# Application form

# to be submitted to the Ethics Committee of the

# Catholic University of Eichstätt-Ingolstadt

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| **I. Information on application** | |
| Date of application |  |
| Type of application | New application  Revised application  Addition/Amendment to application no.: |

|  |  |
| --- | --- |
| **II. Information on study** | |
| Title of study |  |
| Summary of study (no longer than 20 lines) |  |
| Place(s) where study is carried out |  |
| Does the study receive third-party funding? [1] | No  Yes, third-party sponsor: |
| Is the study a multicenter study for which another ethics committee has already issued a vote? [2] | Yes  No |
| Are drugs within the meaning of the German Medicinal Products Act (*Arzneimittelgesetz, AMG*) administered during the study? [3] | Yes  No |
| Are medical products within the meaning of the German Medical Devices Act (*Gesetz über Medizinprodukte, MPG*) used during the study? [4] | Yes  No |
| Is one or more of the following groups of test persons examined? | Minors  Other test persons with limited decision-making powers (e.g.  legally incompetent persons) |

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| **III. Information on applicant** | |
| Name |  |
| Address |  |
| Phone |  |
| E-mail address |  |

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| **IV. Annexes** | |
| Description of research project [5] | required |
| Form(s) for written information for test persons and/or persons entitled to custody | required |
| Form(s) for written declaration of consent by the test persons and/or persons entitled to custody | required |
| Application for third-party funding | Yes  Not required |
| Votes issued by other ethics committees [2] | Yes  Not available |
| Proof of insurance cover | Yes  Not required |
| Documentation of drugs within the meaning of the AMG | Yes  Not required |
| Documentation of medical products within the meaning of the MPG | Yes  Not required |
| Other annexes (e.g. data collection tools) |  |

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Applicant’s signature Place, date

**Explanatory notes**

[1] If the applicant receives third-party funding, the application to the third-party sponsor must be attached.

[2] If other ethics committees have already issued a vote, such vote(s) must be attached.

[3] If drugs within the meaning of the AMG are used for the study, please attach corresponding documentation (Investor’s Brochure and/or specialized information in case of authorized drugs, and, if applicable, current preclinical and clinical data).

[4] If medical products within the meaning of the MPG are used for the study, please attach corresponding documentation (product description, CE marking).

[5] The description of the research project must be comprehensible for laypeople. It should include the following information:

* 1. State of research
  2. Aims
  3. Number of inclusion/exclusion criteria for study participants
  4. Applied methods and type of collected data
  5. Short description of planned experiments/studies
  6. Timeline of the research project
  7. Statement on ethical and legal aspects

Please especially include the following aspects in your statement on ethical and legal aspects:

* Laws, regulations and guidelines that must be observed during the implementation of the research project
* Burdens, risks and consequences that may arise for participants in connection with the experiment/study
* Ratio of the benefits of the research project weighed against the named costs (burdens, risks, consequences)
* Measures that are taken to mitigate and/or avoid these burdens, risks and consequences
* Measures for ensuring that test persons are truthfully and comprehensively informed of project aims and test procedures
* Measures for obtaining declarations of consent for participation and giving participants the possibility to reject participation or withdraw their consent
* For study participants with limited decision-making powers (e.g. children, legally incompetent persons): Regulations for consent to participation in an experiment/study by persons entitled to custody
* If applicable, envisaged insurance cover
* Data protection measures (e.g. data anonymization)

If the application is submitted for a multicenter study for which another ethics committee has already issued a vote, you may use the description of the research project provided in the first application, if this application form contains such information.