**Application for a Research Project within Modules 2 and 3**

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

*Please describe your research project. Please fill out the relevant section 8 for animal studies, if applicable. Please highlight the contribution of this research project to the entire consortium, if applicable. For research projects with and without animal studies the length of the application is limited to 9 and 6 pages, respectively and excluding the appendix. Please prepare your application in English (DIN A4, 11 point Arial, margins of at least 2 cm and single-spaced lines).*

|  |  |
| --- | --- |
| **Title and Acronym** |  |
| **Principal Investigator** | *Name, Institution* |
| **Abstract** | *max. 300 words* |

**1 Working hypothesis and research question(s)**

*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.*

**2 Methodological approach**

*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.*

***3* Own previous work and publications**

*Please describe your previous work related to this topic and include a maximum of 5 relevant publications in the last 5 years as a reference.*

**4****Work plan including milestones**

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

*If the subproject has Dual Use Research of Concern (DURC) potential, please comment on it.*

*Applicable only if this research project is part of a consortium:*

***5* Contribution to the consortium**

*If applicable, please describe how this research project is embedded into the consortium. Please outline the added-value of the research project in the consortium.*

**6****Quality assurance, standardization, data sharing**

*Please describe measures taken to ensure high quality of data, standardization and the sharing of data. These may include precautions to secure validity of test procedures (also across labs), authentication of biological resources (animals, cells, antibodies, media etc.), skills needed, standardized protocols, data management, (pre)registration, reporting guidelines*

*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 details relevant to intellectual property and should therefore not be shared.*

**7****Ethical and legal considerations**

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

*If you plan to conduct animal studies in your research project, please comment on the points made in the ARRIVE Guidelines[[1]](#footnote-1) listed under section 8 or argue why these points do not apply.*

**8****Animal studies**

***Background and objectives:***

*Explain the experimental approach and rationale; and how the animal model being used can address the scientific objectives, explain the study’s relevance to human biology. Discuss briefly the acceptability of the harm incurred by the animals versus the potential benefit for the patient.*

***8.1 Methods****:*

* 1. *Study design (number of experimental and control groups, steps to minimize the effects of subjective bias, experimental unit).*
  2. *Experimental procedures (drug formulation and dose, anesthetic and surgical procedures, equipment – How, When, Where, Why);*
  3. *Experimental animals (species, strain, sex, developmental stage, age, weight, source of the animals, genetic modification status, etc.);*
  4. *Housing and husbandry (type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions, type of food, access to food and water, environmental enrichment etc.)*
  5. *sample size* 
     + *specify the total number of animals used in each experiment, and the number of animals in each experimental group;*
     + *provide details of any sample size calculation used. Indicate the number of independent replications of each experiment, if relevant.*
  6. *Allocating animals to experimental groups (details of how animals were allocated to experimental groups, including randomization or matching if done; order of treatment and assessment)*
  7. *Experimental outcomes (define the primary and secondary experimental outcomes assessed e.g. cell death, molecular markers, behavioral changes)*
  8. *Statistical methods* 
     + *provide details of the statistical methods used for each analysis.*
     + *specify the unit of analysis for each dataset (e.g. single animal, group of animals).*
     + *describe any methods used to assess whether the data met the assumptions of the statistical approach*
     + *Brief outline of the statistical analyses including handling of missing data or clustering/hierarchical structures within the data*
     + *Assumed effect sizes (should be justified by effect sizes from previous studies)*
     + *Description of the primary efficacy analysis and population*

***8.2 Relevance of the Model***

*Which model/models is/are to be used: Please provide details for animal species /cell model, strain, sex, age (developmental stage), weight. Provide source of animals or cells, international nomenclature, genetic modification status, genotype, health/immune status, drug or test naïve, cell line, authentication and characterization, age and sex of donor, nature of tissue specimen, storage and banking.*

*Please provide sound scientific reasoning how and why the chosen model can address the scientific objectives and the study’s relevance to human biology.*

*Consideration of external validity: age, sex of animals or samples, comorbidities, lab variety (number of labs participating in the study).*

**9 Other funding**

*In case you have already submitted the same request for financial support or parts hereof to other funding organizations, 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”.

**10 Financial details of the project**

**10.1 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.*

**10.2 Financial summary**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Personnel for a maximum of 18 months | | | | |
| Position / Salary Group | Total Budget | | Duration (months) | Tasks / Justification |
|  |  | |  |  |
|  |  | |  |  |
| Other resources for a maximum of 18 months | | | | |
| Type | Total Budget | | Specification / Justification | |
| *Consumables* |  | |  | |
| *Animal costs* |  | |  | |
| *Equipment* |  | |  | |
| *Travel* |  | |  | |
| *Other* |  | |  | |
| Sum: Total Budget: | |  | | |
| Institutional Overhead, „Projektpauschale“: | |  | | |
| Sum: Requested Budget(50% BMBF-share for SME) | |  | | |

* + - * 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).*

Appendix

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

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

**2 CVs of other participants WITH LEADING ROLE**

*Include tabular scientific CVs (one page) for other participants playing a leading role including a list of a maximum of 5 publications on the most relevant projects related to this project’s topic by him/her that have appeared during the last five years.*

1. The ARRIVE Guidelines: Animal Research: Reporting of In Vivo Experiments. Originally published in PLOS Biology, June 2010 (<http://www.nc3rs.org.uk/arrive-guidelines>) [↑](#footnote-ref-1)