# Application for an Epidemiological Study within Module 3

This template may be used for stand-alone research project or for research projects within a consortium.

*Please prepare your application in English not exceeding 15 pages (DIN A4, 11 point Arial and 9 point Arial for the synopsis and references, margins of at least 2 cm and single-spaced lines).*

|  |  |
| --- | --- |
| **Coordinating Investigator**  |  |
| **Title of the Study** |  |
| **Subtype of Covid-19** | Please specify (if applicable) which subtype/course of condition your trial is aiming at (e.g. severe, asymptomatic, moderate form) |
| **Objective(s)** |  |
| **Need for the Study** |  |
| **Significance for the Consortium**  |  |
| **Study Type** |  |
| **Target Population & Inclusion / Exclusion Criteria** | *Key inclusion criteria:**Key exclusion criteria:* |
| **Sample Size** | *To be assessed for eligibility (n = …)**To be allocated to study (n = …)**Expected to be analyzed (n = ….)* |
| **Data Collection** |  |
| **Data / Statistical Analysis**  |  |
| **Duration** | *first study subject in to last study subject out**requested duration of funding (months)* |
| **Participating Centers** | *If applicable: How many recruiting centers will be involved? (n)* |

* 1. **Working hypothesis and research questions**

*Please state your working hypothesis and the underlying scientific question in this proposal. What are the objectives and the research goals? Please highlight the novel aspects of this proposal and the future impact of the research results. Please also comment on existing evidence and the current state of research.*

* 1. **Epidemiological and Economical Relevance of the study and Impact on Health Care**

*Please elaborate on the impact the proposed research will have on health care systems in general and on the understanding of the current COVID-19 outbreak in particular. Please comment on the epidemiological and economical relevance of the study proposed.*

* 1. **Justification of the Design Aspects**

*Please comment on each of the aspects listed below. Please elaborate on the methods against bias used, give detailed information about number of probands/patients and anticipated non-response and missing data.*

###  3.1 Reasons for the Study Design

###  3.2 Target / Study Population, Sampling

###  3.3 Feasibility

###  3.4 Data collection

###  3.5 Methods against Bias

* 1. **Statistical Analysis**

*Give a short explanation for the chosen methods and the procedure of analysis. What is the impact of the chosen method for your data? Which instruments will be used?*

*For quantitative data analyses: Please provide examples of statistical models and assumptions that will be used. Justify clearly the sample size necessary for the planned analyses.*

* 1. **Ethical and Legal Considerations**

*A short list of any ethical and legal aspects (e.g. ethics votes, data protection), which must be regulated before the project begins.*

* 1. **Data Handling and Dissemination**

*Please describe measures taken to ensure high quality of data, standardization and the sharing of data. Please state your willingness to share relevant research and project data with other international funding organizations using GloPID-R. Please also indicate which parts of your research contain IP-relevant details and should therefore not be shared.*

* 1. **Study Management**

###  7.1 Major participants

|  |  |  |  |
| --- | --- | --- | --- |
| **#** | **Name** | **Affiliation** | **Responsibility/Role** |
|  |  |  | *Principal/Coordinating Investigator* |
|  |  |  | *Responsible for Special Methodological Aspects / Statistics* |
|  |  |  | *Recruiting centres (e.g. hospitals, nursing homes, network of health care providers)* |
|  |  |  | *Study supporting facilities / institutions (e.g. sickness funds, central laboratories)* |
|  |  |  | *Responsible for Quality Assurance / Data Management* |
|  |  |  | *Self-help, support and advocacy organizations of patients (if applicable)* |

###  7.2 Recruiting Centres / Study-supporting Facilities, Secondary Data Sources

* 1. **References**

*For your references please use the Vancouver style (Further information: International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts submitted to Biomedical Journals. NEJM 1997;336:309-15).*

* 1. **Financial and Time Plan**

###  9.1 Financial Plan

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Item** | **Months** | **Salary Group** | **Detailed Description** | **Requested Resources**  |
| **Personnel** |  |  |   | *€* |
|  *Scientific* |   |  |   | *€* |
|  *Non- Scientific* |   |  |   | *€* |
|  *Other* |   |  |   | *€* |
| **Consumables** | *n.a.* |  | *€* |
| **Subcontracts** | *n.a.* |   | *€* |
| **Travel** | *n.a.* |   | *€* |
| **Total** | *€* |
| **Overhead („Projektpauschale“)** | *€* |
| **Requested Resources (incl. overhead)** | *€* |

*Co-financing of the study by a company (yes/no):*

*Commercial interest:*

*Please describe any potential commercial interest of a company in the results of the study. Please pay particular attention to “Freedom to operate” concerning exploitation of the results of the study.*

###  9.2 Work Plan including milestones

*Please provide details on your working plan and milestones in this project.*

*Describe the work program with a timeline and milestones.*

###  9.3 Other Funding

*In case you have already submitted the same request for financial support or parts hereof to other funding organisations, please mention this here.*

*If this is not the case please declare:*

“A request for funding this project has not been submitted to any other addressee. In case I submit such a request, I will inform the DLR Projektträger immediately”.

* 1. **CVs of the Principal / coordinating investigator**

*Include a tabular scientific CV (max.one page) for the principal / coordinating investigator.*

* 1. Appendix

### Declarations of Commitment of the Participating Centers

|  |  |
| --- | --- |
| *Name of investigator:* |  |
| *Institution:* |  |

**Information on the study**

|  |  |
| --- | --- |
| *Study title:* |  |
| *Inclusion criteria:* |  |
| *Exclusion criteria:* |  |
| *recruitment period (months):* |  |

**Strategy for the determination of recruitment figures**

|  |  |
| --- | --- |
| How many subjects/patients with the condition speci­fied above have you seen in your institution during the last 3 months? |  |
| How many subjects/patients do you estimate to see in the course of the next year |  |
| How many of these subjects/patients would fulfil the inclusion criteria of the above mentioned study? |  |
| How many of these subjects/patients would approximately agree to participate in the above named study per year? |  |
| How many subjects/patients will approximately be recruited during the entire study? |  |

|  |
| --- |
| *Which source/assumption did you use for the estimation of potential participants in the above named study?**[ ]  Individual estimation**[ ]  Hospital data management system**[ ]  Patient registry**[ ]  Others**If others: please specify* |

|  |  |
| --- | --- |
| *Are there any other ongoing clinical studies/ projects competing for the same subjects / patients?* | *[ ]  yes**[ ]  no* |
| *If yes: How will this affect recruitment for the above-named study?*  |

**Commitment to participate**

*I hereby agree to participate in the above-named study and support the study by recruiting subjects / patients.*

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *Date/ Signature*

**Conflicts of Interest**

*I hereby declare that I have no conflict of private, economical or financial interests with regard to the above mentioned study and the investigational drugs that will be used. I have no patents, whether planned, pending or issued, broadly relevant to the work.*

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *Date/ Signature*

### Declarations of commitment of other institutions providing data / secondary data sources

*If data from any other institutions is used for the study, the access to data needs to be clarified and documented.*

|  |  |
| --- | --- |
| *Contact Person:* |  |
| *Institution:**Name of registry:* |  |

**Information on the study**

|  |  |
| --- | --- |
| *Study title:* |  |
| *Inclusion criteria:* |  |
| *Exclusion criteria:* |  |
| *Number of Patients:* |  |

**Information on Data provided**

|  |  |
| --- | --- |
| *Secondary data source* |  |
| *Data provided:* |  |
| *Data protection:* |  |

**Commitment to participate**

*I hereby agree to participate in the above-named study and support the study by providing data, etc.*

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 *Date / Signature*

**Conflicts of Interest**

*I hereby declare that I have no conflict of private, economical or financial interests with regard to the above mentioned study. I have no patents, whether planned, pending or issued, broadly relevant to the work.*

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 *Date / Signature*