Research Permissions Management System (RPMS)

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GO GRANT (National Lib of Med Grant # 1RC2 LM010796)
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 consent versions
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.
Show me how many males with Diabetes over 65 have given permission to be contacted for research.

Other permissions include participation in: Biobank or Disease Registries, etc.
COLLABORATIVE PROJECT – DISTINCT TRACKS
WITH SEVERAL PARTNERS:

- Discovery Phase (USC, MUSC, Clemson)
- Creation of the RPMS application initiated with SAIC and Recombinant – later brought in-house
- Duke Ethics/Legal/Social (ELSI) Process and creation of the General Research Permissions Form
- Clemson Permissions research project and human subjects “Permissions UI Laboratory”

**Design of the end-to-end RPMS application for Pilot**
PHASED PROJECT

- RPMS version 1 (+ end-to-end pilot)

- RPMS version 2 (added features, open source release)
Workflow analyzed at HSSC members (PH, Greenville, MUSC) + All solicited to participate in Pilot.

Select patient registration clinics at MUSC (timing was right)


Clerk Training & Feedback.

Over 2500 patients have been registered using the RPMS pilot at MUSC.

Adopted at University of Florida (for informed consent)
RPMS PILOT WELL RECEIVED
RPMS version 2: KEY FEATURES

- Includes RPMS Pilot functionality for patient registration
- Add Informed Consent and HIPAA Authorizations
- Design: Configurable, Extensible, Easy to Use
- Includes Authoring Module/Form Designer for broad tool applicability
- Ability to embed Rich Media content into forms (e.g. video)
- Robust Architecture: Plug-in style and Ontology-based (graph database at its core)
  - Nodes and relationships are flexible, extensible
  - Handles large and complex datasets (scalable)
  - Indexes to transverse relationships (performance)
- Published as Open Source product (Compared to custom developed application)
Typical Informed Consent for Research Workflow:

- Research coordinator login
- Collecting a consent from the patient
- Document review and witness signature
Research coordinator login
Research coordinator selects clinic (multi-clinic/multi-protocol)
Research coordinator selects Research Participant
If a registered patient – system will find
Encounter ID
Research coordinator selects research Protocol & Language.

Then hands off to Participant.
Participant goes through consent
Participant selects research permissions and signs consent.
Participant completes consent
then hands back to Research Coordinator
The system locks patient out for security.

Research Coordinator has to enter the unlock code.
Research Coordinator reviews consent with Participant
Witness signature
Now ready for next participant

End of Demo
RELEASED AS OPEN SOURCE

http://www.healthsciencessc.org/rpms/

Research Permission Management System (RPMS)

The Research Permissions Management System (RPMS) is a novel and comprehensive mechanism for electronically capturing and managing informed consents, research authorizations, and patient permissions in both clinical care and research settings. RPMS addresses the challenge of patient trust and research participant recruitment by replacing current paper-based methods and simplifying the collection and management of informed consents and research permissions that accrue to an individual through their direct and indirect interactions with the research enterprise.

The RPMS project was supported by a “Grand Opportunity” grant (#RC2LM010795) from the National Library of Medicine at the National Institute of Health to HSSC. A Grand Opportunity grant funds the research development of ideas that will have high-impact on the research community and which may also create a new area of scientific investigation.

RPMS is being released as an open-source software application.

Please review the RPMS Open source licensing agreement prior to downloading the software.

The RPMS software is available for download here.


PENDING JOURNAL SUBMISSIONS:


OPPORTUNITIES

> HSSC Institutions expressed interest: Spartanburg, Hollings Cancer Center
> Collaborations:
  > University of Florida, Clemson.
> NCI FOA: U24
> Commercialization:
  > Discovery Disclosures
  > Exploring business models (Rich content-Player/Distribution)
  > College of Charleston
ACKNOWLEDGEMENTS

RPMS core team
Iain Sanderson, MSc, FRCA
Katrina Fryar
Randall Alexander
Rick Larsen
Dan Rugg
Katie Gerken
Jay Moskowitz, PhD (PI)

Clemson University
Anand Gramopadhye, PhD
Kapil Madathil

Funded by NIH/NLM Grant 1RC2LM010796-01 (09/30/2009 – 09/29/2012)
• An Open Source Research Permissions Framework for South Carolina

And by NCRR/CTSA Grant 1UL1RR029882-01 (7/14/09-03/31/14)
• South Carolina Clinical & Translational Research Institute (SCTR)

And by THE DUKE ENDOWMENT