**Template DPO/legal representative or legal advisor**

Mr/Ms \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Data Protection Officer / legal advisor (counsel) to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (entity)

**Declares that**

|  |  |
| --- | --- |
| ▪ Our processing of personal data complies with the provisions of the General Data Protection Regulation and any national laws that regulate the re-use of health data for secondary purposes. |  |
| That the following measures have been taken in the data set to be shared with EUCAIM: |  |
| ▪ A Data Protection Impact Assessment (DPIA) has been carried out. |  |
| ▪ In case the DPIA is not required, a risk analysis has been carried out (art. 24 and 32 GDPR). |  |
| ▪ The data has been properly anonymised. |  |
| ▪ National Law’s data protection obligations have been fulfilled for data sharing with EUCAIM |  |

**Furthermore, I must inform you that:**

**1. Legal representative:**

Data sharing decisions in the name and on behalf of the data controller, as well as the signing of agreements, commitments and obligations has been delegated to Mr/Mrs \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ by virtue of the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (agreement/law/by statutes of the entity etc.)

Attached supporting documentation

|  |  |
| --- | --- |
|  | Document proving legal representation |
|  | Statutes |
|  | Other: \_\_\_\_\_\_\_\_\_\_\_\_ |

**2. Ethical concerns:**

According to the information provided by the Ethics Committee (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[[1]](#footnote-1))

|  |  |
| --- | --- |
|  | The sharing of data has a favourable report from the Committee. |
|  | The research activity of our employee (data Access requester) has been approved. |
|  | A report from an Ethics Committee is not required in our Legal Framework. |
|  | A self-assessment of ethical risks has been carried out. |
|  | A self-assessment of ethical risks in the area of artificial intelligence has been carried out. |

Attached supporting documentation

|  |  |
| --- | --- |
|  | Ethics Committee’s Approval. |
|  | Ethical protocol. |
|  | Self-assessment on ethical risks. |
|  | Self-assessment on AI ethical risks. |

**3. Information Security**

According to the information provided by the Information Security Officer (or equivalent) our information systems:

|  |  |
| --- | --- |
|  | Apply the security level \_\_\_\_\_\_ of the Applicable National Standard (\_\_\_\_\_\_\_\_\_) |
|  | Apply the certified standard (\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) |
|  | We adhere to the code of conduct \_\_\_\_\_\_\_\_ |
|  | Have been audited and can be accredited as meeting the security measures required to participate in EUCAIM's federated data processing. |
|  | Have been audited and can be accredited as meeting the security measures required to participate in data transfer to EUCAIM's premises. |

Attached supporting documentation

|  |  |
| --- | --- |
|  | Certification of the chief security officer or equivalent. |
|  | Certification of the code of conduct. |
|  | Certification of the security standard. |
|  | Audit report or certificate issued by the independent auditor. |

**4. Additional legal requirements for data sets**

Data sets shared with EUCAIM may not be reused for the following purposes: (please list the restrictions)

▪

▪

▪

Attached supporting documentation

|  |  |
| --- | --- |
|  | National Law. |
|  | Other |

**5. Additional legal requirements for software /Information Systems/AI Systems reuse**

Software resources, information systems, artificial intelligence systems, o the following conditions of use

|  |  |
| --- | --- |
|  | Creative Commons License Type\_\_\_\_\_. |
|  | Other License (describe) |
|  | Forbidden uses (describe) |

Risk management

|  |  |
| --- | --- |
|  | Transparency information |
|  | Instructions for users and risks related with use |

Attached supporting documentation

|  |  |
| --- | --- |
|  | License and/or terms and conditions for use (document, URL etc). |
|  | Transparency Statement (URL etc) |
|  | Users’ guidance |
|  | Users’ guidance on AI |
|  | Evidence on prior authorisation requirements |

Hereby signed

Place:

Date:

Person:

Position/responsibility:

Signature

1. Name, entity etc. [↑](#footnote-ref-1)