MEDICAL UNIVERSITY OF VIENNA

MedUni Vienna Data Clearing House

Request for disclosure of personal data or previously anonymised data to external recipients

1. Applicant at the Medical University of Vienna

Organisational unit

Applicant

Family name | First name | Title

Telephone/Pager | Email

Contact person[1] (if not the applicant)

Family name | First name | Title

Telephone/Pager | Email

2.a. Data recipient

Name of the company / partner organisation

Institute, department, clinic, working group

Is the recipient of the data located within the EU? yes ◯ no ◯

2.b. Sponsor of the project/study

Name of the company/organization

Location | Country

What is the relationship between the applicant and the data recipient? Are the applicant or employees of the applicant also employed by the data recipient?

3. Project

Title

Description: A description of the project is to be attached to the request (refer to Point 6, Annexes).

Organisational units at the MedUni Vienna which are involved

Project duration:
Start date

Finish date

Has the Ethics Commission already been involved? yes ○ no ○

If yes, please add the EC approval number

The application to the Ethics Commission and, if applicable, the vote must be attached (see also point 6, Annexes).

4. Data disclosure

Do (actual / draft) written or oral agreements relating to the data disclosure already exist between the cooperation partners? yes ○ no ○

If yes: which agreements? (Please provide relevant details if the agreement is already stored in the contracts database of MedUni Vienna)

Is there an informed consent for this project? yes ○ no ○
(If yes, please attach it to the annex)

The data disclosure will be

once only	○	Is the intention to disclose only once as a single data packet or is it expected that data will be disclosed multiple times at different points in time (e.g. When new source data are available, follow-ups, etc.)? *
multiple disclosure	○	

	yes	no
Have data already been disclosed in the course of this research activity (or this research project)	○	○

If yes:

Date of data disclosure

Is there an agreement?	○	○
Was the data disclosure authorised by the data clearing house?	○	○

If yes, DC-number / Date

Which data were disclosed?

Reason for disclosure (cooperation, spin-off, multi-centre trial, etc.)

	yes	no
Have these or associated data of the same patient already been published or disclosed to other recipients in the past?	○	○

5. Data

Description: A description of the data is to be attached to the request (refer to Point 6, Annexes).

	yes	no
Is it necessary to be able to re-identify the patients later	○	○

What is the purpose of this?

* If you specify "multiple" submissions, the decision applies to your project and the data set that you have submitted for the duration of the project. If the data set expands after a certain period of time, a new application must be submitted to stating that an application has already been submitted for this project and a decision has been made (specify DC number). In this case, only the new data set will be checked for sufficient pseudonymization.

6. Annexes

	Attached
Project description (see Point 3)	☐
Data description (see Point 5), including the following information • Source (OU, clinic, device) • Storage location • Data types (images, electronic documents, videos, etc.) • Data formats (DICOM, JPG, PDF, Excel, proprietary, etc.) • Data volume (GB, TB, number of investigations, number of patients, etc.) • Will the data be transferred to one or more recipients? Which data is transmitted to which recipients? • Do the data contain personal details (name, occupation, date of birth, medical history, social insurance number, etc.) • Have the data been anonymised / pseudonymised? • Are there requirements in terms of the pseudonymisation of the data? • During the data documentation of a study / trial, are the data entered into a system other than a MedUni Vienna system? • A description of the data storage and processing at the MedUni Vienna and on the part of the data recipient, including a diagram of this. • Which data are extracted, linked, etc.? • How is it intended to disclose the data to the recipient? • Do technical requirements exist on the part of the recipient?	☐
Contracts, draft contracts and, in the case of other agreements, records or correspondence which state the facts should be attached	☐
Data records covering at least 10 cases (investigations, patients, etc.)	☐
If applicable: Study protokoll, clinical trial plan, trial-related record	☐
If applicable: Applicant to the ethics commissions and the voting (current version)	☐
If applicable: Text of the patient consent form (current version)	☐

Date

Applicant: Name in block capitals

Signature of applicant

Date

Principal Investigator (PI): Name in block capitals

Signature of Principal Investigator (PI)