Using Stases to Enrich When and Where Regulations are in Force

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Informed Consent Ontology

ICO is an OWL ontology that represents the informed consent process and other entities in the informed consent domain (e.g., consent form, permission role). Across the life cycle of consent, these entities participate in processes occurring in various jurisdictions (sometimes simultaneously) as they are used or stored for research. One target use is tracking biospecimens and related data as they change hands across regulatory frameworks.

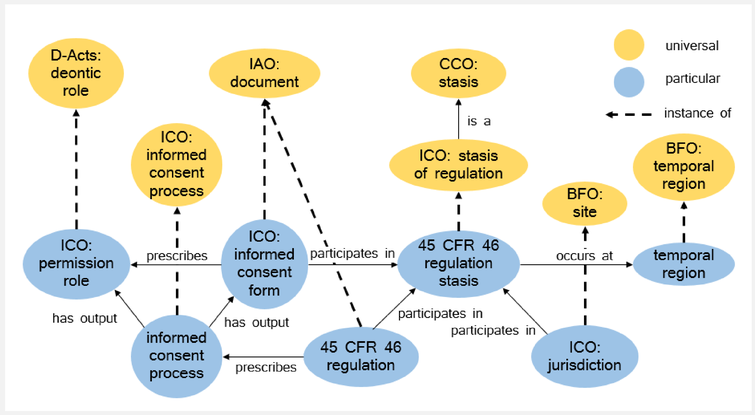

Figure 1. Informed consent process occurring in a stasis of regulation (the US Common Rule, 45 CFR 46) in a particular jurisdiction at a particular time. The relation CCO:*prescribes* holds between a directive and another entity, e.g., a guide for an occurrent, or a model for a continuant.

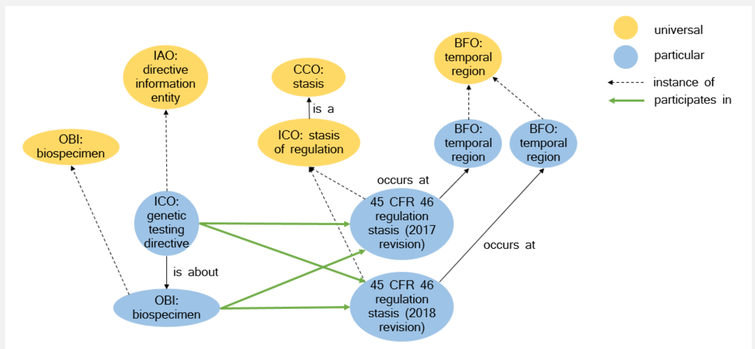

Figure 2. A specimen stored in a biobank is in the purview of one regulation in a ICO:jurisdiction, and in another at a later time (BFO:'temporal region').

The Problem of Changing Regulations

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. This is also the case in spatial regions as well.

For example, an informed consent form may be subject to regulations (IAO:'directive information entity') in a jurisdiction (BFO:site) for a time, yet others later. The representation of which regulation has force at what time and where might not be represented. There may be confusion about what policies are to be followed for some process.

What does CCO 'stasis' provide?

The Common Core Ontologies (CCO) recognize a pattern that enables time-indexing relations between continuants by virtue of their mutual participation another process –namely, a stasis– whereby they both remain unchanged throughout the stasis.

Since OWL is restricted to two place relations, if entities each relate to the same stasis, one may infer additional information. In effect, 'stasis' enables a query to infer the equivalent of a three-place relation. For example, if an informed consent form participates in a stasis, and that stasis occurs at a temporal region, then one may infer that the informed consent form participates at a time.

How 'stasis of regulation' accommodates these concerns

A regulation and the jurisdiction in which it resides both participate in a ICO:'stasis of regulation' that occurs at a particular temporal region. This means that as the time or place changes, one may connect the dots with reference to the stasis, in order to show when and where the directives or policies are in force.

Implications

Utilizing 'stasis' facilitates representation in OWL where three-place relations (e.g., continuant participates in occurrent at time 1). This aids any ontology that would need three place relations, but especially those tracking the status of whether compliance is expected.

Conclusion

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.

Key Class Definitions

CCO: *stasis*
- 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.

ICO: *stasis of regulation*
- A stasis of generically dependent continuant that has participant some information content entity and during which that information content entity is recognized within that jurisdiction and directs governance within that jurisdiction.

ICO: *stasis of law*
- A stasis of regulation that has participant some information content entity and during which that information content entity is recognized as a law within the jurisdiction in which the stasis of regulation is occurring.

ICO: *jurisdiction*
- A site within which a deontic power role may be realized, where that deontic power role inheres in a formally created regulatory body.

D-Acts: *deontic role*
- A role that inheres in an agent and which is externally grounded in the normative expectations that other agents within a social context have concerning how that agent should behave.

ICO: *deontic power role*
- A deontic role that, if realized, is realized in the creation, modification, or revoking of other deontic roles.

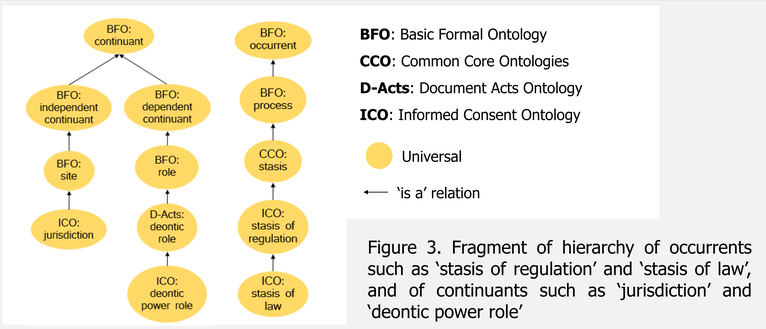

Figure 3. Fragment of hierarchy of occurrents such as 'stasis of regulation' and 'stasis of law', and of continuants such as 'jurisdiction' and 'deontic power role'

Example Query

```
@prefix ico: <http://purl.obolibrary.org/obo/ICO.owl/> .
@prefix obo: <http://purl.obolibrary.org/obo/> .
@prefix rdf: <http://www.w3.org/1999/02/22-rdf-syntax-ns#> .

SELECT ?RegulationOfInformedConsent ?LocationIdentifier ?TemporalRegionIdentifier

WHERE {
      ?RegulationOfInformedConsent rdf:type ico:regulatory_document .
      ?RegulationOfInformedConsent cco:prescribes ?InformedConsentProcess .
      ?InformedConsentProcess rdf:type ico:informedConsentProcess .
      ?RegulationOfInformedConsent obo:participates_in ico:stasis_of_regulation .
      ico:stasis_of_regulation obo:exists_at ico:jurisdiction .
      ?LocationIdentifier iao:designates ico:jurisdiction .
      ico:stasis_of_regulation obo:exists_at bfo:temporal_region .
      ?TemporalRegionIdentifier iao:designates bfo:temporal_region .
      }
```

ONTOLOGY PROJECT FILE LOCATIONS:

Informed Consent Ontology: https://github.com/ICO-ontology/ICO

Document Acts Ontology: https://github.com/d-acts/d-acts

Common Core Ontologies: https://github.com/CommonCoreOntology/CommonCoreOntologies

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