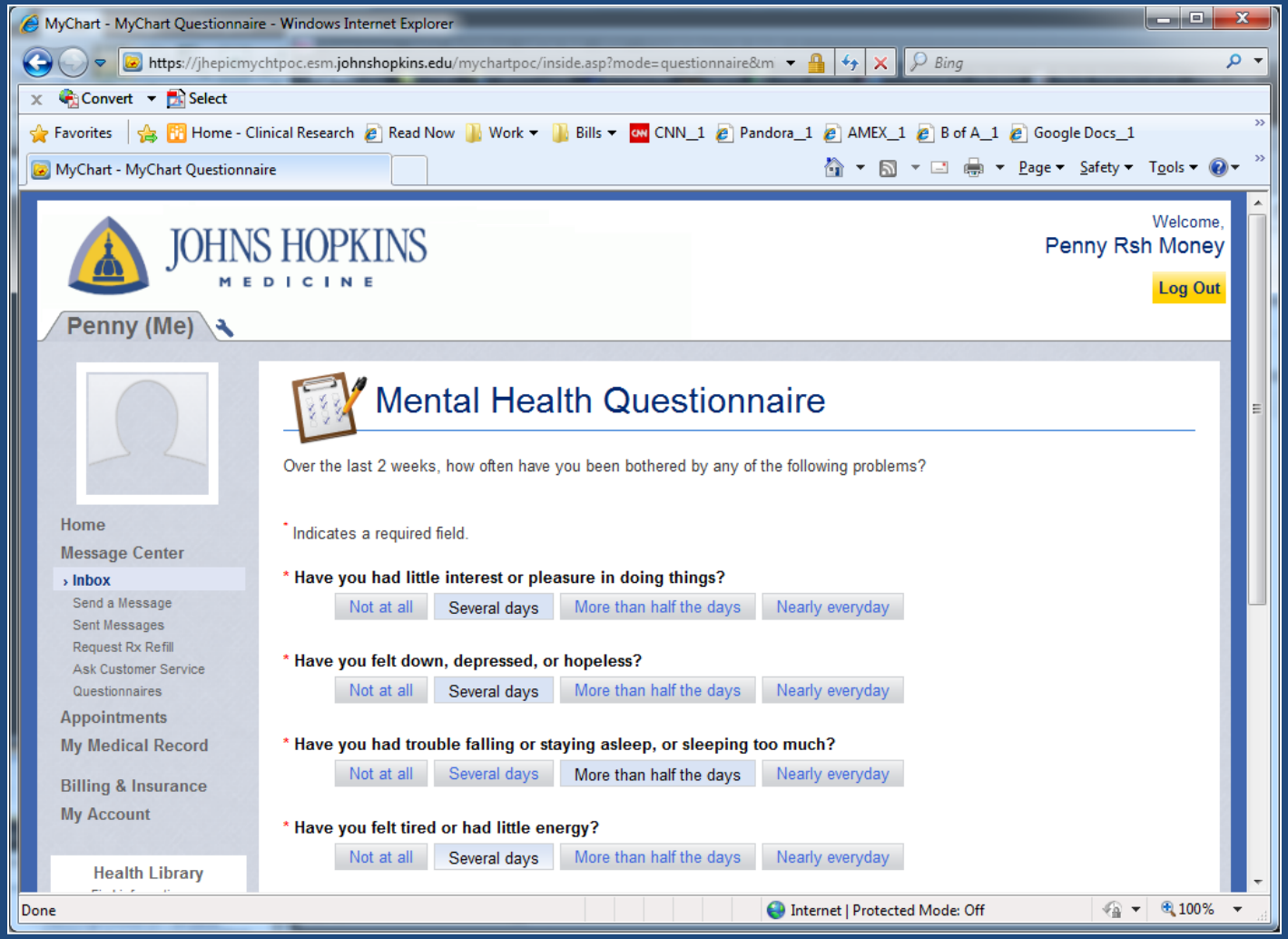
Research Orders & Results



- Can associate a research order with a study
- Research meds – 25 have been built. See naming convention above.
- Research-specific imaging orders built for special research billing rates
- Research blood draws - “nursing communication order” so person doing the draw knows what to draw & who to page once it is available

- Research lab orders in Epic – deferring to future deployment
- Research lab results – come into Epic as unsolicited orders Problematic if seeing result could compromise study blinding. No good solution yet other than to keep it out of Epic.

Patient Reported Outcomes (PRO)



- To date we have built several research PRO
- There is a high demand for research PROs

Research Use of Epic Which Remains Challenging

Challenging Areas

- Quality and consistency of data; sufficient for research use?
- Research note contents & contributors
- Double documenting for sponsored trials with a separate documentation mechanism
- Unsolicited lab results could compromise blinding
- Sensitive studies that shouldn't be in Epic(?)
  - This hasn't happened yet; would complicate billing & safety
- Research coordinator role
- Epic Reports & Registry - Easy access to data, exportability, could lead to misuse

In Summary

- Study participant safety is paramount
- Any research data needed for patient care should be available in the EHR
- Protect study blinding
- Link encounters & orders to studies for accurate billing in research
- Effective governance is crucial