An Ontology for Informed Consents and Other Research Permissions

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Outline

- The need for a Research Permissions Management System (RPMS)
- The need for an Ontology
- The RPMS pilot
- Current development
- The permissions ontology overview
- RPMS2 status
- Lessons learned
Research Permissions Management System (RPMS): The Case For Change

Current Environment

- **Paper-based** consents and permissions
- **Permissions data are unavailable** for analysis
- The number of patients who are generally **favorable to research participation is unknown**
- **Inconsistent process and semantics** in obtaining permissions across multiple hospitals
- **Poor comprehension** and satisfaction in subjects providing permission
- Research volunteer **subject lists are localized**

New Permissions Management

- **Electronic recording** of consents and permissions
- **Access to permission** decisions for research
- Common **permissions terminology**
- **Facilitating research while enhancing compliance with patient wishes**
- Rich **educational opportunities** about the research process
- **Patients will have easy access** to their permission decisions (patient portal)
- **Tracking** of informed consents
Informed Consents vs. Permissions

- Informed consent for research
- Consent to treat: regular patient registration
- Research permissions (can be opt-in or opt-out)
  - To contact for research
  - Use of tissues o/w disposed
Typical Registration Process on Admission

- **Register**
  - Registrar enters patient visit information

- **Print**
  - Consent forms are printed

- **Sign**
  - Patient signs the forms

- **Scan**
  - Signed form is scanned into document Repository

Topaz Signature pad used in some hospitals
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
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.

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

Permission for Inclusion Available to researchers.
Permission as a Searchable Attribute in i2b2

Show me how many males over 65 have given permission to be contacted for research.
RPMS Project – 5 Distinct tracks
with several partners:

- Discovery Phase
- Permissions Ontology Creation – **SAIC** then MUSC
- Duke ELSI Process and creation of the General Research Permissions Form
- Clemson Permissions research project and human subjects “Permissions UI Laboratory”
- Creation of the RPMS application initiated with **SAIC** and **Recombinant** – later brought in-house

Design of the end-to-end RPMS application for Pilot
Ontology Use Cases in RPMS

- **Consents/Permissions**
- **Forms Design**

**Ontology**

**Annotation of data**

**RPMS Data**

**Feeds i2b2 ontology for queries**

**i2b2 Workbench**

**SCTR BIP**

**MUSC Health Sciences South Carolina**

**CTSA Clinical & Translational Science Awards**
Ontology Content: Domain Analysis

- Initial work done by collaborators from HSSC, Clemson and industry consultants (SAIC)
- Analysis of the permission processes at four institutions
- Reviewed various hospital forms, federal regs, and websites
- Reviewed national standards: HITSP, SNOMED, NCI
- Used NCI thesaurus for root classes
- Independent track from software architecture
RPMS Pilot Ontology Content

188 Classes
(80 from NCI classes)

129 Properties (or interrelationships between classes)
RPMS1 Pilot Architecture

EMPI Operational Data Store

Greenville Hospital System
Clemson University
Spartanburg Regional Healthcare System

University of South Carolina

Medical University of South Carolina

XML and Alfresco
Few Ontology classes used

RPMS1

i2b2

PDF of permissions Uploaded to HPF at MUSC

SCTRBIP MUSC CTSA
RPMS1 Pilot Live at MUSC

Working pilot being tested at MUSC in select Patient registration areas.
RPMS1 pilot: hardened iPad, accessories and stylus
RPMS1: RPMS Generated Forms
RPMS Pilot Status

RPMS: Number of Patients Registered

- Hundreds of patients have been registered using RPMS.
- Clerks excited about adopting the iPad.
- Patients cooperative.
- Minimal training required.
- Management looking to extend.
The Project is not over!
RPMS2: Functional requirements

- Include RPMS1 functionality
- Add Informed Consent and HIPAA Authorizations
  - + general research permissions form and text from Duke ELSI group
- Include ability for rich media content (e.g. video)
- Architecture: Ontology–based (graph database at its core)
  - Nodes and relationships are flexible, extensible
  - Handles large and complex datasets (scalable)
  - Indexes to transverse relationships (performance much faster than RDBMS)
- Include consent forms authoring module tied to ontology
- Create a working application and publish it as the foundation of a community open source project
RPMS2 Exploratory Phase

- Looked at VIVO, eagle-i
  - Established good collaborations with UF (used v1 code)
- Difficulty in applying to workflow in RPMS
- Collaborated with UCSD
  - Consent project at CTSA IKFC (Aziz Boxwala / Adela)
  - Teamed up on ontology foundation to avoid duplication
- Decided to balance between perfect ontology and pragmatic design
- Ontology development is hand-in-hand with architecture
RPMS2: Architecture

Platform
Neo4j DB (graph db)

Clojure / JSON

Consumes OWL ontology
RPMS2 Ontology Basis

RPMS2 graph structure extends UCSD’s (based on HL7 Security and Privacy Ontology). Adds types and relationships needed for new requirements.

Baseline Scope

UCSD Ontology (Adela Grando)

Shares some classes from original ontology

RPMS2 Nodes & Relationships
Basic elements of informed consent (from 45 CFR 46) – to serve as IRB consent template

1. The study involves research
2. Risks
3. Benefits from research
4. Alternative options/treatments
5. Confidentiality of records
6. Availability of treatment for adverse results/compensation
7. Contact information
8. Voluntary participation
9. Other…

The ontology defines a well-formed consent.
RPMS2 – Work in Progress

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Lessons Learned

- Ontology development should go hand-in-hand with software architecture design (e.g. VIVO/eagle-i)
  - No turn-key methodology for building ontology-based apps
  - Expertise has been hard to come by

- Pragmatic approach: don’t get too hung up on ontology content – keep milestones and stakeholders in mind (we need to show a win and there is a real need for a functioning application)
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Questions