ITM Data Access Request Form

Applicants who wish to receive access to ITM managed research data must fill out the form below and submit this to: ITMresearchdataaccess@itg.be

Access to data will be conditional upon approval by the ITM Data Access Committee and the signing of a Data Sharing Agreement.

**SECTION A: INFORMATION ABOUT THE RESEARCHER/RESEARCH TEAM**

A.1 Name of applicant:

A.2. Applicant affiliation with institution/organization responsible for signing the Data Sharing Agreement:

A.3. Applicant contact details:

 E-mail:

 Telephone:

A.4. Summary of relevant publications (or attach research CV) (max 2 pages):

A.5. Name, institution and contact details of research partners (collaborators, sponsors, investigators involved in the research (include those having access to the requested Data):

A.6. Do you have any partnerships or other arrangements with the commercial sector?

If yes, please explain:

A.7. Source/name of funder of the research:

**SECTION B: RESEARCH PLAN**

B.1. Title of proposed research (max. 100 words):

B.2. Lay summary of the research (max. 500 words):

B.3. Primary and secondary outcome measures:

B.4. Details of required research ethics and other approvals (include approval dates, reference numbers and committee names):

B.5. Potential outputs (including any contribution to regulatory approvals of new drugs, therapies, devices, solutions, etc.), benefit-sharing plan, and/or publication plan (include timeline, max. 200 words). Also include any anticipated involvement of ITM:

In addition to acknowledgement for use of data, is there any anticipated collaboration with ITM?

**SECTION C: (PERSONAL) DATA REQUIREMENTS**

From which research publication or research project do you wish to receive data *(include title, doi or other reference)*:

 C.1. Selected study population:

C.2. Personal data identifiers requested:

*Due to privacy regulations (e.g. the European General Data Protection Regulation 2016/679), generally only anonymised or pseudonimised personal data can be made accessible for research purposes. Personal data will be minimized as much as possible in datasets.*

🗆 Not applicable (no personal data identifiers requested)

[ ]  No (indirect) identifiers needed (completely anonymous/anonymised dataset)

*(Data can be considered anonymised when it does not allow identification of the individuals to whom it relates, and it is unlikely that any individual could be identified from the data by any further processing of that data or by processing it together with other information which is available or likely to be available, i.e. personally identifiable information was not collected, or if collected, identifiers were not retained and cannot be retrieved)*

[ ]  Direct identifiers required

|  |  |
| --- | --- |
| **Direct identifier** | **Justification (mandatory)** |
| [ ]  Names |  |
| [ ]  Initials |  |
| [ ]  Geographic coordinates (GPS) |  |
| [ ]  Home address |  |
| [ ]  Electronic e-mail address or telephone number |  |
| [ ]  Medical record number |  |
| [ ]  IP-address or URLs |  |
| [ ]  Biometric identifiers |  |
| [ ]  Audio- or videotape of participants |  |
| [ ]  … |  |
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[ ]  Indirect identifiers required

|  |  |
| --- | --- |
| **Indirect identifier** | **Justification (Mandatory)** |
| [ ]  Age *(If age is needed, choose preferably age over year of birth or date of birth)* |  |
| [ ]  Year of birth*(If year of birth is needed, choose preferably year of birth over date of birth)* |  |
| [ ]  Date of birth*(If age is needed, choose preferably age over year of birth or date of birth)* |  |
| [ ]  Sex / gender |  |
| [ ]  Occupation/profession |  |
| [ ]  Rare disease or treatment |  |
| [ ]  Education |  |
| [ ]  Income |  |
| [ ]  Marital Status |  |
| [ ]  Behavioural Data *(esp. sensitive, like drug, alcohol use, or risky behavior)* |  |
| [ ]  Study visit dates |  |
| [ ]  Country of origin |  |
| [ ]  Ethnicity |  |
| [ ]  Caste |  |
| [ ]  Religion |  |
| [ ]  Health center locations, physicians name |  |
| [ ]  Verbatim responses or transcripts |  |
| [ ]  Small denominators (population size <100) |  |
| [ ]  Very small numerators (event counts <3) |  |
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List all other variables requested or include a list in annex (no justification is required):

Other potentially sensitive data that is not personal data (not at participant level, e.g. sensitive health policy/mgmt. data)

Explain any potential risk for identification and stigmatization of communities, populations or even countries,…

C.3. Conditions and timeframe for storage, and destruction of the Dataset(s) requested, upon completion of research:

C.4. Will an Ethics Committee approve the use of the personal data or the secondary research with the requested data?

If yes, include details of the Ethics Committee or a copy of the approval if already obtained.

**SECTION D: POTENTIAL CONFLICTS OF INTEREST**

D.1. Management of conflicts of interest
Please summarise how conflicts of interest related to the funding of the proposed research, other financial relationships, or other conflicts of interest will be managed, for example through disclosure of interests when the research is presented and published.

**Any other comments, requests or additions you wish to include:**

…

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*Privacy statement - Your personal data will be processed by ITM solely for the review of your data access request. It will be shared among the members of the ITM Data Access Committee and possibly Investigators of the primary research or consulted experts in the research field. If access is granted, your personal data will be stored for the duration of the agreement. If access is rejected, your personal data will be stored for a period of 2 years after the decision. In case you have any further questions about the processing of your personal data, please contact informatieveiligheid@itg.be/.*