**Automatable Discovery and Access Matrix (“ADA-M”) v1.0**

**GUIDANCE DOCUMENT**

***Global Alliance for Genomics & Health (GA4GH)  
International Rare Disease Research Consortium (IRDiRC)***

The [Automatable Discovery and Access Task Team](https://genomicsandhealth.org/working-groups/our-work/automatable-discovery-and-access) (“ADA Task Team”), co-chaired by Anthony Brookes (University of Leicester) and John Wilbanks (Sage Bionetworks), is a joint task team of the Regulatory and Ethics Working Group of the Global Alliance for Genomics and Health (“GA4GH”), and the International Rare Disease Research Consortium (“IRDiRC”).

**Definitions used in this document**

**Access**: To retrieve, copy or process a digital, conceptual or physical asset, in whole or in part.

**Discovery**: To search for and thereby determine the existence of and/or characteristics of a digital, conceptual or physical asset, in whole or in part.

**Resource**: Any digital, conceptual or physical asset which could potentially be made available for discovery or access by others. This will typically have been created or isolated by a medical, research, academic or commercial activity, and often constitute some form of data.

**Matrix**: A formalised and versioned information structure, comprising data fields that have specific names, definitions and semantic constraints on the content, with an accompanying set of rules that specify how information may be portrayed within and between the fields. In the case of the ADA-Matrix (ADA-M) the objective is to accommodate information that specifies permissions, limitations and conditions of use of a resource in discovery and/or access scenarios.

**Profile**: A set of information organised into the structured defined by a Matrix. In the case of the ADA-Matrix (ADA-M) the information is that which specifies permissions, limitations and conditions of use of a resource.

**Automatable Discovery and Access**

Comprising over 50 highly active members as listed in Appendix 1, the ADA Task Team works to create tools that can facilitate and increasingly automate the discovery and access of various resources (e.g., data, bio-specimens, subjects, software). This involves issues of consent and other considerations that regulate the acceptable use of resources. Its first work product, the **Automatable Discovery and Access Matrix** (ADA-M), provides a standardized way to represent any and all consent and other conditions of use that apply to a resource, making such information unambiguous, computer-readable and hence directly available for digital communication, searching and automation activities.

ADA-M was conceived in outline by a core of 12 Task Team members who attended an IRDiRC-supported workshop in Paris (November 2015). Principal conditions of use categories were identified based on the experience of team members, existing background work, and a range of documentation (consent forms, data access agreements, etc). ADA-M was designed to organize these concepts into a structure that would enable data use conditions to be represented unambiguously irrespective of their simplicity or complexity. The model was then subjected to extensive alpha-testing over 4 months, by consultation with a wide range of individuals and groups committed to support and collaborate on ADA-M. Cross-mapping exercises were also undertaken (e.g., to datasets managed by EGA to the Broad Institute’s DUOS system, to a database of consent clause, and to Consent Codes). Based on feedback received, iterative rounds of improvement and re-testing were undertaken, involving the whole task team in proposing, debating and democratically deciding upon all such changes.

Making use of ADA-M is expected to reduce the costs and burdens of data stewardship, while increasing the efficiency of responsible data access (discovery and sharing). The matrix acts as a checklist that allows existing regulatory information to be clearly and consistently portrayed, and/or searched/discovered, and/or used as the basis for increasingly automated access procedures. In addition to “control statements” of increasing precision, the matrix includes opportunities to freely list specific terms and constraints. These free text fields can capture factors for which automation may not be feasible, where human judgement of terms and constraints may be needed to ascertain which considerations are relevant when data discoverability and sharing permissions are to be decided. Over time, these details will also assist in identifying ways to improve the granularity of the matrix itself.

**ADA-M Objective and Scope**

ADA-M provides a means to state a series of elemental variables (conditions, permissions or limitations on data discovery, access and use), each of which can optionally be specified at increasing levels of granularity. Using this highly flexible model, any set of use conditions can be expressed as an ADA-M ‘Profile’ (a completed Matrix) which has a standardised structure. The ADA-M Profile is therefore a form of structured metadata (i.e., data about either data or an object annotated by data) which is useful in that it can facilitate the effective communication of use conditions, or provide the basis for the discovery of these conditions, or increasingly automate decisions around granting access based on these conditions.

An ADA-M Profile does not aim to directly recapitulate the exact and complete wording of limitations found, for instance, in consent forms or similar governance documents. Instead, consents provided by subjects, and researcher or institutionally inspired conditions of use, are used to inform the elements of the matrix. Aligning consent language, types of consent, and conditions of use to the ADA-M elements is therefore necessary for its effective use. This will often entail a process of interpretation of the prior documentation, statements and intentions. **It is not the goal of ADA-M to guide or control this step of interpreting the primary information.** Accurate interpretation is, however, a critical and sometimes challenging process, essential for ensuring responsible use of a resource. Once this has been done, **ADA-M merely serves to capture the final result in an unambiguous, comprehensive and standardised format** which can then be used to ensure the referenced resource is used responsibly and efficiently.

As a first global standard of its type, ADA-M is expected to be useful across a number of different use cases, enabled by striking a balance between broad utility and the need for more detailed conditions in certain situations.

**Guidance notes for ADA-M users**

The structure of ADA-M v1.0 includes:   
(i) A Header section to capture contextual information about the ADA-M Profile itself and some basic statements about the resource to which the Profile refers; and   
(ii) A Main Body section that principally specifies and organises 42 general concepts (i.e., non-directive types of use of a resource, that may or may not be employed to define acceptable use and conditions of use in any one setting), some of which are hierarchical to others in the set, and all of which are grouped into three sections, namely ‘Permissions’ (mainly relevant to consent), ‘Terms’ (typically relating to legal/contractual matters), and Meta-Conditions (over-arching topics).

To specify what uses can or cannot be made of a particular entity (material, database, dataset, record, etc), the ADA-M structure fields are ‘filled in’ following certain rules as described below, to produce the final ADA-M ‘Profile’.

**HEADER SECTION**

To formally structure the conditions of use characteristics of a single resource, the Header section is completed only once within a single ADA-M Profile. It comprises 13 items, 3 of which are required (i.e., values must be provided) whereas the other 10 are all optional (may be left empty). Items that are empty need not be reported in the final ADA-M Profile.

The 13 Header section items of ADA-M v1.0 are as follows, with details provided in Appendix 2 (ADA-M Structure)

* “Matrix name” {required}
* “Matrix version” {required}
* “Matrix reference”
* “Matrix profile creation date”
* “Matrix profile updates”
* “Resource name” {required}
* “Resource version”
* “Resource reference”
* “Resource description”
* “Resource data level”
* “Resource contact names”
* “Resource contact emails”
* “Resource contact organisations”

**MAIN BODY**

To formally structure the conditions of use characteristics of a single resource, the Main Body section is completed one or more times within a single ADA-M Profile. Multiple copies of the main body are needed in situations such as:

(i) where more than one different combination of data use criteria (or ‘conditionalities’, as explained below) need to be stated. For example, profit motivated use is permitted in one country if doing research in one disease area, whereas non-profit use is permitted in other countries for research on the same disease.

(ii) where different data use criteria are to apply for Discovery (i.e., enabling a resource to be found and generally characterised) verses Access (i.e., enabling a resource to be shared in a manner that provides access to its constituent parts).

In such situations the different completed copies of the Main Body are entered sequentially in the structure of the completed Profile document, all under one and the same Header section.

The Main Body comprises 42 concepts (or ‘items’), one of which is a required field and so must always be filled in (‘Mode of sharing’, in the Meta-Conditions section) with all other fields being optional so long as at least one of the main fields in the ‘Permissions’ or the ‘Terms’ sections are given a value (so that the Profile asserts at least one actual condition of use). Fields without a value need not be reported in the final ADA-M Profile.

The Main Body of ADA-M also enables **Conditionalities** and **Obligations** to be specified. Conditionalities arise when a particular use permission (e.g., use for research on disease X is allowed) is conditional on some other factor (e.g., if resulting data are made public). Obligations involve situations were a particular resource use is not only permitted to occur but is obligated to occur (e.g., use for research on disease X is a necessity). Further details on how to express these two forms of constraint on a data use condition are provided in the sections below.

**Permissions Section**

The Permissions section covers 26 different data concepts (‘items’) for types of use of a resource. This comprises considerations generally covered by, or otherwise included in, laws, institutional policies (Data/Sample Access Policies, Material/Data Transfer Agreement, Data Access Agreement, etc), and consents. It therefore represents aspects of control which are useful to know about in resource discovery contexts, and also when seeking to actually access a particular resource.

Some of the 26 items are arranged hierarchically. To state a condition or policy of use for any one of these items, a single value must be entered from a list of options permitted for that item. A value can be entered for a child item in a hierarchy without having to enter a value for its parent item, and vice versa. However, if values are entered for both parent and child items in a hierarchy then only some combinations of values are valid (see Appendix 3). Permitted values include “Unrestricted” and ”Limited” which are available for all the items, as well as “Unrestricted[Obligatory]”, ”Limited[Obligatory]” and ”Forbidden” which are additional options for 23 of the 26 items. The latter three options are not available for the three usage items which must unavoidably occur in some manner or another ("use within countries/locations", "use by organisations", "use by categories of person") and so these cannot be logically “Forbidden” or made exceptionally “Obligatory”.

*As an example of how to fill in the Permissions section, if one wanted to assert explicitly that a resource can be used without restriction for any form of method development then “Unrestricted” would be entered for the use category entitled “use for methods development”. Conversely, if no form of method development is permitted then this category would be given the value ”Forbidden”. The value ”Limited” conveys the fact that some but not all forms of method development are allowed. Value options “Unrestricted[Obligatory]” and ”Limited[Obligatory]” provide a way to state that one or more of the forms of method development which are permitted not only can occur but must occur.*

***Free Text Fields:*** Each assertion of a condition of use can optionally also be supported by a free text statement in an accompanying field provided for this purpose. This allows for further elaboration of any condition of use, to be read by human users of the Profile. More specifically, the free text fields are used: to specify what forms of use are allowed, are not allowed or must occur; to elaborate on why a type of use is unrestricted, forbidden, or obligatory; and to state conditionalities of use. Provision of such free text statements is optional regardless of what value is entered into the main permitted options field. No free text field should have anything in it unless its associated main field has been assigned one of the permitted values. When “Unrestricted” or “Unrestricted[Obligatory]” or “Forbidden” is entered into the main field the free text field will typically be left empty. Whereas, when ”Limited” or ”Limited[Obligatory]” are entered it will normally be useful to provide further details in the accompanying free text field. Limitations to use are best provided as a list of permitted or prohibited options (e.g., “Use permitted for research on diseases A, B and C. Use prohibited for research on diseases X, Y and Z.”). If any item on such a permissions list is also to be an obligatory use case (i.e., that specific type of use must occur), this should be indicated by adding the “[Obligatory]” suffix to that item in the list. An example would be “Use permitted for research on diseases A, B[Obligatory] and C” meaning the research use must relate to disease B, but as long as this condition is met that same research may also simultaneously relate to diseases A and/or C.

Information provided in these free text fields will also be useful in guiding the further development of improved versions of ADA-M in the future, wherein we anticipate incorporating ontologies to support automation down to this level of detail.

***To summarise:***

\* “Unrestricted” – This value means that this type of use is allowed, without any restriction. If a parent category is given this value then any child category it sits above that has no value entered can be logically inferred to be “Unrestricted”. Any child category values that are provided must be either “Unrestricted” or “Unrestricted[Obligatory]”. The associated free text field can optionally be filled in with some more details, but this will generally not be necessary.

\* “Unrestricted[Obligatory]” – This value means that this type of use is not only allowed to occur but must occur. If a parent category is given this value then any child category it sits above that has no value entered can be logically inferred to be “Unrestricted”, and also at least one of these child categories (and/or an item on a permitted use in the parent free text statement) must occur. Any child category values that are provided must be either “Unrestricted” or “Unrestricted[Obligatory]”. The associated free text field can optionally be filled in with some more details, but this will generally not be necessary unless the obligatory use case needs to be specified in this field.

\* “Limited” – This value means that for this type of use one or more specific limitations or special requirements apply. When a parent category is given this value then nothing can be inferred about the logical value of any child category it sits above that has no value entered. If no limitation of use is stated in the associated free text field, then any child category values that are provided must include at least one with the value “Limited”, “Limited[Obligatory]” or “Forbidden”. The associated free text field can optionally be filled in with some more details of the limitations that apply.

\* “Limited[Obligatory]” – This value means that for this type of use one or more specific limitations or special requirements apply, but nevertheless one or more of the subset of uses that are permitted must occur. When a parent category is given this value then nothing can be inferred about the logical value of any child category it sits above that has no value entered. If no limitation of use is stated in the associated free text field, then any child category values that are provided must include at least one with the value 'Limited', 'Limited[Obligatory]' or 'Forbidden'. The associated free text field can optionally be filled in with some more details of the limitations and/or the obligations that apply.

\* “Forbidden”– This value means that this type of use is not allowed. If a parent category is given this value then any child category it sits above that has no value entered can be logically inferred to be “Forbidden”. Any child category values that are provided must be “Forbidden”. The associated free text field can optionally be filled in with some more details, but this will generally not be necessary.

The full list of data use items covered by the Permissions section of ADA-M v1.0 is as follows (shown with arrowed indents indicating parent-child hierarchical relationships), with details provided in Appendix 2 (ADA-M Structure):

* “use within countries/locations” [plus an associated free text field]
* “use by organisations” [plus an associated free text field]
* > “use by non-profit organisations” [plus an associated free text field]
* > “use by profit organisations” [plus an associated free text field]
* “use by categories of person” [plus an associated free text field]
* > “use by academic professional” [plus an associated free text field]
* > “use by clinical professional” [plus an associated free text field]
* > “use by profit-making professional” [plus an associated free text field]
* > “use by non-professional” [plus an associated free text field]
* “use for non-profit purpose” [plus an associated free text field]
* “use for profit purpose” [plus an associated free text field]
* “use for research purposes” [plus an associated free text field]
* > “use for methods development” [plus an associated free text field]
* > “use as reference or control material” [plus an associated free text field]
* > “use for research concerning populations” [plus an associated free text field]
* > “use for research concerning ancestry” [plus an associated free text field]
* > “use for biomedical research” [plus an associated free text field]
* > > “use for research concerning fundamental biology” [plus an associated free text field]
* > > “use for research concerning genetics” [plus an associated free text field]
* > > “use for research concerning drug development” [plus an associated free text field]
* > > “use for research concerning any disease” [plus an associated free text field]
* > > “use for research concerning age categories” [plus an associated free text field]
* > > “use for research concerning gender categories” [plus an associated free text field]
* “use for clinical purposes” [plus an associated free text field]
* > “use for clinical decision support” [plus an associated free text field]
* > “use for clinical purposes concerning any disease” [plus an associated free text field]

**Terms Section**

The Terms section covers 11 different areas of control or agreement over the use of a resource. It comprises aspects of governance and behaviour that are generally stipulated by laws, regulations, institutional policies, researchers, or ethics oversight bodies, as a condition of granting access to, or continued use of a given resource. These considerations may be useful to know about in resource discovery contexts, but assist particularly when actually seeking to access a particular resource. Therefore, in Profiles that relate to discovery scenarios, most or all the Terms section will be left empty, as Terms items are generally only relevant to data access settings.

The 11 terms categories are each very broad, intending to together cover all possible relevant considerations. They are not hierarchically arranged. Each category can accept one of two possible values ("True" or "Untrue"), and has an associated free text field that is intended to be read by human users of the Profile. One category (“There is no possibility of recontacting data subjects”) actually has two free text fields, designed to separately capture details on subject recontacts that **may** or **must** occur, respectively. All of these controlled value and free text fields are optional (need not be filled in), but no free text field should have anything in it unless its associated main field has been assigned one of the permitted values.

Each Terms category is expressed as a ‘negative’, for example “There are no requirements regarding collaboration”. Therefore, entering the value "True" directly conveys the fact that no conditions apply which pertain to that aspect of a data sharing relationship. Conversely, the value "Untrue" means that some policy or condition relating to that aspect of sharing does apply. The details of such conditions will typically be quite bespoke and potentially rather complex, and so these can be elaborated in the accompanying free text field. It is not, however, required that the free text field is filled in regardless of whether the "True" or "Untrue" response is given. This is because the resource custodian may, for example, not wish to state the Terms in depth, or may prefer to discuss and negotiate them on a case by case basis. The free text field may also be used to state conditionalities that apply to any Terms item (as explained below). When information is provided in these free text fields it will also be useful in guiding the further development of more comprehensive versions of ADA-M in the future.

The full list of considerations for data sharing covered by the Terms section of ADA-M v1.0 is as follows, with details provided in Appendix 2 (ADA-M Structure)

* “There are no requirements for any formal approval, contract or review conditions to be satisfied” [plus an associated free text field]
* “There are no requirements regarding publication or disclosure of results, or included references or acknowledgements” [plus an associated free text field]
* “There are no timeline restrictions” [plus an associated free text field]
* “There are no requirements regarding data security measures” [plus an associated free text field]
* “There are no requirements regarding withdrawal, destruction or return of any subject data” [plus an associated free text field]
* “There are no restrictions regarding the linking of accessed records to other datasets relevant to subject identifiability” [plus an associated free text field]
* “There is no possibility of recontacting data subjects” [plus an associated free text field]
* “There are no restrictions regarding intellectual property claims based on use of the accessed resource” [plus an associated free text field]
* “There are no requirements to report back regarding use of the accessed resources” [plus an associated free text field]
* “There are no requirements regarding collaboration” [plus an associated free text field]
* “No fees will be levied for access of the resources” [plus an associated free text field]

**Meta-Conditions Section**

This comprises 5 items that sit outside the realm of the Permissions or the Terms sections. It addresses 5 very specific matters, and so each item is designed to be filled in with only one value from its own particular list of permitted values. Only one of these items is required, namely “Mode of sharing”, which specifies the nature of the sharing activities that the Profile concerns (i.e., Discovery and/or Access). If a Profile needs to express different Permissions and/or Terms for Discovery versus Access activities, then this is facilitated by creating a Profile which includes two sequential copies of the Main Body. Each copy will state, in the “Mode of sharing” field, whether it concerns the Discovery or the Access activity, and the rest of the fields will be filled in accordingly.

Three Meta-Conditions items are optional, with one other (“Interpretation rule if multiple Obligatory permissions are specified”) also being optional unless two or more entries in the Permissions and Terms sections are stated to be “[Obligatory]” in which case this field must then be filled in. Only one Meta-Conditions item (“There are no other use restrictions/limitations in force which are not herein specified”) has an accompanying free text field to optionally provide further details. But as with all free text fields, this must not contain a value if the associated controlled value field is empty.

The five Meta-condition items of ADA-M v1.0 are as follows, with details provided in Appendix 2 (ADA-M Structure):

* “Mode of sharing" {required}
* “Interpretation rule if multiple Obligatory permissions are specified” {sometimes required}
* “There are no other use restrictions/limitations in force which are not herein specified”  
  [plus an associated free text field]
* “No special evaluation required for access requests involving sensitive/restricted populations”
* “Identical consent permissions have been provided by all subjects”

**CONDITIONALITIES**

Conditionalities involve situations where a particular resource use permission (e.g., “use for research on cancer is allowed…”) is conditional on some other circumstance occurring (e.g., “…so long as resulting data are made public”). Conditionalities can apply to any Permissions or Terms item, and are expressed in the free text field of the respective Permissions or Terms item. Since ADA-M attempts to be comprehensive in scope, the conditional circumstance will often itself be represented as (at least part of) another item in the Permissions or Terms sections. Therefore, the free text field for that item could also, usefully, contain a reflective statement about this conditionality. For instance, in the above example, the main field for the Permissions item “use for research concerning any disease” would have the value “Limited” and its free text field would include a text such as “Allowed for research on cancer, conditional on the resulting data being made public”. Plus, the main field for the Terms item “There are no requirements regarding publication or disclosure of results, or included references or acknowledgements” would have the value “Limited” and its free text field would include a text such as “Resulting data must be made public if this resource is used for research on cancer”.

**COMPUTING ON ADA-M PROFILES**

Three types of uses of ADA-M are envisaged that will involve computer handling of the completed Profile.

1) A means for **unambiguously communicating data use conditions** from one system to another system, for interpretation or display. Two standard formats are currently available for such transfers – a JSON document and a Key:value pair text document (see Appendix 4) – and widespread use of such formats will increase interoperability between data systems. Nothing is yet stipulated or recommended regarding the best ways to associate or keep together the ADA-M Profile to the resource it provides metadata about, other than naming that resource in the ADA-M Header section.

2) A means for **enabling discovery services to include data use conditions** in the range of characteristics they enable a user to query. Beyond adhering to the core syntax, semantics and validation principles of ADA-M, it is a matter of local choice what document or databasing format and technology a local system choses to use for such applications.

3) A means for **automated decision making on granting access to a resource** in response to a structured request for use. Given the complexity of some usage requests, and of some use condition Profiles, and also considering the vulnerability of some social groups, it is unlikely that this application will ever be fully automated. However, when the decision engine is only having to evaluate the more straightforward Permissions items values (“Unrestricted”, “Unrestricted[Obligatory]”, or “Forbidden”) and Terms item values (“True”), and no vulnerable groups are involved (i.e., Meta-Considerations items “No special evaluation required for access requests involving sensitive/restricted populations” is “True”), then such adjudications could be left to the computer, thereby taking quite a burden off of Data Access Committees. Again, formats and software systems for this can be left to local choices, and this includes the nature of the structured request. That said, the ADA Task Team is considering developing a standardised request matrix that will correspond to ADA-M, as a future work product. As a first step in this direction the group is considering what might or might not be assumed as default values for fields that have been left blank in an ADA-M Profile but which need to be considered for an access decision to be made.

**QUESTIONS AND FEEDBACK**

The ADA Task Team is hoping that many different groups, operating in different data/resource discovery and sharing settings, will consider whether or the not the ADA-M might be useful to them now or in the future. Any and all feedback about its suitability or otherwise will be gratefully received, and should be sent in the first instance to the group’s coordinator Emily Kirby [ekirby@p3g.org] or co-chair Anthony Brookes [ajb97@leicester.ac.uk]. Questions about the ADA-M, and requests for help in refining the matrix should also be directed to this same address, to be forwarded to members of the ADA team most able to assist.

**Appendix 1: ADA Task Team (August 2016)**

*Co-Chairs:* Anthony Brookes; John Wilbanks

*Coordinator:* Emily Kirby

*The ADA Task Team would like to acknowledge the contribution of all team members included in our email distribution list, who have been involved in various stages of the work:*

Vartika Agrawal; Alessia Baretta; Mathieu Boudes; Moran Cabili; Knox Carey; Virginia Chavis; Ed Conley; Primavera De Filippi; Stephanie Dyke; Luca Emili; David Fajgenbaum; Clara Gaff; Chiara Garattini; Jack Goldblatt; Peter Goodhand; Elli G. Gourna; Tudor Groza; Reece Hart; James Hazard; Anneliene Jonker; Petra Kaufmann; Alastair Kent; Warren Kibbe; Bartha Maria Knoppers; Ray Krasinski; Lilian Lau; Josh Leslie; David Lloyd; Hanns Lochmuller; Alex Mankovich; Mauricio Moldes Quaresma; Francis Ouellette; Anthony Philippakis; Barbara Prainsack; Jordi Rambla; Fabien Richard; Olaf Riess; Gregory Rushton; Andrea Saltzman; Mahsa Shabani; Anne Marie Tassé; Adrian Thorogood; Mihaela Ulieru; Susan Wallace; Patrick Woolley; Tomoyuki Yamada; Andreas Zankl.

*Additional substantial contributions are acknowledged, from GA4GH, IRDiRC, P3G and Intel.*

**Appendix 2 : ADA-M v1.0 Structure**

Required fields are **written in bold** in the tables below.

**HEADER SECTION**

|  |  |
| --- | --- |
| **Matrix name** | Required. Enter the one permitted value: "Automatable Discovery and Access Matrix (ADA-M)" |
| **Matrix version** | Required. Enter the ADA-M version number (currently "1.0") |
| Matrix reference | Optionally enter any number of references that point to descriptions of the ADA-M standard being used, E.g., publications, URLs, this dated Guidance Document |
| Matrix profile creation date | Optionally enter the date the Profile was created (as YYYY/MM/DD) |
| Matrix profile updates | Optionally enter a list of Profile update dates and the specifics of the changes made (as YYYY/MM/DD["update1"]; YYYY/MM/DD["update2"]; . . .) |
| **Resource name** | Optionally enter the name of the resource being profiled (e.g. the dataset name) |
| Resource version | Optionally enter the version of the resource being profiled (e.g. the dataset version) |
| Resource reference | Optionally enter any number of references that point to the resource being profiled (e.g., paper citations, DOIs, URLs) |
| Resource description | Optionally enter a brief summary description of the resource being profiled (e.g. Enter dataset) |
| Resource data level | Optionally enter only one of the following six permitted values that specify the type of data resource being profiled:  "Database" [i.e., a data bank or data store],  "Metadata" [i.e., data that describes/contextualises a data object or an entity annotated by data],  "Summarised" [i.e., data that result from the process of aggregation or summarisation of data records],  "Dataset/Recordset" [i.e., a collection of data records with a common origin or purpose],  "Record" [i.e., a single data record pertaining to one item or entity],  "Record Field" [i.e., a single information field in a single data record] |
| Resource contact names | Optionally enter any number of names of entities to contact regarding the resource being profiled |
| Resource contact emails | Optionally enter any number of email addresses of entities to contact regarding the resource being profiled |
| Resource contact organisations | Optionally enter any number of organisations to contact regarding the resource being profiled |

**PERMISSIONS SECTION**

Note:  
- Across the Permissions and Terms sections one field (that is not a free text field) must have a value  
- Arrowed indents in this table indicate parent-child hierarchical relationships between concepts   
- Each item in this section has an associated free text field. These must not be filled in if their associated controlled value field is not filled in. They are used for listing specific types of use that are allowed or not allowed, elaborating on why a type of use may be unrestricted, forbidden or obligatory, or for stating conditionalities.  
- Three of the items have permitted values “Unrestricted” and ”Limited” (as indicated in the table below). All other items have these two permitted values as well as the additional options “Unrestricted[Obligatory]”, ”Limited[Obligatory]” and ”Forbidden”.

|  |  |
| --- | --- |
| “use within countries/locations” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited, in all or only some geographical regions. |
| “use by organisations” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited, by all or only some categories of organisation. |
| > “use by non-profit organisations” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, by all or only some types of one main category of organisation, namely those do not seek to make profits. |
| > “use by profit organisations” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, by all or only some types of one main category of organisation, namely those seek to make profits. |
| “use by categories of person” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited, by all or only some categories of person. |
| > “use by academic professional” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, by all or only some types of one main category of person, namely those whose interest in the resource relates to their work as an academic. |
| > “use by clinical professional” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, by all or only some types of one main category of person, namely those whose interest in the resource relates to their work in clinical care. |
| > “use by profit-making professional” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, by all or only some types of one main category of person, namely those whose interest in the resource relates to their work which seeks to generate profits. |
| > “use by non-professional” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, by all or only some types of one main category of person, namely those whose interest in the resource does not stem from their work. |
| “use for non-profit purpose” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of non-profit motivated purpose. |
| “use for profit purpose” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of profit motivated purpose. |
| “use for research purposes” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some categories of research. |
| > “use for methods development” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of research, namely the development of methods and technologies. |
| > “use as reference or control material” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of research, namely utilisation as benchmark or control purposes |
| > “use for research concerning populations” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of research, namely studies into genetically related populations or groups. |
| > “use for research concerning ancestry” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of research, namely studies into genetic origins. |
| > “use for biomedical research” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of research, namely studies addressing biology or medicine. |
| > > “use for research concerning fundamental biology” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of biomedical research, namely studies concerning the fundamental basis of life. |
| > > “use for research concerning genetics” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of biomedical research, namely studies concerning genes or genomes. |
| > > “use for research concerning drug development” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of biomedical research, namely studies concerning medicinal drugs. |
| > > “use for research concerning any disease” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of biomedical research, namely studies concerning disease. |
| > > “use for research concerning age categories” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of biomedical research, namely studies concerning time periods of human life. |
| > > “use for research concerning gender categories” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of biomedical research, namely studies concerning questions of gender. |
| “use for clinical purposes” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some categories of clinically related use. |
| > “use for clinical decision support” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of clinically related use, namely clinical decision making. |
| > “use for clinical purposes concerning any disease” | With its associated free text field, this item indicates whether use of a resource is unrestricted/limited/forbidden/obligated, for all or only some types of one main category of clinically related use, namely disease management. |

**TERMS SECTION**  
Note:  
- Across the Permissions and Terms sections one field (that is not a free text field) must have a value   
- Each item in this section has an associated free text field. These must not be filled in if their associated controlled value field is not filled in. They are used for providing further specifics when a main field value is “Untrue”, i.e., when some policy or agreement is to be adhered to in a resource sharing relationship.

|  |  |
| --- | --- |
| “There are no requirements for any formal approval, contract or review conditions to be satisfied” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no formal documentation or process need be completed, such as a legal agreement, IRB/IEC review, Data Access Committee (DAC) review, etc. |
| “There are no requirements regarding publication or disclosure of results, or included references or acknowledgements” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no specific agreements are needed regarding the publication or presentation of new data, results or conclusions that are produced by using the resource n question. |
| “There are no timeline restrictions” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no time constraints apply regarding any aspect of that relationship. |
| “There are no requirements regarding data security measures” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no specific hardware, software, or other data security-related procedures must be deployed. |
| “There are no requirements regarding withdrawal, destruction or return of any subject data” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no specific rules are to apply regarding expunging of the provided resource given any eventuality. |
| “There are no restrictions regarding the linking of accessed records to other datasets relevant to subject identifiability” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no limitations apply regarding the integration or linking of data that are shared with other information so as to potentially make any individual more identifiable. |
| “There is no possibility of recontacting data subjects” | With its associated two free text fields, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no option exists for recontacting of individuals represented in the shared resource (e.g., to manage incidental findings). Should this be untrue, the first associated free text field should be used to provide details of what types of recontact **may** occur, and the second free text field should be used to elaborate what types of recontact **must** occur. |
| “There are no restrictions regarding intellectual property claims based on use of the accessed resource” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no agreement is needed regarding how intellectual property rights arising from use of the resource are allocated and controlled. |
| “There are no requirements to report back regarding use of the accessed resources” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no conditions apply regarding mandatory reporting back to the resource providers, or others, about the use of the accessed resource. |
| “There are no requirements regarding collaboration” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no collaboration is needed with certain individuals, groups, organizations or institutions, on matters relating to the resource in question. |
| “No fees will be levied for access of the resources” | With its associated free text field, this item delineates whether for a resource sharing relationship to be established it is true/untrue that no financial fees or other charges will be levied to access and/or use the resource in question. |

**META-CONDITIONS SECTION**

|  |  |
| --- | --- |
| **“Mode of sharing"** | Required. This field specifies the nature of the sharing activities that the Profile concerns. Hence it is a required field, for which the permitted values are as follows:  • "Discovery" = enable the resource to be found and generally   characterised, but not shared in a manner that provides   access to its constituent parts,  • "Discovery and Access" = enable the resource to be found and generally   characterised, and/or shared in a manner that provides   access to its constituent parts,  • "Access" = enable the resource to be shared in a manner that   provides access to its constituent parts.  If an ADA-M Profile needs to express different Permissions and/or Terms for resource Discovery and resource Access activities, then this is facilitated by creating a Profile which includes two sequentially arranged copies of the whole Main Body (i.e., everything except the Header section). Each Main Body copy will state, in its “Mode of sharing” field, whether it concerns a Discovery or an Access activity, and the rest of the fields will be filled in accordingly. |
| **“Interpretation rule if multiple Obligatory permissions are specified”** | Sometimes required. This field serves to ensure ‘obligatory’ statements are interpreted correctly. This field must be filled in when more than one of the Permissions or Terms values include the “[Obligatory]” suffix (i.e., when >1 instances of the string “[Obligatory]” are entered across one or more of all controlled value and free text fields in the Permissions and Terms sections considered together). In such situations there are two alternative allowed ways to interpret such a Profile, and this field is used to indicate which one is to apply. The two options are:  • "Meet all Obligatory permissions" = each use of the resource must satisfy   all the Obligatory conditions,  • "Meet at least one Obligatory permission" = each use of the resource must satisfy   at least one of the Obligatory conditions |
| “There are no other use restrictions/limitations in force which are not herein specified”  - - - - - - - - - - - - - - - - - - - - - -  Associated free text field | Optional. This field provides a way to state that the ADA-M Profile covers all the resource usage considerations that exist (by entering the permitted value "True"), or conversely to indicate that additional Permissions, Terms, Meta-Conditions or parameters exist that cannot be expressed somewhere else in the ADA-M structure (by entering the permitted value "Untrue"). In the latter case, details of those other constraints and factors can optionally be provided in the associated free text field.  Optional - but it must not be filled in if the associated controlled value field is not also filled in. |
| “No special evaluation required for access requests involving sensitive/restricted populations” | Optional. Some uses of a resource might address matters that are particularly sensitive, such as the study of illegal behaviors, addiction, sexual matters, stigmatizing illness, etc. This field enables resources that might be used in such areas of research to be highlighted, as they will typically warrant manual rather than automated evaluation when processing these types of resource access request. Permitted values are "True" and "Untrue". Entering "True" indicates that the resource is confidently deemed to not be relevant to any such use, and so these concerns do not apply. Conversely, entering the value "Untrue" means that the resource could have an impact on one or more sensitive matters, and so this is to be taken into consideration when access decisions need to be made. |
| “Identical consent permissions have been provided by all subjects” | Optional. This field is relevant when the resource the ADA-M Profile refers to is a data resource which comprises, or is derived from, multiple records from different subjects or studies. It provides a way to indicate whether the informed consent given by those subjects in those one or more studies is in all cases identical. Permitted values are "True" and "Untrue". Entering "True" indicates that the consent specifics are the same, and so any consent related item included in the ADA-M Profile will apply equally to all the records in the resource. Entering "Untrue" indicates they are not the same, which then implies that further consideration of individual consent differences may be needed before the data are used. |

**Appendix 3: Rules for Completing a Valid ADA-M v1.0 Profile**

**RULE #1**

At least one ‘Permissions’ or ‘Terms’ category must have a value

**RULE #2**

Values must be entered for required HEADER fields:  
- Matrix name [matrixName(v1)]  
- Matrix version [matrixVersion(v1)]  
- Resource name [resourceName (v2)]

And likewise for META-CONDITIONS field:  
- Mode of sharing [sharingMode(v2)]  
- Interpretation rule if multiple Obligatory permissions are specified [multipleObligationsRule(v1)]   
 **[but ONLY IF >1 [Obligatory] string is present across all Permissions & Terms list and free text fields**

**RULE #3**

Values must comply with permitted values for HEADER fields:  
- Matrix name [matrixName(v1)]  
- Resource data level [resourceDataLevel(v1)]

And likewise for PERMISSIONS fields:  
- use within countries/locations [country(v2)]  
- use by organisations [organisation(v2)]  
 - use by non-profit organisations [nonProfitOrganisation(v2)]  
 - use by profit organisations [profitOrganisation(v2)]  
- use by categories of person [person(v2)]  
 - use by academic professional [academicProfessional(v2)]  
 - use by clinical professional [clinicalProfessional(v2)]  
 - use by profit-making professional [profitMotivatedProfessional(v2)]  
 - use by non-professional [nonProfessional(v2)]  
- use for non-profit purpose [nonProfitPurpose(v2)]  
- use for profit purpose [profitPurpose(v2)]  
- use for research purposes [research(v1)]  
 - use for methods development [methodsDevelopment(v3)]  
 - use as reference or control material [control(v1)]  
 - use for research concerning populations [populationResearch(v3)]  
 - use for research concerning ancestry [ancestryResearch(v3)]  
 - use for biomedical research [bioMedicalResearch(v3)]  
 - use for research concerning fundamental biology [fundamentalBiologyResearch(v3)]  
 - use for research concerning genetics [geneticResearch(v3)]  
 - use for research concerning drug development [drugDevelopmentResearch(v3)]  
 - use for research concerning any disease [diseaseCategoriesResearch(v4)]  
 - use for research concerning age categories [ageCategoriesResearch(v2)]  
 - use for research concerning gender categories [genderCategoriesResearch(v3)]  
- use for clinical purposes [clinicalPurpose(v3)]  
 - use for clinical decision support [clinicalDecisionSupport(v1)]  
 - use for clinical purposes concerning any disease [diseaseCategoriesClinicalPurpose(v4)]

And likewise for TERMS fields:  
- There are no requirements for any formal approval, contract or review conditions to be satisfied [noAuthorizationTerms(v2)]  
- There are no requirements regarding publication or disclosure of results, or included references or acknowledgements [noPublicationTerms(v3)]  
- There are no timeline restrictions [noTimelineTerms(v2)]  
- There are no requirements regarding data security measures [noSecurityTerms(v2)]  
- There are no requirements regarding withdrawal, destruction or return of any subject data [noExpungingTerms(v2)]  
- There are no restrictions regarding the linking of accessed records to other datasets relevant to subject identifiability [noLinkingTerms(v3)]  
- There is no possibility of recontacting data subjects [noRecontactTerms(v2)]  
- There are no restrictions regarding intellectual property claims based on use of the accessed resource [noIPClaimTerms(v2)]  
- There are no requirements to report back regarding use of the accessed resources [noReportingTerms(v2)]  
- There are no requirements regarding collaboration [noCollaborationTerms(v2)]  
- No fees will be levied for access of the resources [noPaymentTerms(v2)]

And likewise for META-CONDITIONS fields:  
- Mode of sharing [sharingMode(v2)]  
- Interpretation rule if multiple Obligatory permissions are specified [multipleObligationsRule(v1)]  
- There are no other use restrictions/limitations in force which are not herein specified [noOtherConditions(v2)]  
- No special evaluation required for access requests involving sensitive/restricted populations [sensitivePopulations(v1)]  
- Identical consent permissions have been provided by all subjects [uniformConsent(v1)]

**RULE #4**

No free text field should have anything in it unless its associated main field has been assigned a (permitted) value

**RULE #5**

The following must apply:

|  |  |
| --- | --- |
| **If a parent category is:** | **Then its child categories must:** |
| NULL | be NULL  or anything |
| 'Unrestricted'  or  'Unrestricted[Obligatory]' | be NULL  or 'Unrestricted'  or 'Unrestricted[Obligatory]' |
| 'Limited'  or  'Limited[Obligatory]' | be NULL  or sit under a parent 'free text' statement  or include at least one 'Limited'  or include at least one 'Limited[Obligatory]'  or include at least one 'Forbidden' |
| 'Forbidden' | be NULL  or be 'Forbidden' |

**Appendix 4: Document Formats for ADA-M v1.0 Profile**

***Complete JSON Template Specification:***(note: fields without values need not be included in the JSON formatted profile)

{

"Header": {"version": "1",

"matrixName": {"version": "1", "label": "Matrix name", "value": ["Automatable Discovery and Access Matrix (ADA-M)"]},

"matrixVersion": {"version": "1", "label": "Matrix version", "value": ["<No value>","<Version number of whole matrix (currently 1.0)>"]},

"matrixReference": {"version": "1", "label": "Matrix reference", "value": ["<No value>","<E.g., publications, URLs, that describe this version of the matrix>"]},

"matrixProfileCreateDate": {"version": "1", "label": "Matrix profile creation date", "value": ["<No value>","<Date the profile was created, as YYYY/MM/DD>"]},

"matrixProfileUpdates": {"version": "1", "label": "Matrix profile updates", "value": ["<No value>","<List of profile update dates and changes, as YYYY/MM/DD[update1];YYYY/MM/DD[update2];...>"]},

"resourceName": {"version": "2", "label": "Resource name", "value": ["<No value>","<Name of the resource (e.g., a dataset name)>"]},

"resourceVersion": {"version": "1", "label": "Resource version", "value": ["<No value>","<Version of the resource (e.g., a dataset version)>"]},

"resourceReference": {"version": "1", "label": "Resource reference", "value": ["<No value>","<References (e.g., publications, URLs) for the resource>"]},

"resourceDescription": {"version": "1", "label": "Resource description", "value": ["<No value>","<Description of the resource>"]},

"resourceDataLevel": {"version": "1", "label": "Resource data level", "value": ["Database","Metadata","Dataset/Recordset","Record","Summary"]},

"resourceContactNames": {"version": "1", "label": "Resource contact names", "value": ["<No value>","<Semicolon separated list of name(s) of those to contact regarding the resource>"]},

"resourceContactEmails": {"version": "1", "label": "Resource contact emails", "value": ["<No value>","<Semicolon separated list of email(s) of those to contact regarding the resource>"]},

"resourceContactOrganisations": {"version": "1", "label": "Resource contact organisations", "value": ["<No value>","<Semicolon separated list of organisation(s) of those to contact regarding the resource>"]}

},

"Profile": {"version": "1",

"Permissions": {"version": "2",

"country": {"version": "2", "label": "use within countries/locations", "value": ["<No value>","Unrestricted","Limited"],

"allowedCountries": {"version": "1", "label": "within specified countries/locations", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"organisation": {"version": "2", "label": "use by organisations", "value": ["<No value>","Unrestricted","Limited"],

"allowedOrganisations": {"version": "1", "label": "for specified categories of organisation", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]},

"nonProfitOrganisation": {"version": "2", "label": "use by non-profit organisations", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedNonProfitOrganisations": {"version": "1", "label": "by specified non-profit organisations", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"profitOrganisation": {"version": "2", "label": "use by profit organisations", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedProfitOrganisations": {"version": "1", "label": "by specified profit organisations", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}}},

"person": {"version": "2", "label": "use by categories of person", "value": ["<No value>","Unrestricted","Limited"],

"allowedPersons": {"version": "1", "label": "for specified categories of person", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]},

"academicProfessional": {"version": "2", "label": "use by academic professional", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedAcademicProfessionals": {"version": "1", "label": "by specified categories of academic professional", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"clinicalProfessional": {"version": "2", "label": "use by clinical professional", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedClinicalProfessionals": {"version": "1", "label": "by specified categories of clinical professional", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"profitMotivatedProfessional": {"version": "2", "label": "use by profit-making professional", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedProfitmakingProfessionals": {"version": "1", "label": "by specified categories of profit-making professional", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"nonProfessional": {"version": "2", "label": "use by non-professional", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedNonProfessionals": {"version": "1", "label": "by specified categories of non-professional", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}}},

"nonProfitPurpose": {"version": "2", "label": "use for non-profit purpose", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedNonProfitPurposes": {"version": "1", "label": "for specified non-profit purposes", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"profitPurpose": {"version": "2", "label": "use for profit purpose", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedProfitPurposes": {"version": "1", "label": "for specified profit purposes", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"research": {"version": "1", "label": "use for research purposes", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedResearch": {"version": "1", "label": "for specified categories of research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]},

"methodsDevelopment": {"version": "3", "label": "use for methods development", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedMethodsDevelopment": {"version": "1", "label": "for specified categories of methods development research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"control": {"version": "1", "label": "use as reference or control material", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedControl": {"version": "1", "label": "for specified categories of control or reference use", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"populationResearch": {"version": "3", "label": "use for research concerning populations", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedPopulationResearch": {"version": "1", "label": "for specified categories of populations research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"ancestryResearch": {"version": "3", "label": "use for research concerning ancestry", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedAncestryResearch": {"version": "1", "label": "for specified categories of ancestry research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"bioMedicalResearch": {"version": "3", "label": "use for biomedical research", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedBioMedicalResearch": {"version": "1", "label": "for specified categories of biomedical research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]},

"fundamentalBiologyResearch": {"version": "3", "label": "use for research concerning fundamental biology", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedFundamentalBiologyResearch": {"version": "1", "label": "for specified categories of fundamental biology research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"geneticResearch": {"version": "3", "label": "use for research concerning genetics", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedGeneticResearch": {"version": "1", "label": "for specified categories of genetics research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"drugDevelopmentResearch": {"version": "3", "label": "use for research concerning drug development", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedDrugDevelopmentResearch": {"version": "1", "label": "for specified categories of drug development research", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"diseaseCategoriesResearch": {"version": "4", "label": "use for research concerning any disease", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedDiseaseCategoriesResearch": {"version": "2", "label": "for research regarding specified categories of disease", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"ageCategoriesResearch": {"version": "2", "label": "use for research concerning age categories", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedAgeCategoriesResearch": {"version": "2", "label": "for research regarding specified age categories", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"genderCategoriesResearch": {"version": "3", "label": "use for research concerning gender categories", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedGenderCategoriesResearch": {"version": "2", "label": "for research regarding specified gender categories", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}}}},

"clinicalPurpose": {"version": "3", "label": "use for clinical purposes", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedClinicalPurpose": {"version": "2", "label": "for specified categories of clinically related use", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]},

"clinicalDecisionSupport": {"version": "1", "label": "use for clinical decision support", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedClinicalDecisionSupport": {"version": "1", "label": "for specified categories of clinical decision support", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}},

"diseaseCategoriesClinicalPurpose": {"version": "4", "label": "use for clinical purposes concerning any disease", "value": ["<No value>","Unrestricted","Unrestricted[Obligatory]","Limited","Limited[Obligatory]","Forbidden"],

"allowedDiseaseCategoriesClinicalPurpose": {"version": "3", "label": "for clinical purposes regarding specified categories of disease", "value": ["<No value>","<Semicolon separated list of free text values, each with optional suffix [Obligatory]>"]}}}

},

"termsOfOperation": {"version": "2",

"noAuthorizationTerms": {"version": "2", "label": "There are no requirements for any formal approval, contract or review conditions to be satisfied", "value": ["<No value>","True","Untrue"],

"whichAuthorizationTerms": {"version": "2", "label": "Formal approval, contract or review conditions are to be met, as specified", "value": ["<No value>","<free text>"]}},

"noPublicationTerms": {"version": "3", "label": "There are no requirements regarding publication or disclosure of results, or included references or acknowledgements", "value": ["<No value>","True","Untrue"],

"whichPublicationTerms": {"version": "2", "label": "Publication or disclosure of derived results is subject to restrictions, as specified", "value": ["<No value>","<free text>"]}},

"noTimelineTerms": {"version": "2", "label": "There are no timeline restrictions", "value": ["<No value>","True","Untrue"],

"whichTimelineTerms": {"version": "2", "label": "The period of access has time limitations, as specified", "value": ["<No value>","<free text>"]}},

"noSecurityTerms": {"version": "2", "label": "There are no requirements regarding data security measures", "value": ["<No value>","True","Untrue"],

"whichSecurityTerms": {"version": "2", "label": "User must have adequate data security measures, as specified", "value": ["<No value>","<free text>"]}},

"noExpungingTerms": {"version": "2", "label": "There are no requirements regarding withdrawal, destruction or return of any subject data", "value": ["<No value>","True","Untrue"],

"whichExpungingTerms": {"version": "2", "label": "Some subject data must be withdrawn, destroyed or returned, as specified", "value": ["<No value>","<free text>"]}},

"noLinkingTerms": {"version": "3", "label": "There are no restrictions regarding the linking of accessed records to other datasets relevant to subject identifiability", "value": ["<No value>","True","Untrue"],

"whichLinkingTerms": {"version": "2", "label": "Accessed records may only be linked to other datasets, as specified", "value": ["<No value>","<free text>"]}},

"noRecontactTerms": {"version": "2", "label": "There is no possibility of recontacting data subjects", "value": ["<No value>","True","Untrue"],

"allowedRecontactTerms": {"version": "2", "label": "Subject recontact may occur in certain circumstances, as specified", "value": ["<No value>","<free text>"]},

"compulsoryRecontactTerms": {"version": "2", "label": "Subject recontact must occur in certain circumstances, as specified", "value": ["<No value>","<free text>"]}},

"noIPClaimTerms": {"version": "2", "label": "There are no restrictions regarding intellectual property claims based on use of the accessed resource", "value": ["<No value>","True","Untrue"],

"whichIPClaimTerms": {"version": "2", "label": "Options for intellectual property claims based on use of the accessed resources are limited, as specified", "value": ["<No value>","<free text>"]}},

"noReportingTerms": {"version": "2", "label": "There are no requirements to report back regarding use of the accessed resources", "value": ["<No value>","True","Untrue"],

"whichReportingTerms": {"version": "2", "label": "Reporting on use of the accessed resources may be required, as specified", "value": ["<No value>","<free text>"]}},

"noCollaborationTerms": {"version": "2", "label": "There are no requirements regarding collaboration", "value": ["<No value>","True","Untrue"],

"whichCollaborationTerms": {"version": "2", "label": "Collaboration may be required, as specified", "value": ["<No value>","<free text>"]}},

"noPaymentTerms": {"version": "2", "label": "No fees will be levied for access of the resources", "value": ["<No value>","True","Untrue"],

"whichPaymentTerms": {"version": "2", "label": "Fees may be levied for access of the resources, as specified", "value": ["<No value>","<free text>"]}}

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"metaConditions": {"version": "1",

"sharingMode": {"version": "2", "label": "Mode of sharing", "value": ["Discovery","Access","Discovery and Access"]},

"multipleObligationsRule": {"version": "1", "label": "Interpretation rule if multiple Obligatory permissions are specified", "value": ["<No value>","Meet all Obligatory permissions","Meet at least one Obligatory permission"]},

"noOtherConditions": {"version": "2", "label": "There are no other use restrictions/limitations in force which are not herein specified", "value": ["<No value>","True","Untrue"],

"whichOtherConditions": {"version": "1", "label": "Other permissions/limitations may apply as specified", "value": ["<No value>","<free text>"]}},

"sensitivePopulations": {"version": "1", "label": "No special evaluation required for access requests involving sensitive/restricted populations", "value": ["<No value>","True","Untrue"]},

"uniformConsent": {"version": "1", "label": "Identical consent permissions have been provided by all subjects", "value": ["<No value>","True","Untrue"]}

}

}

}

***Complete Key:Value Template Specification:***(note: fields without values need not be included in the Key:Value formatted profile)

{

"Header": {"version": "1",