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| Lääkealan turvallisuus- ja kehittämiskeskus FIMEA | DATA PERMIT APPLICATION | 1 (4) |

## Study/report

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| --- |
| Name of the study/report      |
| Start date      End date       |

## Application type

|  |
| --- |
| [ ]  New application |
| [ ]  Application for a variation[ ]  Material expansion, which variation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Application for extension of an earlier authorisation until \_\_\_\_\_\_\_\_\_\_\_[ ]  Application for extension of a previously notified research team, what change to the members of the study group \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other, please specify \_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Other, please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| In case of a change permit application, document numbers of previous permits      |

## Purpose of the materials

|  |
| --- |
| [ ]  Scientific research [ ]  Inquiry or planning task of an authority[ ]  Development or innovation operations [ ]  Education[ ]  Statistics [ ]  Other, please specify       |
| * 1. For a thesis(es)
	2. [ ]  Yes, how many theses

[ ]  No |
| * 1. Objective and purpose of the research/study in brief
	2.
 |
| * 1. Research publication plan
	2.
 |

## Required information/ extraction description. Fill in below or in a separate appendix [ ]

|  |
| --- |
| * 1. From which register/repository the data is extracted. In the case of an extension of research data, an explanation of the new data to be retrieved.
	2.
 |
| * 1. Which persons' information is extracted / how the target group is formed.
	2.
 |
| * 1. Will control persons be selected for the target group.

      |
| * 1. What information is extracted (specify, for example, background and result variables) and from which period.

      |
| * 1. Further information about the required information

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## Other materials to be combined with the data (The merging of data from different registers requires applying for a data access authorisation from Findata instead of an individual data controller.)

|  |
| --- |
| Authorisation issuer, diary number or other identifying information, date of authorisation decision and expiration date      |

## Authors of the study/report

[ ]  Authorisation applicant / person responsible

|  |  |
| --- | --- |
| Name      | Degree      |
| Assignment:      | Email address      |
| Applicant organisation and business ID      | Business ID      |
| Address      | Telephone number      |
| Affiliation relationship (work or official relationship) with the applicant organisation[ ]  Yes [ ]  No | Processes the data to be retrieved[ ]  Yes [ ]  No |

[ ]  Researchers and supervisors

|  |  |
| --- | --- |
| Name, degree/position, role in the study/report      | Organisation      |
| Affiliation relationship (work or official relationship) with the applicant organisation[ ]  Yes [ ]  No | Processes the data to be retrieved[ ]  Yes [ ]  No |

[ ]  Researchers and supervisors

|  |  |
| --- | --- |
| Name, degree/position, role in the study/report      | Organisation      |
| Affiliation relationship (work or official relationship) with the applicant organisation[ ]  Yes [ ]  No | Processes the data to be retrieved[ ]  Yes [ ]  No |

[ ]  Researchers and supervisors

|  |  |
| --- | --- |
| Name, degree/position, role in the study/report      | Organisation      |
| Affiliation relationship (work or official relationship) with the applicant organisation[ ]  Yes [ ]  No | Processes the data to be retrieved[ ]  Yes [ ]  No |

[ ]  Authors of theses

|  |  |
| --- | --- |
| Name, degree/position, role in the study/report      | Organisation      |
| Affiliation relationship (work or official relationship) with the applicant organisation[ ]  Yes [ ]  No | Processes the data to be retrieved[ ]  Yes [ ]  No |

[ ]  Other participants, statisticians, research assistants, etc.

|  |  |
| --- | --- |
| Name, degree/position, role in the study/report      | Organisation      |
| Affiliation relationship (work or official relationship) with the applicant organisation[ ]  Yes [ ]  No | Processes the data to be retrieved[ ]  Yes [ ]  No |

## Other data processing organisations to which data is provided

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| --- |
| Organisations, countries      |
| Data access environment       |
| Data transfer agreement required[ ]  Yes [ ]  No |

## Further information

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|       |

## Attachments (mandatory attachments marked with an asterisk \*)

[ ]  Research material application plan (max 4 pages)\*

[ ]  Data utilisation plan\*

[ ]  Confidentiality agreements\*

[ ]  Required information / extraction description (If necessary, specify the information in a separate appendix as accurately as possible.)

[ ]  Privacy notice for scientific research/study, if the requested material contains personal data\*
(also applies to indirect personal data.)

[ ]  Data protection impact assessment (DPIA) (\*Mandatory attachment if the application concerns the secondary use of health and social data.)

[ ]  Ethical committee approval or ethical committee opinion (if required by applicable legislation.)

[ ]  Other appendix, please specify

## Contact person for application issues:

|  |  |
| --- | --- |
| Name      | Degree/position      |
| Organisation      | Address      |
| Telephone number      | Email address      |

## Person to whom the decision is sent

|  |  |
| --- | --- |
| Name      | Organisation      |
| Telephone number      | Email address      |

## I wish to receive the decision (only select one)

[ ]  By email [ ]  On paper by post

## Invoicing details

|  |
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|       |

## Signature of the authorisation applicant or person responsible for the study/report

I have checked the accuracy of the permit application and its appendices. The application has been completed and its appendices have been made in accordance with the instructions on Fimea's Data Access Authorisations website.

|  |
| --- |
| Location and date:      |
| Signature and clarification of signature |
|       |
| Position and organisation      |

## Signature of the official representative of the applicant, if other than the responsible person

|  |
| --- |
| Location and date:      |
| Signature and clarification of signature |
|       |
| Position and organisation      |

Submit the application and its appendices to Fimea's registry, either using Fimea's secure mail or by sending it to P.O. Box 55, 00320 Fimea.

If the right to use confidential information is granted on the basis of the permit, a decision on the data permit is made subject to a fee. The applicant commits to complying with the conditions set out in the decision. In other situations, an agreement will be concluded on the conditions for use of data.