

# Enhancing Data Use Ontology (DUO) for Health-Data Sharing by Extending it with ODRL and DPV

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**Abstract.** The Global Alliance for Genomics and Health is an international consortium that is developing the Data Use Ontology (DUO) as a standard providing machine-readable codes for automation in data discovery and responsible sharing of genomics data. DUO concepts, which are encoded using OWL classes, only contain only the textual descriptions of regarding the conditions for data use they represent, and do not specify the intended permissions, prohibitions, and obligations explicitly - which limits their usefulness in automated systems. We present an exploration of how use of the Open Digital Rights Language (ODRL) can be used to explicitly represent the information inherent in DUO concepts make these conditions explicit as rules, and combine them to create policies that can be attached to that are then used to represent conditions under which datasets are available for use, conditions in requests to use them, and to generate agreements based on a compatibility matching between the two and used to identify compatibility with a data request. We also address a current limitation of DUO regarding specifying information To associate the use of DUO and the ODRL policies with concepts relevant to privacy and data protection law by using the, we use the Data Privacy Vocabulary (DPV) which supports expressing legal concepts. Through this, we show how policies can be declared in a jurisdiction-agnostic manner as well as, and extended as needed for specific laws like the GDPR. Our work supports the existing acknowledges the socio-technical governance processes involving use of importance of DUO by providing a, and therefore is intended to be complementary complimentary to it rather than a replacement approach. To support this and improve assist in the improvement of DUO, we provide a description of how our system can be deployed with a proof of concept demonstration that uses provide ODRL rules for all DUO of its concepts, and uses them to generate agreements through matching of requests to data offers an implementation of the matching algorithm, and a demonstration showing it in practice. All resources described in this article are available at: <https://w3id.org/duodrl/repo>.

Keywords: health data, biomedical ontologies, policy, regulatory compliance, GDPR

## 1. Introduction

### 1.1. Background & Motivation

The sharing of health-related data holds great promise for enhancing research and applying advanced computational and statistical techniques for progress in medicine. At the same time, such sharing and use of health-related

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1 data is required to be regulated at legal and institutional levels given its sensitive nature and the ability to have significant impacts. The current landscape consists of institutions such as hospitals assessing each data use request through  
2 a dedicated committee that is responsible for the evaluation and decision making regarding the release of data under  
3 their custody. To assist in this process, the Global Alliance for Genomics and Health<sup>1</sup> (GA4GH) was formed as  
4 an international consortium for developing standards and responsibly sharing genomics data. Of its various initia-  
5 tives addressing different components and processes involved in data sharing, it has developed a machine-readable  
6 ontology called Data Use Ontology<sup>2</sup> (DUO) [1, 2] for expressing “Data Use Limitations” (DUL) – conditions and  
7 constraints expressed by data providers and adhered to by requestors.

8  
9 DUO is an OWL ontology based on (and part of) Open Biological and Biomedical Ontology<sup>3</sup> (OBO). Through the  
10 use of OBO upper ontologies and guidelines, DUO offers (semantic) interoperability with a variety of biomedical  
11 ontologies part of the OBO family. The intended use of DUO is to annotate datasets with DUL codes to indicate  
12 usage conditions, expressing data use requests, and identifying or discovering compatible datasets automatically by  
13 comparing the request with dataset specific DULs. More information about DUO is provided in Section.2.1.

14 DUO concepts specify the DULs as human-readable text within their description (using the `obo:IAO_0000115`  
15 relation), which restricts their usefulness to humans or explicitly encoded systems that can only function on known  
16 concepts. In addition, DUO concepts are not linked to relevant legal concepts, which creates confusion and am-  
17 biguity as to the implications of using these in a system or jurisdiction such as the EU where the General Data  
18 Protection Regulation (GDPR) [3] introduces additional accountability and compliance requirements which must  
19 be identified and applied. The existing documentation notes that the applicability of laws is the responsibility of the  
20 adopter, and that DUO terms have not been considered for implications under the the GDPR. However, compatibility  
21 with existing regulations is an important and mandatory requirement which each adopter and data user must fulfil,  
22 and where the lack of support from the specification risks harming the interoperability through fragmentation in  
23 approaches. Additionally, for future endeavours, especially since the EU envisions a ‘Health Data Space’<sup>4</sup> where  
24 machine-readability and automation will play an important role in facilitating the exchange of data without prejudice  
25 to existing regulations such as the GDPR.

## 26 27 1.2. Research Objectives and Contributions

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29 Our argument is that *true machine-readability* requires the information intended to be conveyed through DUO  
30 concepts about the specific permissions, prohibitions, constraints, requirements, and so on to be (also) represented as  
31 machine-readable *rules* that utilise semantic concepts. With this, the DULs inherent in the descriptions of each DUO  
32 concept are made explicit through formal representation as a set of *rules* that can be attached and used alongside the  
33 data as a *sticky policy*.

34 For assessing whether a data use request is compatible with the dataset DULs, both data provider’s and requestor’s  
35 ~~set and request~~ conditions for data use are expressed as policies, and are compared to evaluate whether the intended  
36 use is permissible ~~dataset policy’s rules are satisfied by the request policy~~. While DUO is already being used in this  
37 manner, such as within the Data Use Oversight System<sup>5</sup> (DUOS), this is done by checking hierarchical compatibility  
38 between request concepts and data use conditions through subclass relations between concepts. This approach is  
39 limited in ability and expressiveness for specifying rules and their use in automated systems as not all relevant  
40 information can be explicitly represented.

41 More importantly, to automate this process, a set of requirements should be taken into consideration when choos-  
42 ing a vocabulary to express dataset usage conditions, such as: (i) the expressiveness for defining it ~~does not take~~  
43 ~~advantage of existing research and functional solutions for expressing~~ specifics of rules and policies, i.e., the speci-  
44 fication of actions, purposes, or other constraints as concepts that can be independently expressed and assessed, and  
45 their combinations to represent different categories of policies; (ii) the ability to associate and check, ~~for checking~~

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48 <sup>1</sup><https://www.ga4gh.org/>

49 <sup>2</sup><http://purl.obolibrary.org/obo/duo>

50 <sup>3</sup><https://obofoundry.org/> The prefix `obo` has the IRI <http://purl.obolibrary.org/obo/>

51 <sup>4</sup>[https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space\\_en](https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en)

<sup>5</sup><https://duos.broadinstitute.org/>

their conformance and compliance with legal requirements; and (iii), ~~and~~ the ability to specify requirements in machine-readable form and use them to assess correctness and completeness of information ~~have mathematical guarantees regarding correctness and consistency~~. Such solutions have existed for a while now – for example Answer Set Programming (ASP) ~~the use of~~ logic-based semantic reasoners, ~~and~~ have been utilised in a variety of domains – including for ~~representing information and using it for checking~~ legal compliance ~~forwith the~~ GDPR (see Section.2.2).

With the above motivation, we present an approach for representing the inherent information and rules in DUO concepts explicitly in RDF through use of the Open Digital Rights Language<sup>6</sup> (ODRL) [4] ~~it is the W3C standard developed explicitly to model rules and policies and also concerns the intended requirements for which DUO was created~~. We specifically chose ODRL because: (i) ~~it is a standard developed explicitly to model rules and policies;~~ (ii) it uses RDF and is machine-readable; (ii) ~~it provides concepts modelling the domain-specific and legally-relevant terms can be used~~ to represent constraints - e.g. spatial and temporal, and types of policies - e.g. offers, requests and ~~or~~ agreements, along with the flexibility to use them in similar manner as the conventional contents and structures of legal agreements; (iii) the use of ODRL can be validated<sup>7</sup> and a formal semantics specification<sup>8</sup> is being actively developed by the W3C ODRL Community Group (ODRL CG)<sup>9</sup> to ensure correctness and consistency on the deployments of services that use ODRL; (iv) ~~its terms are aligned with legal vocabularies~~ the specification provides the ability to develop extensions through ODRL profiles<sup>10</sup>; and (iv) ~~its use can be limited to declaration of information (e.g. what rules apply) or also for their validations and conformance checking (i.e. using an ODRL validator~~.

In addition to these, we also consider ODRL the most suitable candidate for representing DUO concepts as it can be used without requiring any of the existing DUO-based data use or request governance processes to make radical and incompatible changes. That is, the existing practices and processes by which DUO codes are added as annotations to datasets and are used to request access to them can continue without hindrance, and ~~DUO stakeholders~~ can choose which aspects of our ODRL solution they want to adopt within their practices.

ODRL, by modelling terms regarding rights and licensing, also offers a compatible segue for DUO to be linked with relevant legal concepts, ~~for which we use~~ ~~We further enhance these through use of~~ the Data Privacy Vocabulary<sup>11</sup> (DPV) [5], an output of the W3C Data Privacy Vocabularies and Controls Community Group<sup>12,13</sup> (DPVCG). DPV provides an extensive vocabulary of concepts, can be expanded or specialised for jurisdictional requirements, provides legal bases and rights – including from GDPR, is open and accessible, and can be easily integrated into DUO's use-cases.

The contributions of this work are summarised through the following research objectives:

- RO1** Specifying DUO concepts and conditions for data use as machine-readable policies using ODRL
- RO2** Developing an algorithm for consolidating data use conditions into a single ODRL policy
- RO3** Developing an algorithm for identifying compatible datasets with data use requests based on ODRL policies
- RO4** Enabling expression of legal concepts and restrictions with(in) ODRL policies for DUO concepts using DPV
- RO5** Elucidating relevance of DUO concepts and associated ODRL+DPV policies for GDPR obligations

The rest of this article presents: an overview of DUO and its applications in Section.2.1, relevant work in state of the art regarding machine-readable policies for GDPR in Section.2.2, our use of ODRL to represent DUO concepts and perform matching with requests in Section.3, expression of legal concepts using DPV in Section.4, a demonstration through proof-of-concept in Section.5, a discussion on integrating this work into existing DUO-based workflows in Section.6, and concluding statements in Section.7.

<sup>6</sup><https://www.w3.org/TR/odrl-vocab/> The prefix `odrl` has the IRI <http://www.w3.org/ns/odrl/2/>

<sup>7</sup>Implementation of a ODRL validator using SHACL available at <https://odrlapi.appspot.com/>.

<sup>8</sup>ODRL Formal Semantics CG report available at <https://w3c.github.io/odrl/formal-semantics/>.

<sup>9</sup>Note: The author (Beatriz Esteves) is a contributing member of the ODRL CG's work on development of a formal semantics specification.

<sup>10</sup>ODRL Profile Best Practices CG report available at <https://w3c.github.io/odrl/profile-bp/>.

<sup>11</sup><https://w3id.org/dpv> The prefix `dpv` has the IRI <https://w3id.org/dpv#>

<sup>12</sup><https://www.w3.org/community/dpvcg/>

<sup>13</sup>Note: Both authors are active contributing members to DPV

## 2. Relevant Work and State of the Art

### 2.1. Data Use Ontology (DUO) and Aligned Efforts

DUO concepts are structured across three taxonomies. The *Data Use Permission* taxonomy, with base class `obo:DUO_0000001`, represents permissions for purposes regarding data use. The *Data Use Modifier* taxonomy, with base class `obo:DUO_0000017`, represents 'modifiers' or conditions to be applied in addition to permissions. The *Investigation* taxonomy, with base class `obo:OBI_0000066` from the Ontology for Biomedical Investigations<sup>14</sup> (OBI), represents 'investigations' or planned processes for which the data is requested for use. Along with these, the concept `obo:DUO_0000010` represents the relation *is\_restricted\_to* which is used to restrict or scope specific concepts to some context, for example with domain as `obo:DUO_0000022` representing limitation on use within a geographic region, and range as `obo:GAZ_00000448` from the Gazetteer<sup>15</sup> (places) ontology.

DUO is the result of earlier efforts to create codes regarding data use, and use them as machine-readable information towards automation. The first iteration was based on Consent Codes [6] which provided concepts representing permission to use data. The second iteration adopted some terms from the Automatable Discovery and Access Matrix<sup>16</sup> (ADA-M) [7] framework which has similar aims and concepts. The use of DUO as intended towards collection of consent for dataset sharing and reuse is specified in the 'Machine-readable Consent Guidance'<sup>17</sup>. A brief outline and summary of DUO and its use to streamline access to biomedical datasets is presented in [1], and a list of GA4GH initiatives and standards along with relevance of DUO within those is presented in [2].

The Data Use Oversight System<sup>18</sup> (DUOS) is a platform based on DUO that provides semi-automated data access management for use of datasets. It uses DUO annotations for adding new datasets and in data access requests, which are then matched using an algorithm based on hierarchical compatibility i.e. permitted conditions identified based on establishing subclass relations between request and dataset DUO codes. The output of the matching process is then used as part of a review by a 'Data Access Committee' (DAC). An evaluation of DUOS's automation process found it to be comparable to decision making by human data access committees [8]. DUOS is currently being implemented in an ongoing large scale pilot [9].

Other uses of DUO include specification of informed consent for health and genomics research in Africa [10], along with ADA-M for representing consent for health data sharing in a blockchain [11], and in CTRL [12] - an online platform that uses DUO to provide dynamic consent interfaces and tools for large-scale genomics research programs. Potential uses of DUO are described in the Data Tags Suite (DATS) [13] where DUO is a candidate vocabulary in its framework for discovering data access based on metadata, and as part of a roadmap for accessing 1 million human genomes across EU infrastructures [14]. We found only one article that provided a machine-readable metadata representation of information using DUO - which used SWRL<sup>19</sup> to express the rules [15]. Further overview of DUO and its relevant approaches amongst other rights and licensing initiatives, approaches, and tools for health data sharing is provided by Grabus and Greenberg [16].

Of note in these identified articles and other resources is that we did not find a clear example or workflow for how the machine-readability of DUO should be associated with datasets, expressed as part of a request, or how the matching algorithm should function. The article presenting DATS [13] also refers to this difficulty in establishing the permissions and prohibitions when using DUO, and mentions ODRL as an alternative model providing clearer expression of permissions and prohibitions. The DUOS framework offers the best (available) description for how DUO can be applied, but does not offer much guidance on how the matching is performed between datasets and requests annotated with DUO concepts. From these, we establish the necessity of providing *RO1*, *RO2*, and *RO3*.

<sup>14</sup><http://obi-ontology.org/>

<sup>15</sup><https://environmentontology.github.io/gaz/>

<sup>16</sup><https://www.ga4gh.org/genomic-data-toolkit/regulatory-ethics-toolkit/>

<sup>17</sup>[https://www.ga4gh.org/wp-content/uploads/Machine-readable-Consent-Guidance\\_6JUL2020-1.pdf](https://www.ga4gh.org/wp-content/uploads/Machine-readable-Consent-Guidance_6JUL2020-1.pdf)

<sup>18</sup><https://duos.broadinstitute.org/>

<sup>19</sup><https://www.w3.org/Submission/SWRL/>

## 2.2. Expression of Machine-readable Information and Policies for GDPR

Given that health data ~~is may be regarded as~~ personal data, it is subject to regulations such as the GDPR as well as other domain and sector specific laws such as Health Insurance Portability and Accountability Act<sup>20</sup> (HIPAA). By also annotating datasets with machine-readable metadata that relates to such laws, automation can also be used to assist stakeholders in identifying and meeting their compliance requirements [17].

In this, the state of the art consists of substantial research and development in modelling and using legal ontologies (see survey by Rodrigues et al. [18]). Of note regarding the matching of DUO dataset annotations is the policy checking algorithm for GDPR developed by SPECIAL H2020 project [19] which offers a fast matching algorithm based on subsumption between OWL2 concepts with logical consistency and correctness guarantees. In principle, this is similar to DUOS's matching algorithm where the concepts to be matched in a policy are pre-determined.

While ODRL, being a standard for expressing policies, provides concepts with legal interpretation (e.g. *Asset* or *Party*), it deviates from or does not contain terms such as *Controller* or *Legal Basis* which carry important obligations under regulations such as the GDPR. Vos et al. address this by extending ODRL as a 'Regulatory Compliance Profile' which is used for expressing policies associated with GDPR [20]. In this, the relevant concepts in ODRL are extended with those from GDPR to construct ODRL rules reflecting GDPR's compliance requirements. In approaches providing a vocabulary for use regarding GDPR, GDPRtEXT [21] provides vocabulary of concepts, and GConsent [22] provides an OWL2 modelling of consent information. While these approaches are illuminating in how to describe GDPR's requirements, their use would restrict the created policies to be operationally limited for application under GDPR.

In contrast to these, the Data Privacy Vocabulary (DPV) [5] provides a taxonomy of concepts which can be used as jurisdiction-agnostic terms with an extension for specific concepts from GDPR<sup>21</sup> such as its legal bases and rights. DPV is, to our knowledge, the most comprehensive vocabulary for modelling concepts associated with privacy and data protection laws. It also offers different semantic serialisations (i.e. SKOS, RDFS, OWL) which facilitate integration into use-cases.

Two recent surveys provide an overview of existing efforts that have utilised semantic web technologies to address GDPR compliance. The first, by Kurteva et al. [23], describes the approaches associated with consent, and the second, by Esteves and Rodrigues-Doncel [24], analyses ontologies and policy languages for modelling information flows. Both highlight the variety of approaches available, and offer opinionated suggestions regarding use of ODRL and DPV – which we have incorporated in our choice of implementations<sup>22</sup>. Based on ~~on~~ these identified works and existing surveys, we chose ODRL and DPV to create jurisdiction-agnostic policies that can be specialised for GDPR, thus addressing *RO4* and *RO5*.

## 3. Rewriting DUO using ODRL

As presented in Section.2.1, DUO concepts are structured across three taxonomies with textual description of the DULs they represent. The goals of this work, in terms of research objective *RO1* is to analyse this implicit information and express it explicitly using ODRL, with the additional goal of keeping compatibility with existing uses and workflows that use DUO so as to not cause large disruptions to GA4GH's current and future activities.

We consider DUO's primary attractiveness to be the ease with which its concepts can be easily constructed from input mechanisms (such as a form) and simply 'tagged' onto a dataset as an annotation. In this, the textual clauses used to describe the concepts are based on well-defined clauses from consent forms<sup>18</sup>. The role of ODRL, therefore, is not to replace DUO, but to provide additional machine-readable information for each DUO concept that provides explicit conditions currently inherent in the textual clauses i.e. as ~~conditionsrules~~ that can be checked, verified, and consumed in an automated manner ~~to perform tasks associated with validation of dataset policies, querying to~~

<sup>20</sup><https://www.govinfo.gov/link/plaw/104/public/191?link-type=html>

<sup>21</sup>DPV-GDPR: GDPR Extension for DPV <https://w3id.org/dpv/dpv-gdpr>

<sup>22</sup>It would be prudent to point out that while both authors of this paper are also authors on the cited surveys, the justification offered here is that these prior efforts provide clear evidence on the strengths of choices made in our implementations.

discover suitable datasets, and to aid in matching requests with available data and its usage conditions. We also considered the contextual cases for representing additional conditions or information requirements such as records-keeping by institutions or for legal compliance, for which ODRL is also suitable as highlighted in our motivation.

Our methodology in this was to ~~To do this, we~~ first analysed ~~deleted~~ DUO concepts and ~~performed a manual alignment of the~~ textual information to identify their relevant representation ~~as with~~ ODRL concepts. We then constructed rules expressing identified conditions and expressed them using ODRL along with identifying three categories of ‘policies’ from GA4GH’s cases reflecting data usage, data request, and an agreement based on compatibility between the two. We then constructed a matching algorithm that utilised developed ODRL policies to compare a request policy with a dataset’s policy to determine compatibility and to create an agreement where both were found to be compatible.

### 3.1. Identifying ODRL equivalents for DUO concepts

For each concept in DUO, we first sought to identify the constraints or conditions by interpreting the textual description and identifying whether it related to a permission, prohibition, or obligation, and the specific context of how those are to be applied. In doing this, we observed duplicity and overlap between DUO’s data use permissions and modifiers as both contained *purpose-based conditions* without a clear distinction between their semantics and interpretation, and regarding permission or prohibition of that purpose as an indication of *consent*. For example, DUO\_0000011 represents permission and DUO\_0000044 represents prohibition for “population origins or ancestry research”, with the former being a data use permission and the latter a data use modifier.

We suggest restructuring the taxonomies in DUO to address this by considering a single purpose-based taxonomy specifying research concepts that either have variants for permission and prohibition (i.e. two distinct concepts), or to explicitly provide a data use modifier concept representing permission or prohibition that is applied over a specified research purpose. This is based on DUOS’s data collection input forms and ADA-M’s concepts where each research purpose can be individually consented (or restricted) to, with possible implications arising from lack of any permission or prohibition. For example, the DUO concept for code HMB should be expressed in terms of it being a *permission for purpose* of type HMB which is also not a purpose of type POA. In this manner, the concept (HMB) is better expressed and applied by exposing its underlying concepts (*purpose*) and rules over it (*permission*). See Section 3.3 for more examples of using semantic concepts to represent implicit information in DUO codes, and DPV [5] for for additional taxonomies and concepts available to further specify relevant information.

After analysing DUO’s concepts and identifying inherent conditions, we formulated the relevant ODRL rules for expressing those conditions. Where this was not possible because of ODRL lacking the required concept, we created proposed extensions of its concepts to enable rule expressions. For each concept, we constructed an `odrl:Set` instance representing the specific rules (see Section.3.2), and consolidated these rules into an `odrl:Offer` representing a collective singular policy for a dataset (see Section.3.3). A complete collection of the interpretations made for each DUO concept is presented in Table 1.

Table 1  
Interpretation of conditions inherent in DUO concept descriptions as ODRL rules

| Concept    | Code                       | Rule Type   | Constraint  | Placeholder          |
|------------|----------------------------|-------------|---|----------------------|
| DUO0000001 | <b>Data Use Permission</b> |             |   |                      |
| DUO0000042 | GRU                        | Permission  | Purpose is :GRU   |                      |
| DUO0000006 | HMB                        | Permission  | Purpose is :HMB and not :POA  |                      |
| DUO0000007 | DS                         | Permission  | Purpose is :DS and mondo:0000001  | :TemplateDisease     |
| DUO0000004 | NRES                       | Permission  | Purpose is odrl:Purpose   |                      |
| DUO0000011 | POA                        | Permission  | Purpose is :POA   |                      |
| DUO0000011 | POA                        | Prohibition | Purpose is not :POA   |                      |
| DUO0000017 | <b>Data Use Modified</b>   |             |   |                      |
| DUO0000043 | CC                         | Permission  | Purpose is :CC  |                      |
| DUO0000020 | COL                        | Duty        | Action is :CollaborateWithStudyPI: <del>COL</del>   |                      |
| DUO0000021 | IRB                        | Duty        | Action is :ProvideEthicalApproval: <del>IRB</del>   |                      |
| DUO0000016 | GSO                        | Permission  | Purpose is :GS or :GSG:GeneticStudies   |                      |
| DUO0000016 | GSO                        | Prohibition | Purpose is :GS and not :GSG:PhenotypeResearch and not :GeneticStudies   |                      |
| DUO0000022 | GS                         | Permission  | Spatial is equal to specified :Location   | :TemplateLocation    |
| DUO0000022 | GS                         | Permission  | Spatial is not equal to specified :Location   | :TemplateLocation    |
| DUO0000028 | IS                         | Permission  | Assignee is :ApprovedInstitution  | :TemplateInstitution |
| DUO0000028 | IS                         | Prohibition | Assignee is not :ApprovedInstitution  | :TemplateInstitution |
| DUO0000015 | NMDS                       | Prohibition | Purpose is :MDS   |                      |
| DUO0000018 | NPUNCU                     | Permission  | Assignee is :NonProfitOrganisation: <del>NotForProfitOrg</del> and Purpose is :NCU: <del>NotForProfit</del>     |                      |
| DUO0000018 | NPUNCU                     | Prohibition | Assignee is :ForProfitOrganisation and Purpose is :NCU  |                      |
| DUO0000018 | NPUNCU                     | Prohibition | Assignee is :NonProfitOrganisation: <del>NotForProfitOrg</del> and Purpose is not :NCU: <del>NotForProfit</del> |                      |
| DUO0000046 | NCU                        | Permission  | Purpose is :NCU: <del>NotForProfit</del>  |                      |
| DUO0000046 | NCU                        | Prohibition | Purpose is not :NCU: <del>NotForProfit</del>  |                      |
| DUO0000045 | NPU                        | Permission  | Assignee is :NonProfitOrganisation: <del>NotForProfitOrg</del>  |                      |
| DUO0000045 | NPU                        | Prohibition | Assignee is :ForProfitOrganisationnot : <del>NotForProfitOrg</del>  |                      |
| DUO0000044 | NPOA                       | Prohibition | Purpose is <del>not</del> :POA  |                      |
| DUO0000027 | PS                         | Permission  | Project is :ApprovedProject   | :TemplateProject     |
| DUO0000027 | PS                         | Prohibition | Project is not :ApprovedProject   | :TemplateProject     |
| DUO0000024 | MOR                        | Duty        | Action is odrl:distribute :ResultsOfStudies with odrl:dateTime  | :TemplateDateTime    |
| DUO0000019 | PUB                        | Duty        | Action is odrl:distribute :ResultsOfStudies   |                      |
| DUO0000012 | RS                         | Permission  | Purpose is specified :Research  | :TemplateResearch    |
| DUO0000012 | RS                         | Prohibition | Purpose is not specified :Research  | :TemplateResearch    |
| DUO0000029 | RTN                        | Duty        | Action is :ReturnDerivedOrEnrichedData  |                      |
| DUO0000025 | TS                         | Permission  | Time is less than specified :TemplateDateTime   | :TemplateDateTime    |
| DUO0000026 | US                         | Permission  | Assignee is :ApprovedUser   | :TemplateUser        |
| DUO0000026 | US                         | Prohibition | Assignee is not :ApprovedUser   | :TemplateUser        |
| OBI0000066 | <b>Data Use Permission</b> |             |   |                      |
| DUO0000034 |                            | Permission  | Purpose is :AgeCategoryResearch for specified age categories  | :TemplateAgeCategory |
| DUO0000033 |                            | Permission  | Purpose is :POA   |                      |
| DUO0000037 |                            | Permission  | Purpose is :HMB   |                      |
| DUO0000040 |                            | Permission  | Purpose is :DS and mondo:0000001  | :TemplateDisease     |
| DUO0000039 |                            | Permission  | Purpose is :DrugDevelopment   |                      |
| DUO0000038 |                            | Permission  | Purpose is :GSG:GeneticStudies  |                      |
| DUO0000035 |                            | Permission  | Purpose is :GenderCategoryResearch for specified categories   | :TemplateGender      |
| DUO0000031 |                            | Permission  | Purpose is :MDS   |                      |
| DUO0000032 |                            | Permission  | Purpose is :PopulationGroupResearch for specified population  | :TemplatePopulation  |
| DUO0000036 |                            | Permission  | Purpose is :ResearchControl   |                      |

We faced challenges in interpreting specific phrases such as “*is limited to*” which imply that usage is permitted ~~within and~~ only within that specific scope. If this interpretation is correct, then DUO should clarify how potential conflicts should be resolved, for example between rules expressing exclusive limitations and other permissive expressions (e.g. “*is allowed for*”). Our suggestion is to take advantage of ODRL’s ability to express these rules as code through which it can ~~explicitly express the underlying concepts and how they are applied to create permissions, prohibitions, and obligations, and then using existing methods for ODRL [20, 25] and OWL [19] to reason over them. identify when a given collection of rules associated with a single dataset are contradictory or impossible to satisfy, e.g. by checking the satisfiability of a policy against itself.~~

Currently, DUO concepts are limited to representing conditions for data use, with suggestions referring to external ontologies for additional concepts required for expressing scope or restrictions. For example, `DUO_0000007` represents permission for disease-specific research, with recommendation to use MONDO ontology<sup>23</sup> for specifying diseases. Other specific concepts mentioned in the textual descriptions but not modelled explicitly include codes inherited from predecessors, such as *CC* for Clinical Care Use, or *GRU* for General Research Use. Expressing ODRL rules requires these concepts to be explicitly defined e.g. as *Disease* for the disease-specific research, upon which permissions or prohibitions are then expressed.

For our implementation, we identified and collected such ‘missing terms’ into an ad-hoc vocabulary to permit ODRL rules to be expressed correctly for each DUO concept. We recommend DUO to adopt these or to create a similar vocabulary for explicitly providing the concepts and their descriptions separate from the data use conditions in which they are used. This also has the added advantage of providing better documentation of information represented by those concepts. For e.g. by modelling *IRB* as a concept representing Ethics Review Board approval, it is possible to add information about what processes and requirements are needed in such reviews. It also permits further rules pertaining to ethics approvals to be semantically associated with a base concept, e.g. to indicate it must be carried out prior to data use, or periodically, or before publishing any outcomes.

For data use requests (specified as *investigations* in DUO), we again found duplicity with concepts in data use permission and data modifiers. For example, `DUO_0000040` represents a request and `DUO_0000007` represents a permission for research for specific diseases. Semantically, both refer to the same concept regarding ‘research for specific diseases’, with the distinction of one being a request and the other being a permission. Similar to the earlier suggestion on reorganisation of DUO’s taxonomies to be based on research purposes, we also recommend applying the same approach for consistency in concepts used for requesting use of data. Doing so permits clarity, reduces disambiguity, and assists in matching as the same concept would be associated with a dataset using `odrl:Offer` and a request using `odrl:Request` (see Section. 3.4).

Apart from the expression of conditions for data use and requests to use that data, DUO concepts also have applications in *recording* the outcomes of matching processes where access has been granted. This is an important and yet unexplored area in the currently identified uses of DUO, especially since any sharing of data would be expected to be accompanied with information about the entities involved, provenance associated with grant process, and details regarding how the conditions have been met at the time or later in the future. We present how ODRL is useful in representing this information as instances of `odrl:Agreement` (see Section. 3.5) which can contain all the above information, and also be used in automated approaches that can periodically check if the pending conditions for an agreement have been met, e.g. fulfilment of publishing results.

### 3.2. Data use restrictions as `odrl:Set`

Each DUO restriction is represented as an instance of `odrl:Set`, which must contain at least one permission, prohibition, or duty, and one resource (here a dataset) to be a valid ODRL policy. Its use does not grant any access or privileges, and only represents a collection or *set* or rules ~~that are indicated as being applicable~~ over the resource.

Interpreting the textual descriptions accompanying each DUO concept, we used `odrl:permission` when the condition granted access to data, `odrl:prohibition` when it denied access, and `odrl:duty` when it specified obligations to be fulfilled. We included DUO’s textual descriptions using `rdfs:comment` for convenience, and indicated association with the DUO concept using `dct:source`.

<sup>23</sup><https://obofoundry.org/ontology/mondo>



It was challenging for us to construct a valid policy which required specifying the resource (dataset), because DUO concepts only represent abstract conditions that don't relate to a specific dataset. DUO also does not specify how to indicate or identify values associated with conditions such as specific diseases or temporal duration. To ensure ODRL policies are always valid, and to clearly indicate how to later apply or *instantiate* them for a dataset, we created the class `TemplateQuery` whose instances represent a placeholder to be substituted with the actual value(s) retrieved by executing a SPARQL query associated with it through the property `sparqlExpression`. In Table.1 these are indicated as *Placeholder*. To apply queries over the specific context, the variable `?dataset` is replaced with the IRI of the dataset whose policy is being generated, and `?this` is replaced with the IRI of placeholder instance. For associating datasets, the instance `TemplateDataset` with the SPARQL query `SELECT ?dataset WHERE { ?dataset o ?p }` is used. We also defined placeholders for other restrictions, for example the instance `TemplateDisease` for use in disease-specific restrictions with the SPARQL query `SELECT ?disease WHERE { ?this obo:DUO_0000010 ?disease }`. Examples of this can be seen in Listing 3 for a `odrl:Set` representing a DUO permission which is then used in a request. The placeholders are used to indicate datasets and assignee's which are not known ahead of time, and which are substituted with actual instances in real policies by using the SPARQL queries associated with each placeholder.

Another challenge we faced was for indication of scoped restrictions e.g. specifying the location when use is limited to a geographic location. DUO contains the property `obo:DUO_0000010` that describes the relation `is_restricted_to` which we interpret as intending to be used to specify the specific values or instances, e.g. diseases or locations, such as scopes in restrictions. However, DUO concept descriptions only state "this should be coupled with an ontology term describing the (concept) the restriction applies to", and we could not find an example showing how it should be used in this manner. Further, ODRL requires all constraints to be specified directly over the *Asset* (i.e. dataset). Therefore even if this property were available, its use would complicate the expression of rules in ODRL.

We discussed possible solutions to this, and identified four potential avenues: (i) use of OWL class expressions<sup>24</sup>; (ii) use of SHACL shapes to indicate a constraint; (iii) creating a new ODRL mechanism that takes property paths as *Operand*; and (iv) declaring the concept directly as an instance of the scoping concept (e.g. for disease-specific restriction, the concept would be an instance of the appropriate DUO class as well as the disease class). Each of these have a bearing on how a condition is expressed, and on the performance and capability of matching processes for comparing two policies. For example, use of (i) would require executing an OWL2 reasoner prior to the matching process, and (ii) would require a SHACL validator. In our implementation, we used (iv) by declaring the concept as an instance of both DUO and scoping classes as it was the simplest method, did not require any additional tools or changes to ODRL, and could be replaced trivially with a different method in the future. However, we explicitly indicate this issue as requiring further investigation. The `odrl:Set` defined to represent DUO's concept on "population origins or ancestry research only" is presented in Listing 1.

### 3.3. Dataset policies as `odrl:Offer`

When using DUO concepts to annotate datasets, each dataset can contain multiple DUO concepts that must be interpreted in combination as an offer for using that dataset. This is expressed in ODRL as an instance of `odrl:Offer` containing the union of all `odrl:Set` instances associated with DUO concepts for a given dataset. In doing this, the *Offer* represents a single policy for that dataset that can be used in matching requests, or embedded as metadata to form a *sticky policy*. When creating offers, each individual rule retrieved from the merged set policies is maintained (as an individual rule) to facilitate the matching process with rules from data use requests. This also facilitates potential annotations for rules, such as specifying their provenance or adding additional information for their interpretation within that offer. An example `odrl:Offer`, which merges `:DUO_0000042`, `:DUO_0000025` and `:DUO_0000020`, is presented in Listing 2.

The construction of the `odrl:Offer` instance uses the following algorithm:

1. For a given dataset, retrieve all DUO data use permissions and modifier concepts it was tagged with.

<sup>24</sup>A short and informative summary provided by Protégé <https://protegeproject.github.io/protege/class-expression-syntax/>

**Listing 1** An `odrl:Set` representing DUO\_0000011 regarding Population Origins or Ancestry research (POA). The permission and prohibition over the same purpose is based on interpretation of the phrase “*is limited to*” to indicate use if permitted only for that research

```

1 :DUO_0000011 a odrl:Set ;
2   rdfs:label "DUO_0000011" ;
3   rdfs:comment "This data use permission indicates that use of the data is limited to the
4     ↔ study of population origins or ancestry (POA - population origins or ancestry research
5     ↔ only)" ;
6   dct:source obo:DUO_0000011 ;
7   odrl:permission [
8     odrl:action odrl:use ;
9     odrl:target :TemplateDataset ;
10    odrl:constraint [
11      odrl:leftOperand odrl:purpose ;
12      odrl:operator odrl:isA ;
13      odrl:rightOperand :POA ] ] ;
14   odrl:prohibition [
15     odrl:action odrl:use ;
16     odrl:target :TemplateDataset ;
17     odrl:constraint [
18       odrl:leftOperand odrl:purpose ;
19       odrl:operator :isNotA ;
20       odrl:rightOperand :POA ] ] .

```

2. For each DUO concept retrieved, fetch its relevant `odrl:Set` policy by using the `dct:source` association.
3. If a retrieved policy uses an instance of a `:TemplateQuery`, execute its associated SPARQL query, and replace the instance with retrieved value(s).
4. Create an instance of `odrl:Offer` containing all extracted rules<sup>25</sup>.
5. Add provenance information or other additional documentation, e.g. `dct:dateSubmitted` for when the dataset was added to a system.

### 3.4. Data use requests as `odrl:Request`

To represent data use requests, termed as investigations within DUO, instances of `odrl:Request` are used along with permissions for specific research purposes. In this, the DUO concepts representing requests for use are defined as instances of `odrl:Set`, similar to Section.3.2, and are combined together to create a single request, similar to Section.3.3. A request for genetic studies (`:DUO_0000038`), and the respective `odrl:Set` which was used to generate it, is presented in Listing 3.

### 3.5. Data use decisions as `odrl:Agreement`

Instances of `odrl:Agreement` are recorded outcomes of **decisions resulting from** matching processes where access to the data has been granted **or denied**. In this, the ODRL terms assist in specifying who has granted **or denied** the access (`odrl:assigner`), to whom (`odrl:assignee`), for what **resources** (`odrl:Asset`), and the conditions over it (`odrl:Rule`). The rules mentioned in an agreement are the same specific rules and obligations as that specified for a dataset (i.e. from `odrl:Offer`) and in a request (i.e. `odrl:Request`). Through these rules, an agreement references the specific DUO concepts part of the agreement. An example representation of a data use decision as an `odrl:Agreement` between a data depositor and a data requestor for the purpose of genetic studies is presented in Listing 4.

The following algorithm is used to create the `odrl:Agreement` instance:

<sup>25</sup>Note: each rule is still associated with DUO concepts using `dct:source` to indicate which concepts are being used in the policy

**Listing 2** An example `odrl:Offer` containing a permission for general research use, from `DUO_0000042`, a time limit on the use, from `DUO_0000025`, and a duty to collaborate with the studies' primary investigator, defined from `DUO_0000020`.

```

1 :Offer a odrl:Offer ;
2   rdfs:label "Offer to use dataset for GRU within time limits" ;
3   odrl:target <https://example.com/Dataset> ;
4   odrl:action odrl:use ;
5   dct:source :DUO_0000042, :DUO_0000025, :DUO_0000020 ;
6   dct:dateSubmitted "2022-04-30"^^xsd:date ;
7   odrl:permission [
8     odrl:duty [ odrl:action :CollaborateWithStudyPI ] ] ;
9   odrl:permission [
10    odrl:constraint [
11      odrl:leftOperand odrl:elapsedTime ;
12      odrl:operator odrl:lteq ;
13      odrl:rightOperand "2022-12-31"^^xsd:date ] ] ;
14   odrl:permission [
15     odrl:constraint [
16       odrl:leftOperand odrl:purpose ;
17       odrl:operator odrl:isA ;
18       odrl:rightOperand :GRU ] ] .

```

**Listing 3** An `odrl:Set` and `odrl:Request` containing a request for the purpose of genetic research created from `DUO_0000038`.

```

1 :DUO_0000038 a odrl:Set ;
2   rdfs:label "DUO_0000038" ;
3   rdfs:comment "Request for biomedical research concerning genetics (i.e., the study of
4     ↪ genes, genetic variations and heredity)" ;
5   dct:source obo:DUO_0000038 ;
6   odrl:permission [
7     odrl:action odrl:use ;
8     odrl:target :TemplateDataset ;
9     odrl:assignee :TemplateAssignee ;
10    odrl:constraint [
11      odrl:leftOperand odrl:purpose ;
12      odrl:operator odrl:isA ;
13      odrl:rightOperand :GS ] ] .
14 :Request_for_GS a odrl:Request ;
15   rdfs:label "A request for GS (DUO_0000038)" ;
16   rdfs:comment "Request for biomedical research concerning genetics (i.e., the study of
17     ↪ genes, genetic variations and heredity)" ;
18   dct:source :DUO_0000038 ;
19   dct:dateSubmitted "2022-05-01"^^xsd:date ;
20   odrl:permission [
21     odrl:action odrl:use ;
22     odrl:target :TemplateDataset ;
23     odrl:assignee <https://example.com/SomeRequestor> ;
24     odrl:constraint [
25       odrl:leftOperand odrl:purpose ;
26       odrl:operator odrl:isA ;
27       odrl:rightOperand :GS ] ] .

```

1. Retrieve the `odrl:Request` and dataset's `odrl:Offer`.
2. Match the `odrl:Offer` with the `odrl:Request` (the algorithm is defined in Section.3.6).

3. Record the result where `odrl:target` property specifies the dataset, and `odrl:assignee` and `odrl:assigner` identify the data provider and the requestor respectively.
4. If the matching result shows a compatibility between the request and the offer, then access is expressed as permissible by using a permission with a constraint on the requested purpose for access is added to the policy, as well as any other additional constraints, e.g., spatial, temporal, or duties on the `odrl:assigner`. If the access is denied, similar information is added to policy as an prohibition.
5. `dct:references` is used to associate the agreement with the `odrl:Offer` and `odrl:Request` that are being matched.
6. Provenance and other relevant information, e.g., `dct:dateAccepted` is added to document the agreement's creation and acceptance amongst the parties.

---

**Listing 4** An `odrl:Agreement` representing a decision for use of a dataset

---

```

14 1 :Agreement a odrl:Agreement ;
15 2   dct:references <https://example.com/Offer>, <https://example.com/Request_for_GS> ;
16 3   dct:dateAccepted "2022-05-31"^^xsd:date ;
17 4   odrl:permission [
18 5     odrl:action odrl:use ;
19 6     odrl:target <https://example.com/Dataset> ;
20 7     odrl:assignee <https://example.com/SomeDepositor> ;
21 8     odrl:assigner <https://example.com/SomeRequestor> ;
22 9     odrl:constraint [
23 10      odrl:leftOperand odrl:purpose ;
24 11      odrl:operator odrl:isA ;
25 12      odrl:rightOperand :GS ] ] .

```

---

In the matching algorithm, we only considered the case where a request is matched with a dataset's offer. In practical situation, there may be a single broad request that could have potential matches with several datasets, and it may be undesirable to run the matching against all possible combinations of requests and datasets. To select relevant datasets, a filtering mechanism can be used, such as based on the request's specified purpose, and the dataset's policies could be indexed in a database to enable efficient retrieval and matching. We note these as candidates for future improvements in progression of this work.

Note that ODRL defines `odrl:Agreement` as the granting or acknowledgement of a rule between the parties. This definition is agnostic to the contents of that agreement, which means that the agreement could be a permission granting access to a dataset, or one that prohibits or denies it. While the above example uses the agreement to represent a use case considered use of agreements only in the cases where access was granted, this definition makes it clear that they can also be used to record instances where the request was denied.

### 3.6. Matching algorithm using ODRL for identifying compatible datasets for a request

The matching algorithm in DUO is based on comparing and identifying compatibility between a dataset's data use conditions with data use requests. In our ODRL implementation, this is done by comparing the dataset's `odrl:Offer` with an `odrl:Request`. Given two sets of concepts representing an offer and a request, the matching algorithm can utilise two different and incompatible notions for how access is determined. The first, which is the more common semantic interpretation, is based on considering classes as sets and determining access based on set membership. For a class  $P$  and its subclass  $C$ , a request for accessing  $P$  would also permit use of  $C$  since a member of  $C$  is always a member of  $P$ . But a request for  $C$  would not permit use of  $P$  as not all members of  $P$  are members of  $C$ . This approach has been used in matching policies for GDPR compliance [19] and for granting access to resources in Solid [26].

The second approach, which is what DUO describes in its documentation, is based on identifying applicability of a concept based on its specificity. For a class  $P$  and its subclass  $C$ , a request for accessing  $P$  would not grant

access to  $C$  since it is more specific, but a request for accessing  $C$  would grant use of  $P$  as it is less specific. Using subsumption as a criteria, the first approach grants access when the data policy subsumes the request policy, whereas the second approach grants access when the request policy subsumes the data policy. Thus, both of the former mentioned approaches (i.e., [19] and [26]) can be reused here by *reversing* the direction of subsumption.

Another consideration for the matching algorithm is the resolution of permissions and prohibitions in terms of their order of evaluation and conflicts. It is possible to interpret a policy in several incompatible ways, such as first checking for permissions and granting access at the first satisfied permission, i.e., a permissive model, and its opposite where prohibitions are first checked and access is denied for first unsatisfied prohibition, i.e., a prohibitive model. When a conflict occurs for a permission and a prohibition over the same resource, the resolution would be based on the precedence of one over the other. In DUO, the matching algorithm is prohibitive since prohibitions take precedence over permissions. This means that if a request either does not satisfy a permission or satisfies a prohibition, the request is denied. The policies are considered compatible only when all permissions are satisfied and all prohibitions remain unsatisfied.

Based on these considerations, our matching algorithm consists of checking for subsumption or satisfiability between `odrl:Offer` and `odrl:Request` instances. We adapted it from a prior implementation that also utilised ODRL in a matching algorithm for granting access [26]. The algorithm simply checks whether the dataset policy conditions are satisfied by the request policy in case of permission, or violated in case of prohibition. If any prohibitions are found, the result is that conditions are non-compatible access is rejected. If no prohibitions are found and all permissions are satisfied, then the result is that the conditions are compatible access is granted, i.e., the term *access* indicates an outcome where policies match – no actual access is provided. Note that here the matching only asserts the compatibility of the dataset usage policy and request, whose result is then used to make a decision on whether to grant or refuse access.

---

**Algorithm 1** Pseudo-code of the matching algorithm
 

---

```

for prohibition ← odrl:Offer do
  if odrl:assignee ∈ offer:permission then
    if offer:assignee ≡ request:assignee then decision ← DENY
  for constraint ← prohibition do
    if odr:spatial ∈ constraint then
      if offer:spatial ≡ request:spatial then decision ← DENY
    else if duodrl:Project ← constraint then
      if offer:project ≡ request:project then decision ← DENY
    else if odrl:dateTime ← constraint then
      if today – moratoriumDate < 0days then decision ← DENY
    else if offer:purpose ≡ request:purpose then decision ← DENY
  for permission ← odrl:Offer do
    if odrl:assignee ∈ offer:permission then
      if offer:assignee ≠ request:assignee then decision ← DENY
    for constraint ← permission do
      if odrl:dateTime ∈ constraint then
        if timeLimit – today < 0days then decision ← DENY
      else if request:purpose ∈ groupResearchPurposes then
        if offer:group ≠ request:group then decision ← DENY
      else if offer:purpose ≠ request:purpose then decision ← DENY
  if #DENY then decision ← GRANT
  
```

---

Algorithm 1 provides a pseudo-code representing the steps to be performed for policy matching. Please note that the algorithm only represents a broad indication of actions and that the DUO documentation lacks specifics for correctly interpreting aspects of semantics. For example, where we specify membership ( $\in$ ) or equivalence ( $\equiv$ ),

we mean semantic matching processes involving IRI matching, using `owl:sameAs`, and `rdfs:subClassOf`. Given that this interpretation has a significant impact on the decision-making within DUO's processes and that DUO only specifies interpretation of hierarchical concepts only for purposes but not others (e.g. location, users, projects) – we explicitly identify this as a topic that requires further consideration and investigation in terms of better understanding and expressing the interpretation of DUO's conditions in approval decision-making processes. To remedy this lack of information, except for the purposes in DUO's concepts, we followed existing implementations for legally relevant interpretation of hierarchical concepts [19] where a narrower concept or a sub-class cannot be considered compatible with a request for a broader concept or parent-class. For example, a permission for city as a location cannot be satisfied by a request for a region containing that city.

The algorithm reflects DUO's prohibitive preference in matching where the offer's prohibitions are checked and ensured to be satisfied before any permissions are checked.

1. access is denied if offer has a prohibition related to an assignee present in the request;
2. access is denied if offer has a spatial constraint matching or not satisfying the request;
3. access is denied if offer has a project prohibition matching the project in request;
4. access is denied if there is a moratorium with a date in future; and
5. access is denied if offer has a purpose matching the purpose in request.

If no prohibitions are found, the permissions are checked next:

1. access is denied if the offer assignee does not match the assignee of the request;
2. access is denied if offer time limit on use has lapsed;
3. access is denied if offer has a group research permission, e.g., `PopulationGroupResearch` and the request purpose does not match the same group, e.g. for `Age` or `Gender`; and
4. access is denied if offer purpose does not match request purpose, e.g., DUO's general research use purpose `GRU` in an request does not match a health, medical or biomedical research purpose `HMB` in an offer as `GRU` is a superclass of `HMB`.

These steps are checked for all prohibitions and permissions of the dataset's offer and if all permissions and prohibitions are satisfied without violations, access to the dataset can be granted. The proof-of-concept demonstration described in Section 5 uses these steps to match an offer with a request policies.

#### 4. Expressing Legal Compliance Concepts using DPV

The DUO concepts and terms used are different from those as used in legal compliance tasks. By using ODRL concepts, the terms involved are expressed in a language that has legal interpretation (e.g. *Asset* or *Party*). The ODRL vocabulary also contains additional terms which may be used with DUO for specific legal interpretations, such as *ConsentingParty*, *InformedParty*, and *obtainConsent*. While these terms are sufficient for a policy to have legal interpretations, they are insufficient to incorporate the specifics of laws such as GDPR which assign specific roles to parties and require use of specific legal basis in processing of data. At the same time, if the terms are made specific only for a single law such as the GDPR, the usefulness and applicability of the resulting policies would be restricted to only that law without a clear recourse for adopting other laws and jurisdictions. To address this gap, we utilised the Data Privacy Vocabulary (DPV) which provides terms that are intended to be jurisdiction-agnostic and can be used without being restricted to a specific law.

To utilise DPV, we first performed an alignment between its concepts and ODRL where DPV concepts that have an overlap with ODRL concepts are defined as their subclasses (e.g. `dpv:Entity` is the subclass of `odrl:Party`). This utilised the approach from existing work regarding extending ODRL concepts for GDPR [20]. Where DPV concepts had no direct equivalent in ODRL, such as for legal basis, we used them directly within ODRL rules as instances of the relevant concepts (e.g. `dpv:hasLegalBasis` as `odrl:LeftOperand`). Table 2 describes the performed alignment<sup>26</sup> between ODRL and DPV concepts to define DUO concepts.

<sup>26</sup>We intentionally restricted the alignment to only concepts required for using DUO so as to not introduce additional external interpretations.

Table 2

Alignment between DPV and ODRL for use in policies expressing DUO concepts

| DPV Concept                           | ODRL Concept     | Relationship |
|---------------------------------------|------------------|--------------|
| dpv:Entity                            | odrl:Party       | subclass     |
| dpv:Purpose                           | odrl:Purpose     | subclass     |
| dpv:Processing                        | odrl:Action      | subclass     |
| dpv:PersonalData                      | odrl:Asset       | subclass     |
| dpv:LegalAgreement                    | odrl:Policy      | subclass     |
| dpv:hasTechnicalOrganisationalMeasure | odrl:LeftOperand | instance     |
| dpv:hasLocation                       | odrl:LeftOperand | instance     |
| dpv:hasJurisdiction                   | odrl:LeftOperand | instance     |
| dpv:hasApplicableLaw                  | odrl:LeftOperand | instance     |
| dpv:hasLegalBasis                     | odrl:LeftOperand | instance     |
| dpv:hasRecipient                      | odrl:LeftOperand | instance     |
| dpv:hasRight                          | odrl:LeftOperand | instance     |
| dpv:hasRisk                           | odrl:LeftOperand | instance     |

Using DPV enabled modelling rules regarding restrictions on legal basis (e.g. consent), explicit acknowledgement of roles (e.g. data controllers), limitations on third-party recipients, and indicating applicability of a specific law using `dpv:hasApplicableLaw`. The DPV's "technical and organisational measures", which consist of concepts such as data security and impact assessments, can be used to further enrich DUO's data use modifiers and create a clear delineation between research purposes, measures required, and limitations or conditions of use.

To explicitly specify GDPR as the applicable law and utilise its legal bases and rights, we utilised the DPV-GDPR<sup>27</sup> extension which provides these concepts. Through this separation (between DPV and DPV-GDPR), the policies can be declared in an jurisdiction-agnostic manner using DPV, and made specific to a law such as the GDPR by checking additional contextual information such as the locations of patients whose data is involved, or that of the requesting party. The separation also provides a clear path for applying other jurisdictional laws and concepts on top of DPV by creating extensions of its concepts similar to DPV-GDPR. Listing 5 includes two ODRL offer policies that use DPV and DPV-GDPR to invoke jurisdiction-agnostic data protection and GDPR-specific terms, respectively.

DUO states the interpretation and applicability of GDPR's requirements is the responsibility of the adopter. This follows from the complexities of determining their applicability before any request is known, or because of the differences between stakeholder jurisdictions. To assist with this process, we recommend adding or providing relevant methods that are necessary to identify the applicability of the GDPR (or other laws). For example, GDPR is applicable (to simplify the condition) when an organisation operates within the EU or processes the personal data of people in EU. This translates to knowing the locations of people whose data is being offered for use as well as the requesting entity location.

Using DPV, both of these can be expressed using the appropriate Entity concepts and `dpv:hasLocation`. This enables [expressing using ODRL](#) creating further data use limitations such as data being available only when the request acknowledges the applicability of the GDPR, or permitting use only within GDPR-governed jurisdictions, and checking [these as permissions or prohibitions to be satisfied](#) ~~this condition~~ when matching a request with a dataset by using a matching algorithm as in Section 3.6 along with an encoding of GDPR's requirements such as those from Vos et al. [20]. The DPV-LEGAL<sup>28</sup> extension providing Jurisdictions, Laws, and Authorities for DPV is helpful in representing these conditions.

<sup>27</sup><https://w3id.org/dpv/dpv-gdpr>

<sup>28</sup><https://w3id.org/dpv/dpv-legal>

**Listing 5** Two `odrl:Offer` policy instances that use DPV concepts to indicate conditions of use. `Offer1` is jurisdiction-agnostic and requires use of consent and an Impact Assessment. `Offer2` is GDPR-specific, and requires use of Explicit Consent and DPIA.

```

1 PREFIX dpv: <https://w3id.org/dpv#>
2 PREFIX dpv-legal: <https://www.w3id.org/dpv/dpv-legal#>
3 PREFIX dpv-gdpr: <https://w3id.org/dpv/dpv-gdpr#>
4 :Offer1 a odrl:Offer ;
5   rdfs:label "Offer to use dataset using Consent, and requiring an Impact Assessment" ;
6   odrl:target <https://example.com/Dataset> ;
7   odrl:action dpv:Use ;
8   odrl:permission [
9     odrl:constraint [
10      odrl:leftOperand dpv:hasLegalBasis ;
11      odrl:operator odrl:isA ;
12      odrl:rightOperand dpv:Consent ] ] ;
13   odrl:permission [
14     odrl:constraint [
15      odrl:leftOperand dpv:hasOrganisationalMeasure ;
16      odrl:operator odrl:isA ;
17      odrl:rightOperand dpv:ImpactAssessment ] ] ;
18 :Offer2 a odrl:Offer ;
19   rdfs:label "Offer to use dataset using GDPR's Explicit Consent, and requiring a DPIA" ;
20   odrl:target <https://example.com/Dataset> ;
21   odrl:action dpv:Use ;
22   dpv:hasApplicableLaw dpv-legal:EU-GDPR ;
23   odrl:permission [
24     odrl:constraint [
25      odrl:leftOperand dpv:hasLegalBasis ;
26      odrl:operator odrl:isA ;
27      odrl:rightOperand dpv-gdpr:A6-1-a-explicit-consent ] ] ;
28   odrl:permission [
29     odrl:constraint [
30      odrl:leftOperand dpv:hasOrganisationalMeasure ;
31      odrl:operator odrl:isA ;
32      odrl:rightOperand dpv:DPIA ] ] ;

```

## 5. Demonstration and Evaluation Using a Proof-of-Concept

In this section, we describe the implementation of a User Interface to generate dataset policies and a prototype implementation of the matching algorithm is available at <https://w3id.org/duodrl/demo/>. [The prototype can be installed and used locally and an online demonstration is available at https://w3id.org/duodrl/app/](#).

Figure 1 shows two examples of the developed UI to edit `odrl:Offer` policies, which relies on both ODRL and the ad-hoc vocabulary created to cover missing terms<sup>29</sup>. The first example (a) uses only the DUO concepts, and the second example (b) includes both DUO and DPV to construct `odrl:Offer`.

Upon selecting the relevant DUO concept in the UI, the application retrieves the associated `odrl:Set` instance representing data use permissions and data use modifiers as ODRL policies, combines them, and displays them on screen. The code and data used in this is available online (link in abstract). The matching algorithm used here was adapted from prior work in utilising ODRL for GDPR-based policy matching [26]. We modified it as per the requirements elicited in Section.3.

For the matching process, the conditions represented in an `odrl:Request` instance should be [compatible with a subset of](#) those specified in the `odrl:Offer` instance associated with a dataset. This means the permissions and prohibitions from the offer instance should be satisfiable by the [one from](#) request. Once this is determined to be valid,

<sup>29</sup>Ad-hoc vocabulary available at <https://w3id.org/duodrl>.



Fig. 1. Proof-of-concept implementation showing generation of `odrl:Offer` policies

**Dataset policy offer editor**  
Generate an `odrl:Offer` to express the access conditions to a certain dataset

**Target dataset**

**Data use permission**

**Data use modifier**

```

@prefix dct: <http://purl.org/dc/terms/>.
@prefix duodri: <https://w3id.org/duodri#>.
@prefix odr: <http://www.w3.org/ns/odrl/2/>.

<https://example.com/offer> a odr:Offer;
dct:source duodri:DUO_0000006;
duodri:DUO_0000019;
odr:permission [ odr:action odr:use;
  odr:duty [ odr:action odr:distribute;
    odr:output duodri:ResultsOfStudies ];
  odr:target <https://example.com/Dataset> ],
[ odr:action odr:use;
  odr:constraint [ odr:leftOperand odr:purpose;
    odr:operator odr:isA;
    odr:rightOperand duodri:HMB ];
  odr:target <https://example.com/Dataset> ],
[ odr:action odr:use;
  odr:constraint [ odr:leftOperand odr:purpose;
    odr:operator duodri:isNotA;
    odr:rightOperand duodri:POA ];
  odr:target <https://example.com/Dataset> ].

```

**Dataset policy offer editor**  
Generate an `odrl:Offer` to express the access conditions to a certain dataset

**Target dataset**

**Data use permission**

**Data use modifier**

```

@prefix dct: <http://purl.org/dc/terms/>.
@prefix dpv: <https://w3id.org/dpv#>.
@prefix duodri: <https://w3id.org/duodri#>.
@prefix odr: <http://www.w3.org/ns/odrl/2/>.

<https://example.com/offer> a odr:Offer;
dct:source duodri:DUO_0000042;
odr:permission [ odr:action dpv:Use;
  odr:constraint [ odr:leftOperand dpv:hasLegalBasis;
    odr:operator odr:isA;
    odr:rightOperand dpv:Consent ];
  odr:target <https://example.com/Dataset> ],
[ odr:action dpv:Use;
  odr:constraint [ odr:leftOperand dpv:hasOrganisationalMeasure;
    odr:operator odr:isA;
    odr:rightOperand dpv:ImpactAssessment ];
  odr:target <https://example.com/Dataset> ],
[ odr:action odr:use;
  odr:constraint [ odr:leftOperand odr:purpose;
    odr:operator odr:isA;
    odr:rightOperand duodri:GRU ];
  odr:target <https://example.com/Dataset> ].

```

(a) from DUO concepts

(b) from DUO and DPV concepts

the policies are considered compatible and access can be authorised. For data discovery, a request policy must be compared with policies of every dataset. This process can be made faster and convenient through pre-computations and optimisations - though we did not do these in our implementation as it is intended to only be a proof-of-concept.

The data discovery algorithm starts by checking if there is a specific rule within a dataset's policy for the purposes stated in the `odrl:Request` - if a permission is found for a purpose  $P$  then access to the dataset can be granted and if a prohibition is found then access is rejected. A similar exercise is then performed to check for additional restrictions related to other constraints (described on Table 1), e.g. restrictions on the type of assignee of the offer, or on the location or time of data use, and in case a prohibition is found then access to the dataset is denied and in case a permission is found access can be granted.

In the event additional duties are imposed for dataset use, such as agreeing to collaborate with the primary study investigator or providing documentation of ethical approval, these are included in the `odrl:Agreement` that establishes the final conditions for dataset use. If there are conflicting policies, resulting from the merging of different DUO permissions and modifiers, by default, the prohibition takes precedence, similar to the default behaviour of the algorithm for the case where no permission or prohibition is specified for a particular purpose. In such cases, access is denied.

To record the result of the matching algorithm, an `odrl:Agreement` is created with a permissive or prohibitive rule to indicate the case where `odrl:Request` is allowed or denied. This agreement policy also includes the date where the agreement was created and/or reached, using the `dct:dateAccepted` property, and the `dct:references` property to indicate the identifiers of the `odrl:Offer` and `odrl:Request` used to reach the result of the matching agreement. The depositor of the dataset is added as the `odrl:assignee` and the requestor as the `odrl:assigner` of the agreement. When the request is allowed/denied due to a particular purpose, this purpose is recorded as a constraint of the permission/prohibition in the agreement. If further constraints are specified in the associated `odrl:Offer` and are allowed/denied, these are also included in the per-

mission/prohibition of said agreement. In addition to this, if the agreement in question has a permissive result, any duties that might be present in the related `odrl:Offer` are copied to the agreement as duties to be fulfilled for the allowed access to the dataset. In this manner, the `odrl:Agreement` instance represents and can be used to create suitable legal documents to document and communicate the agreement based on the issued request. The computational cost to generate such an agreement is not in the scope of analysis of this work as it is highly dependent on the use case and on the interpretation of the DUO concepts/rules, which DUO does not explicitly provide, hence reflect the authors' own interpretation of such concepts. Therefore, this work focuses on representing the information in an explicit manner through the usage of ODRL policies, which can be made more efficient by using existing reasoning approaches, such as by converting it to specific OWL forms that permit efficient reasoning [19].

## 6. Discussion on Integration into Existing DUO-based Workflows

DUO represents one facet of GA4GH's ambition to facilitate responsible genomics data sharing for health and medicine related research. It plays an important part given that its role is to increase automation in data discovery and assist in ensuring data use is permitted with accountability and oversight. Its use is thus part of a workflow consisting of different components, processes, and stakeholders who have differing requirements for how they use DUO. Any changes proposed to the way in which DUO is modelled, is applied for dataset discovery, or is used in automation for identifying compatibility with requests may have consequences on these existing workflows. While better design and performance are valid technological goals, they should be evaluated within the lens of socio-technical applications they are a part of. This section therefore discusses the influence and impact of our work on existing DUO-based workflows and offers suggestions on how this work can be best utilised.

### 6.1. Design of DUO concepts

As we outlined in Section.3.1, the concepts within DUO have duplicity in semantics, and do not present the conditions they represent as explicit machine-readable code. This has an impact on the ability to use these for expression of policies and the implementation of automation in dataset discovery and request matching processes, as well as the inability to further use this information in other processes such as to keep records and create documentation. In addition, the structuring of concepts requires clarity on their intended role without overlap (i.e. permissions, modifiers, and investigations), and should have separation of concerns (i.e. purposes from modifiers). Through this, the use of concepts becomes clearer and consistent, and provides the ability to introduce additional conditions and constraints without impact on existing concepts. We recommend following the ODRL model and concepts in terms of representing rules (permission, prohibition, duty), and constraints (purposes, scopes) separately from one another.

For further refinement of DUO terms and their interpretation, the textual descriptions provided should utilise controlled natural language (see survey on [27] for variety of approaches) that match the expression of rules (as in ODRL) so as to provide a reduced level of ambiguity and high-degree of specificity in the terms used. Through these, the descriptions can be made self-sufficient in terms of describing how they should be applied, or when (i.e. before or after data has been released), which can benefit the non-technical processes and stakeholders in understanding and using them. In addition, the specificity of descriptions will also assist approaches such as ours in constructing machine-readable rules that match the exact intention of that concept.

By specifying policies in ODRL (or other similar policy-based semantic models), ~~the use of~~ DUO gains additional automation potential where policies may encompass other requirements (e.g. legal), or have information about the provenance of the data access committees and other relevant processes. This would aid in maintaining documentation, further using validation and other forms of automation to ensure it is complete and correct, and perform follow-up actions periodically or as contextually required. In all of these, the benefits do not require everyone to adopt a large amount of technical debt, and adopters of DUO can choose the extent of what and how they wish to utilise our suggestions - such as ~~in our case the choice of~~ adopting just the ODRL rules, or its matching algorithm, or also the connection to legal compliance using DPV. Our primary contribution is in demonstrating their usefulness and providing a path for their development and adoption.

## 6.2. Integration into Existing Implementations

We acknowledge that some of our proposed changes may break backwards or existing compatibility with DUO utilising systems, and therefore suggest any adopter to perform an assessment regarding whether the gains obtained from such changes outweighs the cost of making these changes. In our opinion, our changes do offer more advantages than disadvantages in longer term, and therefore they should be adopted gradually if not immediately. We recommend the adoption of equivalent ODRL policies for DUO concepts and the (re-)structuring of existing taxonomies and concepts as the first steps. After this, systems such as DUOS can take advantage of the increased availability of machine-readable data to enhance their data discovery and matching algorithms.

We also acknowledge the value of DUO concepts in being simple for stakeholders to understand and utilise, and their basis in ‘textual clauses’ such as those offered in informed consent or data donation/release forms. With this in mind, our modelling of ODRL policies ensures that there is no immediate need to replace the use of DUO concepts since the ODRL policies are ~~complementary~~ *complimentary* to these i.e. the ODRL policy is linked to DUO concepts rather than replacing them entirely. Thus, stakeholders who lack or have limited technical expertise can continue to utilise DUO concepts as they have, with machine-based implementations taking advantage of the increased clarity and specificity of ODRL rules associated with those DUO concepts. An important advantage this provides, that is not possible in the current DUO based implementations, is from the underlying constraints or conditions being made explicit, thereby providing a larger avenue for where *further research into use of* automation and logic-based reasoning can be ~~investigated~~ *applied. This makes it possible* to scale the approach to larger and more diverse use-cases than is currently feasible with DUO.

It also offers the possibility to encode as machine-readable metadata what is currently external information i.e. (i) who: the data is about, requested access, was granted access; or (ii) followup duties once data has been released: checking whether it has been fulfilled, documenting fulfilment or violation; (iii) legal obligations associated with data use. All these information and factors are what DUO-utilising systems currently utilise (such as DUOS) and will do so in any practical use-case in the future. By providing a clear path for adopters to express this information, the use of DUO can be made more systematic and consistent - thereby also increasing the potential co-operation between adopters and facilitating cross-boundary data requests and access as envisioned by GA4GH *as well as the EU’s Health Data Space ambitions*.

## 6.3. Assisting with Legal Compliance

Currently DUO or GA4GH do not provide information on how the use of its efforts relate to legal interpretation and obligations, though they have ongoing discussions for the same. This is a particularly challenging task given the global scope of the work which encompasses different jurisdictions and their laws, and that laws such as GDPR are fairly recent in terms of how their obligations are understood to be applied. We suggest the use of domain-agnostic vocabularies such as ODRL and DPV to first provide a clear indication of how DUO and DUO-based systems relate to specific concepts within legal terminology. By using these within ODRL policies, DUO can provide what is effectively a digital contract.

Further specific jurisdictional applications can then be introduced as an extension of these. For example, the DPV-GDPR extension provides a convenient way to specify GDPR’s legal bases and rights alongside DPV. This reduces the burden on adopters who do not want to express this information or do not want to express any jurisdiction-specific information. For example, a data depositor who only stipulates use of data should be based on consent without explicitly defining the conditions for that valid consent can be expressed as a policy using ODRL and DPV. The oversight committee or an ethics board can then evaluate this further based on their knowledge of the valid consenting requirements, and add additional restrictions or obligations to follow a specific regulation such as the GDPR before permitting use of that data by using DPV-GDPR.

This freedom also offers benefits for systems like DUOS that can explicitly denote datasets as requiring GDPR-level consenting or its applicability by adding relevant metadata to the dataset policy. Doing so assists the matching process to also check for legal obligations and compatibility, such as by requiring specific information about the requestor (e.g. a Data Protection Officer), or requiring additional legal bases and safeguards for transfer of that data (e.g. outside EU). Through this, DUO and its applications can gain a wider legal applicability across the globe and

also have the means and mechanisms to address specific interpretations of the law. And given that all this information would be machine-readable and shareable with the dataset, it can be used by both provider and requesting entity for automation in identifying and checking fulfilment of legal obligations based on utilising the existing state of the art.

## 7. Conclusion

The Data Use Ontology (DUO) is an important initiative to enable wider data sharing towards the goal of progressing health and medical research. Its design and application is driven by the workflows and use-cases present in a socio-technical system consisting of a data repository, utilising a data access committee or approval board, and maintaining compatibility with textual clauses and machine-readable metadata.

We provide an argument for why the design of DUO concepts should be enhanced in terms of making its data use conditions explicit – also as machine-readable data and to utilise these in the matching of data use policies and requests. For this, we have demonstrated the applicability, suitability, and potential of ODRL as a standardised language to express all facets of DUO’s applications. We provide: (i) ODRL rules for each DUO concept; (ii) Integration of DUO concepts into an ODRL policy for a dataset; (iii) ODRL policy representing a data use request; and (iv) [Demonstrating their use in Automated](#) checking for compatibility between dataset and request policies. Through these, we provide a better mechanism for the use of machine-readable information and its use in automation of tasks regarding matching requests with policies and creating documentation as compared to the current DUO implementation.

In addition to the above, we also demonstrated how the use of DPV within ODRL policies enables connection with privacy and data protection laws without making it specific to a particular jurisdiction. For cases where a specific law is needed, the DPV concepts can be easily extended, which we showed for GDPR. Along with the descriptions of our research, we also provided links to resources and a demonstration of its implementation to assist adopters of DUO in assessing and using our work.

Importantly, rather than suggesting a radical new method of doing things, we started with the goal of constructing a mechanism that complements DUO rather than replacing it. As we’ve shown, using ODRL and DPV alongside DUO is [feasiblepossible](#), and can be done with minimum disruption. Through this, we hope to have our work influence and improve existing DUO-related efforts, and in doing this to bring DUO and the GA4GH closer towards implementing the EU’s Health Data Space vision.

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