Using Stases to Enrich Queries for When and Where Regulations Are in Force

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Abstract

Ontologies in OWL suffer limitations in time-indexing, yet these difficulties may be overcome with the use of the class 'stasis' in the Common Core Ontologies. The Informed Consent Ontology exemplifies an effective implementation of stases for tracking whether a biospecimen or informed consent process is subject to regulations in the relevant jurisdiction. Other OBO Foundry ontologies may be similarly improved by using stases.

Keywords:

Common Core Ontologies, Stasis, Regulation

Introduction

Ontologies in OWL (Web Ontology Language) inherit limitations in time-indexing that can impact referent tracking. In Basic Formal Ontology (BFO), relations between continuants are three place, holding between two continuants and a temporal region; in the OWL version of BFO, only two place relations are possible and the temporal dimension is often unrepresented. The Common Core Ontologies (CCO) recognize a pattern that aids tracking when relations between continuants hold: such continuants also participate in a stasis of an associate type, where CCO defines 'stasis' as "A Process in which some Independent Continuant endures and one or more of the dependent entities it bears does not change in kind or intensity".[1] Hence, a regulation and the jurisdiction in which it resides both participate in a stasis of regulation that occurs at a particular temporal region.

Here, we showcase how this approach effectively facilitates queries regarding whether, where, and when a regulatory document (e.g., US law, company policy) is in force. Our target case involves highly regulated environments, such as clinical and research contexts, for obtaining consent for procuring, storing, and using biospecimens and associated data, for which biobanks have an urgent need to monitor and track. The Informed Consent Ontology (ICO) [2] enumerates classes we employ to represent the regulatory and policy decisions involved in regulated research, as well as a representation of the permissions that result.

Methods

ICO imports the top-level ontology, Basic Formal Ontology (BFO), as well as the Information Artifact Ontology (IAO), and the Document Acts Ontology (D-Acts). Since BFO is a formal ontology containing only high-level terms, it is suitable for use across domains and facilitates semantic interoperability with other ontologies that import it.[3] IAO is a mid-level ontology that models information entities such as documents, data, and plan specifications.[4] D-Acts is an extension of IAO and represents document acts (e.g. creating obligations through a contract) and deontic roles (e.g., a role based on normative expectations of how the bearer should behave).[5] ICO incorporated components of the Common Rule Ontology (CRO), which represents the US Common Rule,[6] and generalized the classes for international use.

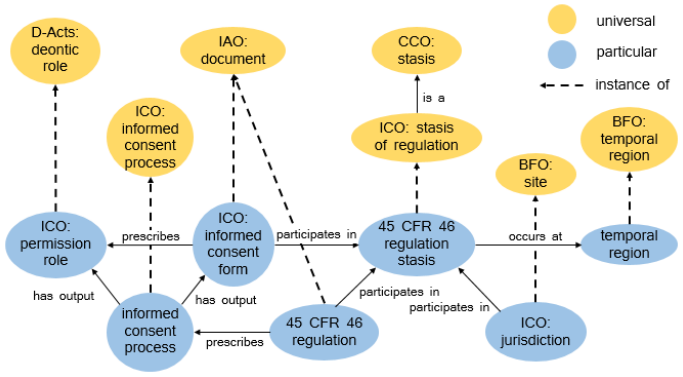

Figure 1 An informed consent form regulated by the Common Rule

Results

Ontologies enriched with stases allow queries for when and where regulations of various kinds of activities hold. We provide sample queries employing of the new classes now available in ICO. Our poster contains: an outline of the relevant entities and their placement in BFO-conformant ontologies, an explanation of the relationships that regulations have to the processes they govern, and some sample queries showing the robustness of our representation which would be impaired without stasis.

Conclusions

We believe this pattern may be generalized and that stases will prove useful to other OBO Foundry ontologies as they deal with the limitations of OWL for temporal reasoning.

Acknowledgements

This work was supported in part by NIH/NHGRI 5U01HG99454 (Tao, PI), and University of Michigan MIDAS data science challenge award (Harris, co-PI).

References

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