Coordinated Evolution of Ontologies of Informed Consent

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Abstract

I. The Informed Consent Life Cycle

Informed consent, whether for health or behavioral research or clinical treatment, rests on notions of voluntarism, information disclosure and understanding, and the decision-making capacity of the person providing consent. Whether consent is for research or treatment, informed consent serves as a safeguard for trust that permissions given by the research participant or patient are upheld across the informed consent (IC) lifecycle. The IC lifecycle involves not only documentation of the consent when originally obtained, but actions that require clear communication of permissions from the initial acquisition of data and specimens through handoffs to, for example, secondary researchers, allowing them access to data or biospecimens referenced in the terms of the original consent.

What unifies the informed consent lifecycle is a complex chain of distinct authorizations that flow from a person's consent to a researcher or clinician who operates under rules of specific institutions as well as federal regulations. This flow of authorizations may further pass through the institution's authority derived from its legal authority and the documented consent provided by the person, which may be exercised further in authorizing other institutions and individuals to perform additional actions (such as taking possession of a biospecimen where it may be subject to further restrictions. Throughout this lifecycle, various actions involving patient data or biospecimens derived from the patient are performed, and come under different sets of policy and legal prescriptions as they transferred from one researcher in one institution to another researcher in other institutions or organizations. Some of these prescriptions may hold across wide jurisdictions, as in the case of government policy at the level of national and international governing bodies, while others may be local and locally created, such as directives issued by an institutional review board.

II. Representation and Use

Tracking not only these materials and data sets, their locations, and the changing nature of directives to which their use is subject, is an enormous task for healthcare professionals, researchers, and institutions. Software systems that aid in tracking such entities are piecemeal, and hampered greatly by a lack of representation of the consent life cycle itself. Furthermore, even for those departments and review boards that have good consent tracking resources available to them, there is not a standard for such resources, and so intra-organizational data requires time intensive recoding.

Such a representation could make it easier to:

- access data sets and biospecimens for secondary researchers across institutions;
- organize biospecimens stored within a biorepository and facilitate sharing among repositories;
- query the content of laws, policies, and directives concerning particular consent types; and
- facilitate the study of informed consent processes and patient outcomes across institutions.

Presently, there are a number of consent life cycle tracking software tools, but most of these have been developed for the domain of web platforms that seek to protect user data.[1] These do not address the domain of informed consent within the domain of clinical care and health and behavioral research, and are largely proprietary.

While there are many open-source ontologies that represent informed consent within the domain of clinical care and research, these ontologies often focus on a single part of the consent life cycle, and restrict their representations to rules, codes, and specifications regarding consent, and include no representation of processes [2]. For this reason, they have avoided representing processes of providing consent, processes of transferring a consent power among institutions, and processes of a consent power being revoked—all of which are necessary for tracking consent across the consent lifecycle. In addition, many of these ontologies are built for particular applications that occur in a language parochial to a context of use, and which contain classes and axioms that may be inappropriate in other institutional contexts. Few of these ontologies have adopted a realist approach that is characteristic of reference ontologies [3].

III. The Informed Consent Ontology

In Spring 2018, the collaborators for this project came together to revise and broaden the existing OBO Foundry ontology, the Informed Consent Ontology (ICO), with the goal of harmonizing it to work with a number of related ontologies, including:

- The Document Acts Ontology (D-Acts),
- The Data Use Ontology (DUO), and
- Regulatory Basis for Informed Consent Ontology (RUBRIC).

The goal is to develop the Informed Consent Ontology (ICO) into a reference ontology[2] of the consent life cycle, capable of integrating other ontologies that may represent parts of the informed consent domain at certain stages, but which lack a unified framework for tracking consent across the lifecycle.

This work also includes an extension of D-Acts, which was necessary in order to provide a treatment of deontic roles and deontic power roles. Deontic roles include, for instance, the permission role that inheres in an organization following a patient having provided consent to that organization. Deontic powers are also deontic roles on this account, and are distinguished by being realized in the creation, modification, or revocation of an existing role. On this view, a patient's right to consent and the patient's right to later revoke their consent are deontic power roles, for each either issues a deontic role that inheres in another, or revokes that permission role.

The Data Use Ontology (DUO) is an ontology representing consent codes that label datasets. The hierarchy of consent codes is based upon categories reported in Dyke et al. [4], and the ontology extends this representation by relating them to data restrictions. In revising ICO, part of our goal is also to extend the representation available in DUO, so that it forms part of a shared representation that includes a treatment of deontic roles.

The Regulatory Basis for Informed Consent Ontology (RUBRIC) was originally an ontology of the Common Rule, a U.S. federal policy regarding biomedical and behavioral research for human beings [5]. In this revision, its treatment of rules is broadened within the framework of Basic Formal Ontology (BFO) and the Information Artifact Ontology [IAO]. The goal in further elucidating these rule types in RUBRIC is to render RUBRIC appropriate as a reference ontology for the international context of informed consent regulation. This is achieved in three ways. First, there is further elucidation of the IAO's treatment of rules, policies, laws, and—more broadly—directive information content entities as differentiated by their logical forms (for instance, conditional rules and their parts). Second, we provide a hierarchy of directives further distinguished by the content of these rules (i.e. to what class of actions they apply). Third, we introduce the framework of the document act, as well as a class 'stasis of law', which allows one to say that following a document act (such as the legislative signing of a bill), that a document enters into a stasis of law, whereupon the document has the status of law—a status that may be lost by further legislation or judicial rules.

IV. Summary of the Poster

In this poster, we report on the progress we have made in bringing these ontologies together, our motivations, and the relation to other ontologies, including Basic Formal Ontology (BFO) from which all of these ontologies derive their top-level representation.

In addition, we also provide clear representations of use cases at different stages along the consent life cycle, showing both classes in the ontology, as well as their instances in the use cases. Furthermore, all files, documents, and slides related to the project will be publicly available on GitHub repositories, whose links will be available on the poster.

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References

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