PILOTTING A RESEARCH PERMISSIONS MANAGEMENT SYSTEM ON A PORTABLE DEVICE

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Topics

• The need for a Research Permissions Management System (RPMS)
• RPMS version 1: HIPAA and General Permissions
• Architecture
• Ontologies in Consent Systems
• Next Steps: RPMS2
Research Permissions – What are They?

- Informed consent for Clinical trials
- Permission to be contacted for future research
- Permission to be contacted about research related to a specific topic eg Your underlying diagnoses.
- Permission to allow your data to be used for research
- Permission to allow discarded blood or tissue to be used for research
- Permission to allow your genomic information to be used for research
- Permission to be contacted in the future about research related to your genomic information
- The ability to “opt out” of all research initiatives
“Research Permissions” – Regulatory Definitions

Permission to use identifiable health information (1)

“Authorization” to allow external researchers to contact individual (A)

“Authorization” to use and disclose information for research (B)

Permission to participate (2)

“Informed Consent” to participate in specific research project or clinical trial

Permission to retain biospecimens (3)

“Consent” to retain biospecimens

HIPAA Privacy Rule

Common Rule
The Need for an Ontology

• Standardize across institutions
• Make permissions and consent assumptions explicit
• Allow sharing of consistent data
• Allow analysis across institutions
• Reuse in other projects
Typical HIPAA Authorization Process on Admission to SC Hospitals

- Registrar enters patient visit information
- Consent forms are printed
- Patient signs the forms
- Signed form is scanned into document Repository

Topaz Signature pad is used at one hospital
Research Permissions Management System (RPMS): The Case For Change

Current Environment

- No electronic capture of permissions
- Inconsistent process and semantics in obtaining permissions across multiple hospitals
- Poor comprehension and satisfaction in subjects providing permission or opting out
- Permissions data are unavailable for analysis
- The number of patients who are generally favorable to research participation is unknown
- Research volunteer subject lists are localized

New Permissions Management

- Electronic recording of permission decisions
- Access to permission decisions for research
- Common permissions ontology, terms and UI
- Common process for gathering and reviewing permission decisions
- Facilitates the identification and contact of patients who want to participate in research
- Rich educational opportunities about the research process
- Patients will have easy access to their permission decisions
A Research Permission Management System – GO grant Concept.

Central Repository Of Research Permissions Data (an i2b2 cell). Collected from individuals as Part of the clinical and research Process at HSSC hospitals.

Greenville Hospital System
Clemson University
Spartanburg Regional Healthcare System
Palmetto Health
University of South Carolina
Central Repository

“My Permissions” Portal as part of an Individual’s PHR.

Permission for Inclusion Available to researchers.
Permission as a Searchable Attribute in i2b2
RPMS1 Project – 5 Distinct tracks

• Discovery Phase
• Permissions Ontology Creation – SAIC, MUSC and CTSA PODs group
• Duke ELSI Process and creation of the General Permissions Form
• Clemson Permissions research project and human subjects “Permissions UI Laboratory”
• Creation of the RPMS application by SAIC and Recombinant

Design of the end-to-end RPMS1 application for Pilot
RPMS1 Pilot Architecture in SC

EMPI/Operational Data Store

Greenville Hospital System
Clemson University
Spartanburg Regional Healthcare System

University of South Carolina

RPMS1

XML and Alfresco Minimal Ontology

Medical University of South Carolina

i2b2

PDF of permissions Uploaded to HPF at MUSC

CTSA Clinical & Translational Science Awards

SCTR BIP

MUSC
RPMS1 Project Status

Project Initiation

Technical Design

Pilot Implementation

Business Analysis
- “As Is”
- “To Be”
- Gap Analysis

Technical Development

Pilot implementation at MUSC Registration areas
RPMS1 Pilot at MUSC
RPMS1 pilot: iPad and accessories
RPMS1: EMPI Patient lookup
RPMS1: Forms are Input Intensive
RPMS1: Patient Data / Form Selection
RPMS1: Other permissions

I understand that MUSC is an academic medical center providing healthcare, teaching, and research. I also understand that I may be cared for by physicians and other healthcare providers in training. My care will be supervised by an attending physician and staff. The information related to the health care I receive may be used for training or for scientific study purposes. I understand that if information contained in my health care record is used for such purposes, precautions will be taken to carefully preserve my anonymity. I also understand that pictures or other recordings may be made for purposes of my treatment or for educational purposes.

In addition, I understand that if I have questions about my medical care I can speak to my attending physician, nurse, resident, or medical student. In addition, I can contact my attending physician or the House Services Coordinator through the operator at 792-8080 (2-8080 from the bedside phone).

I acknowledge that I have received a copy of the brochure entitled "Medical University of South Carolina, An Academic Medical Center of Excellence" explaining the role of residents and students in my care.

Signature of Carl W. Beck
RPMS1: Research Permissions

Retention / Disposal and Use of Blood, Body Fluids, or Tissue

I understand and agree that any blood, body fluids or tissues normally removed from my body by MUSC in the course of any diagnostic procedures, surgery, or medical treatment that would otherwise be disposed of may be retained and used for research, including research on the genetic material (DNA) or other information contained in those tissues or specimens. I acknowledge that such research by MUSC may result in new inventions that may have commercial value and I understand that there are no plans to compensate me should this occur, regardless of the value of any such invention. I understand that any research using these leftover specimens or tissues will be done in a way that will not identify me.

I also understand that if I do not want research to be done using my leftover blood, body fluids or tissue, I need to check the box shown below. If I have questions, I should call (843) 792-8300.

- [ ] I DO NOT agree to have my tissue or blood used for future research studies.

Permission to Contact for Research Studies

I agree to be contacted about future research studies at MUSC for which I may be eligible. I understand that if I do not want to be contacted about future research studies, I need to check the box shown below.

- [ ] I DO NOT agree to be contacted for future research studies.

Patient Name: Carl W. Beck  Encounter ID: 1000012  MRN: 0000011
RPMS1: Spanish Translations

Retención / eliminación y uso de sangre, fluidos corporales o tejidos

Entiendo y acepto que cualquier sangre, fluido corporal o tejido que normalmente se extraiga de mi cuerpo por MUSC en el curso de cualquier procedimiento diagnóstico, cirugía o tratamiento médico, que de otra manera sería eliminado, puede ser conservado y utilizado para investigación, incluyendo investigación sobre el material genético (ADN) u otra información contenida en esos tejidos o muestras. Reconozco que dicha investigación de MUSC puede generar nuevas invenciones que pueden tener valor comercial y entiendo que no recibiría compensación si esto ocurriera, sin importar el valor de cualquier invención. Entiendo que cualquier investigación que utilice estas muestras o tejidos sobrantes se llevará a cabo de una manera que no me identifica.

☑ Yo NO ACEPTO que mis tejidos o mi sangre se utilicen para futuros estudios de investigación.
RPMS1: RPMS Generated Forms

Permission to Contact for Research Studies
I agree to be contacted about future research studies at MUSC for which I may be eligible. I understand that if I do not want to be contacted about future research studies, I need to check the box shown below.

Agreement: agree

Admission Photographs
I agree that my photograph may be taken for purposes of identifying me, or providing treatment to me. This photograph may become part of my medical record and may be disclosed if copies of my medical record are disclosed.

Responsible for Personal Items
I understand that The Hospital is not responsible for valuable items which I bring with me. I understand it is my responsibility to send my valuable items (such as medications, money, jewelry, electronics, etc.) home for safe keeping. Any items left at the hospital in excess of 30 days will be disposed of.

Agreement: agree

I received a copy of the MUSC "Notice of Privacy Practices".

Agreement: agree

I certify that I have read and have had read to me this consent and agree to its terms. I also certify that I am the patient, or an duly authorized by the patient, or am duly appointed to sign this agreement. I accept and understand its terms.

Date and Time
03/19/2012 5:13 PM

Signature of Patient
signature

Print full name ALERT TEST

Advance Directives Information given: Yes

My referrin doctor is (please print full name): JOHN CUSACK
City: Rock Hill, SC
My Primary Care Physician is (please print full name): CONNER FNP, RUTH S
City: Charleston, SC

Medicare Patient Certification (Medicare patients only)
I hereby certify that I have provided information about all insurance coverage available to me, including liability or worker's compensation insurance that is the information provided is correct and complete. I hereby authorize The Hospital and/or my doctors to release to the Social Security Administration, its intermediaries, or carriers any information needed for this or a related Medicare claim. I hereby authorize the payment of benefits to The Hospital or my doctors.

Agreement: agree

Retention / Disposal of Blood, Body Fluids, or Tissue
I understand and agree that any blood, body fluids, or tissues normally removed from my body by MUSC in the course of my diagnostic procedures, surgery, or medical treatment that would otherwise be disposed of may be retained and used for research, including research on the genetic material (DNA) or other information contained in those tissues or specimens. I acknowledge that such research by MUSC may result in new inventions that may have commercial value and I understand that there are no plans to compensate me should this occur, regardless of the value of any such invention. I understand that any research using these leftover specimens or tissues will be done in a way that will not identify me.

I also understand that if I do not want research to be done using my leftover blood, body fluids or tissue, I need to check the box shown below. If I have questions, I should call (843) 792-8500.
Results from Pilot

Hundreds of patients have been registered using iPad

Clerks excited about adopting the iPad

Patients cooperative

Minimal training required

Management looking to extend to other registration areas
Next Steps

Complete the RPMS1 pilot at MUSC

Make RPMS1 available to other HSSC South Carolina hospitals

RPMS2: A Reference Application for Informed Consent and HIPAA Authorizations
RPMS2: Functional requirements (1)

- Unconstrained by Existing forms at SC hospitals
  - Use best practice set of forms and text from Duke ELSI group
  - No pilot at this point
- Create a working application and publish it as the foundation of a community open source project
- Include Informed Consent and HIPAA Authorizations
- Include ability for rich media content (video, audio)
- An Ontology –based application (not ontology driven)
  - The research community really needs a functioning system and we are running out of time
- Include a Form – Builder application
- Completed by Sept 30
RPMS2: Role of the Ontology

Library of Text and rich media content

Authoring tool

Well-formed Informed Consents/Permissions

RPMS Ontology
RPMS2: Application Components and Architecture

RPMS2 Platform

Neo4j DB
JSON
Clojure

Consumes OWL ontology
RPMS2 Project Status

Iteration 3 sprint has started with 4FTE developers, 1 UA and 1 PM.
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Questions ????