Refactoring and Expanding the Informed Consent Ontology (ICO)

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The Informed Consent Ontology (ICO) represents the domain of informed consent, including the process of informed consent and related processes (e.g. informing a patient of their rights), the information produced by consent, and the resulting consent powers[1]. Since sensitive materials such as specimens and data change hands across organizations governed by different policies and regulations, tracking the moving parts is critical to consent provenance. Our work addresses the need for ICO to have greater generality and granularity for widespread use as a reference ontology.

To improve this representation, the developers coordinated with the Document Acts Ontology (D-Acts), Ontology for Biobanking (OBIB), the Common Rule Ontology (CRO), and the Data Use Ontology (DUO). D-Acts represents document acts (e.g., signing contracts) and deontic roles (e.g., a role permitting a physician to perform surgery)[2,3]. The Ontology for Biobanking (OBIB) extends the Ontology for Biomedical Investigations (OBI), focusing on annotation terms relevant to biorepositories[4]. CRO represents the US Common Rule[5]. DUO represents consent codes to annotate data with usage permissions[6]. We used common refactoring methods applied in software development whereby code is improved through restructuring while preserving functionality while it is expanded and reevaluated. We reviewed every ICO term, marking for revision or deprecation in a spreadsheet. Use cases tested design flaws and maturity. Coordination with other ontologies promoted interoperability and avoided redundancy. We annotated blank consent forms with classes to show coverage of relevant terms. OWL reasoners, e.g., HermiT, checked for consistency.

ICO's new release is improved for use as a reference ontology. The most general terms were revised in tandem with ontologies being importing in whole (denoted by black arrow in Figure 1) or in part (yellow arrow). Entities too specific for a reference ontology were recast or deprecated. The model of informed consent forms and their parts, e.g., directives, is enhanced. ICO incorporates CRO (purple arrow), enabling better representation of types of regulations across contexts. ICO's new term 'stasis of regulation' is attractive to biobanks interested in tracking inventory over time or in querying when and where regulations are in force. This poster shows hierarchies of ICO and collaborated ontologies, and samples for intended use.
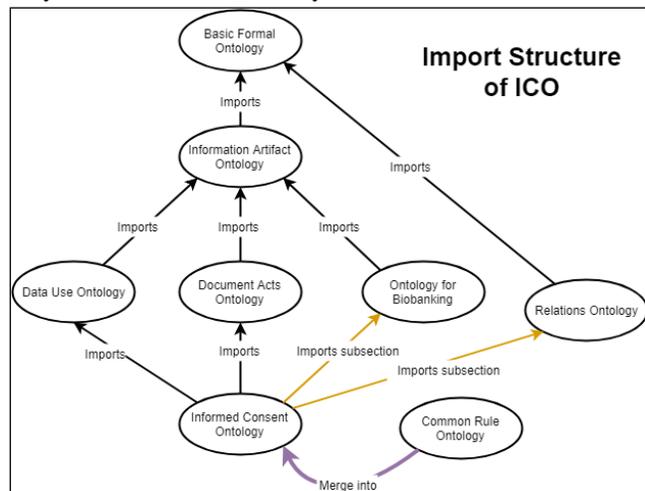

Figure 1. ICO's import structure and integration of CRO

References

1. https://github.com/ICO-ontology/ICO/
2. https://github.com/d-acts/d-acts
3. Almeida, MB, Slaughter, L, Brochhausen, M. Towards an Ontology of Document Acts: Introducing a Document Act Template for Healthcare. In Herrero P, Panetto H, Meersman R, Dillon T (eds.) *On the Move to Meaningful Internet Systems: OTM 2012 Workshops. Lecture Notes in Computer Science*, 2012;7567. Springer, Berlin, Heidelberg.
4. https://github.com/biobanking/biobanking
5. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html
6. https://github.com/EBISPOT/DUO