iCONS aims to address the lack of a standard for capturing, reasoning, integrating and sharing consent permissions provided by subjects for reusing clinical data and samples for research. iCONS also meets the ethical imperative of educating patients on the consequences of consenting to share their data.

**Introduction**

The goals of our research are:

- Educate subjects so that they are truly informed before and after they consent to participate in research
- Propose a standard to facilitate the capturing and reasoning on permissions given by the subjects through informed consent
- Maximize researchers’ access, usage and sharing of resources that are already available in different bio-repositories and clinical data warehouse, while providing compliance with subjects’ permissions

**Abstract**

To achieve our research goals, iCONS is composed of four components (Figure 1):

- **Electronic Informed Consent Management System** - A web-based tool to educate the subject during and after consenting to participate in a study. Includes:
  - Multimedia to enhance understanding
  - Follow-up registry to inform the subject how the data are being used and in what research
- **Permission Ontology** - Captures the subject's consent in a machine-interpretable and implementation-independent format
- **Permission Repository** - Saves the subject’s consent, which are expressed in the permission ontology
- **Resource Mediator** - An ontology-based reasoning tool to check compliance with previously granted permissions for sharing clinical data and biorepositories

**Methods**

**Results**

We developed the following components:

- **Electronic Informed Consent Management System** (Figure 2)
  - Tailored for a study for sharing urine, blood and tissue samples (UCSD Moores Cancer Center)
  - Populated with multimedia resources to further educate the subject
- **Permission Ontology**
  - Developed using the Web Ontology Language (OWL)
  - Extends the HL7 Security and Privacy Ontology for healthcare information exchange
  - Tested using consent documents from the VA hospital and Moores Cancer Center
- **Resource Mediator**
  - Tested with patient data and researchers’ resource requests provided by Moores Cancer Center Biorepository

**Future plans**

- Conduct a case-controlled evaluation of the benefits of the electronic informed consent management system vs. paper-based consent forms
- Use the permission ontology (available through NCBO bio-portal) to engage the community on the development of a standard
- Deploy a resource mediator as an eXtensible Access Control Markup Language (XACML) policy engine provided with ontological reasoning mechanisms

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This research was supported by the iDASH NCBC through the NIH Grant U54 HL108460 to the University of California, San Diego.