

# RQ5: Automating normative control for Healthcare research eFlint specification for regulatory documents in DIPG-research

Milen G. Kebede

Informatics Institute, University of Amsterdam  
m.g.kebede@uva.nl

April 22, 2021

Supervisors : Prof. Tom van Engers, Dr. Thomas van Binsbergen, Dr. Dannis van Vuurden



- Diffuse Intrinsic Pontine Gliomas(DIPG) registry: rare disease repository that allows researchers to access patient data that can lead to discovering new treatment and prognosis factors.

## 1. DEFINITIONS

1) In this Regulatory Document the following terms have the meanings ascribed to them below:

- Access: Access to certain Datasets in accordance with Section 5.
- Coded: processed through pseudonymisation pursuant to the GDPR i) by or on behalf of the Member making available Data to the DIPG Registry and ii) by or on behalf of the DIPG Network making available a Dataset to a Researcher.
- Data: The information collected from Donors that is transferred to and stored in the DIPG Registry in Coded form.
- Dataset: the Data from the DIPG Registry made available for the purpose of a Project.
- Donor: Any individual who's Data are transferred to the DIPG Registry in compliance with the terms and conditions of this Regulation.
- Dutch Childhood Oncology Group (DCOG): Dutch foundation and National Paediatric Haematology-Oncology Society, in which all Dutch paediatricians and other professionals specialized in research and treatment of children with cancer (paediatric oncology) are organized. DCOG will have tasks related to the DIPG Registry as outlined under 3.
- Executive Committee: The board that in accordance with the DIPG Network Bylaws has the authority to make decisions with respect to:
  - Access for a Project; and

7) Access to Data shall at least be conditional to the following:

- The Researcher shall be responsible for obtaining the permits and approvals necessary in its own country and the policies of its institution.
- The Researcher shall use the Data for the approved Project only. In case of deviations or changes in the project the Executive Committee shall have the right to terminate Access without any liability at its sole discretion
- The Researchers shall bear sole responsibility for the handling and use of the Data in accordance with applicable law and legislation
- The Researcher shall not duplicate the Data or have them duplicated
- The Researcher shall not disclose or provide access to the Data to any third party without the prior written consent of Executive Committee.
- The Researcher shall report the progress of the Project and Findings in a frequency as outlined in the Letter of Approval
- Findings must be shared with the research community at large and therefore be scientifically published in accordance with the Terms and Conditions.

## GDPR concepts(Art.4)

- (7) 'controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;
- (8) 'processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;
- (11) 'consent' of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;

Fact subject

Fact data

Fact purpose

Fact subject-of Identified by subject \* data

Fact controller

Fact processor

· Fact processes Identified by  
processor \* data \* controller \* purpose

· Fact consent Identified by  
subject \* controller \* purpose

· Fact accurate-for-purpose Identified by  
data \* purpose

## DIPG Reg. terms

- 5) The Researcher shall be considered a controller under the GDPR in relation to the Dataset. The Letter of Approval shall include provisions imposing on the Researcher the obligations of the Researcher as controller under the GDPR.

DIPG Registry are performed exclusively on behalf of the DIPG Network Members. DCOG is considered a processor under the GDPR.

- 1) Members shall transfer into the DIPG Registry free of charge, Coded Data of patients that consented and are eligible to participate in the DIPG Registry. The Data in the DIPG Registry shall be used for further research purposes.

```
#include "terms.eflint".
```

```
#include "gdpr/consent.eflint".
```

Fact controller Derived from member

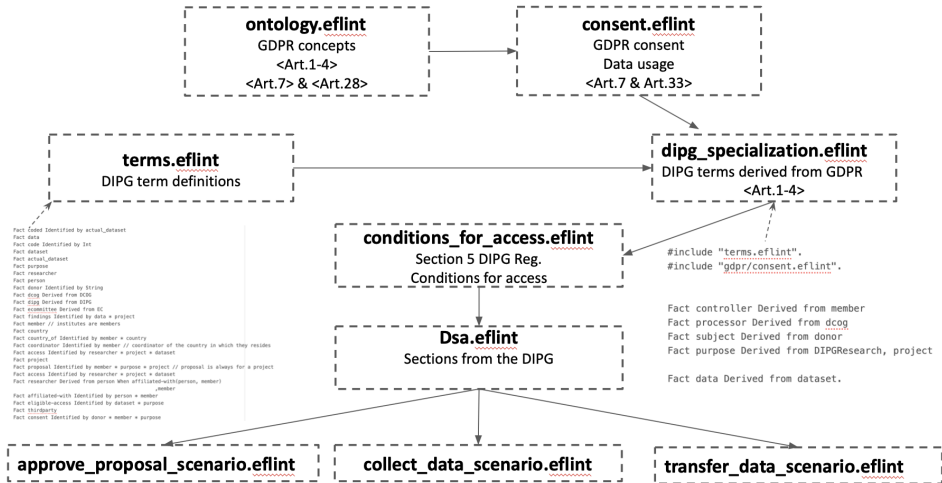
Fact processor Derived from dco

Fact subject Derived from donor

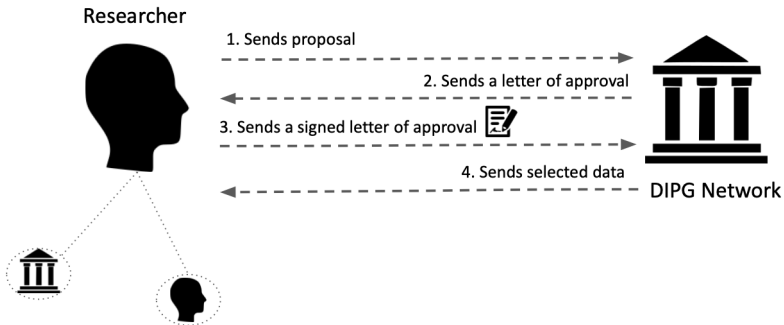
Fact purpose Derived from DIPGResearch, project

Fact data Derived from dataset.

# DIPG Regulatory articles



# Accessing the registry



# Policy specification with eFLINT

## Send project proposal

```
Act propose-project
  Actor researcher
  Recipient ecommittee
  Related to project
  Creates proposal(researcher,project,
    project) When member(researcher)
    ,proposal(member, project,
    project) When
    affiliated-with(researcher,member)
  Holds when researcher && ecommittee
```

## Approve Project proposal

```
Act approve-project
  Actor ecommittee
  Recipient member
  Related to project
  Creates approved(project, member)
  Holds when ecommittee && member &&
    proposal(member, project, project)
  Fact approved Identified by project *
    member
```

```
Act send-letter-of-approval
  Actor dipg
  Recipient member
  Related to project
  Creates letter-of-approval-sent(project, member)
  Holds when dipg && member && approved(project, member)
  Fact letter-of-approval-sent Identified by project * member
  Fact letter-of-approval-signed Identified by project *
    member
  Act sign-letter-of-approval
  Actor researcher
  Recipient ecommittee
  Related to project
  Creates letter-of-approval-signed(project, researcher)
  When member(researcher)
    ,letter-of-approval-signed(project, member) When
    affiliated-with(researcher,member)
    ,duty-to-select-data(ecommittee, researcher,
    project) When member(researcher)
    ,duty-to-select-data(ecommittee, member, project)
  When affiliated-with(researcher,member)
    ,duty-to-send-data(ecommittee, researcher,
    project) When member(researcher)
    ,duty-to-send-data(ecommittee, member, project)
  When affiliated-with(researcher,member)
  Holds when
    researcher && ecommittee &&
    letter-of-approval-sent(project, researcher) &&
    member(researcher)
    ,researcher && ecommittee &&
    letter-of-approval-sent(project, member) &&
    affiliated-with(researcher, member)
```

# Project approval scenario

```
+dataset(D1).
+member(STa).
+person(Eve).
+project(P1).
+affiliated-with(Eve,STa).
propose-project(Eve,EC,P1).
approve-project(EC,STa,P1).
send-letter-of-approval(DIPG,STa,P1).
sign-letter-of-approval(STa,EC,P1).
?duty-to-select-data(EC, STa, P1).
?duty-to-send-data(EC, STa, P1).
select-data(EC, STa, P1, D1).
?!duty-to-select-data(EC, STa, P1).
?duty-to-send-data(EC, STa, P1).
send-data(EC, STa, D1).
?!duty-to-send-data(EC, STa, P1).
```

- The formalization that we are making matches the formalization of the DIPG document
- Representing a member who can either be a researcher or an institution

```
Fact researcher Derived from person When affiliated-with(person, member)
                                     ,member
```

- Signing letter of approval creates two duties

```
Duty duty-to-select-data
  Holder ecommittee
  Claimant member
  Related to project

Duty duty-to-send-data
  Holder ecommittee
  Claimant member
  Related to project
```



## Future work

- Generic data sharing ontology
- Enforcing higher level policies
- Establish a connection with lower level policies

# RQ5: Automating normative control for Healthcare research eFlint specification for regulatory documents in DIPG-research

Milen G. Kebede

Informatics Institute, University of Amsterdam  
m.g.kebede@uva.nl

April 22, 2021