Guidelines for Quality-Improving Aspects in Clinical and Biomedical Research

Prepared by the "Quality in Clinical Research" Working Group of the DFG Senate Commission on Key Questions in Clinical Research

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The purpose of these guidelines is to provide orientation to prospective applicants, reviewers and review boards about which aspects of scientific quality assurance may be relevant to DFG proposals in the fields of medicine and biomedicine. Recommendations and questions are presented here as examples to help increase the quality of research projects and the reproducibility of the results obtained, as well as to raise awareness of quality-improving aspects in the review and evaluation of proposals.

Guidance note for applicants:

It is recommended to present the essential information on quality-improving aspects for your project as succinctly and coherently as possible in the project description[1] in the work programme. Please be aware that there are specific subsections in the proposal preparation instructions related to aspects such as relevance of sex, gender and/or diversity, general ethical aspects, animal experimentation,[2] and data handling. More detailed information on these points can be provided there.

Guidance note for reviewers and review boards:

It is recommended that specific quality-improving aspects in the project be addressed in the written reviews[3] or in review board evaluations, thus acknowledging the efforts of the applicants to ensure the quality of the project and of the knowledge gained by means of suitable measures. When assessing the research performance of the applicants, their research contributions with regard to the quality of research should therefore be taken into account.

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[1] See guidelines for applying for individual research grants – 54.01 Proposal Preparation Instructions – Project Proposals [04/21]
https://www.dfg.de/en/research_funding/programmes/individual/research_grants/index.html
[2] See Guidelines of the Permanent Senate Commission on Animal Protection and Experimentation of the DFG for the Design and Description of Animal Experimental Research Projects
https://www.dfg.de/download/pdf/dfg_im_profil/geschaeftsstelle/publikationen/handreichung_sk_tierversuche_en.pdf
[3] See 10.20 Guidelines for the Written Review [04/21] https://www.dfg.de/formulare/10_20/10_20_en.pdf

Choice of research model, data sets/biosamples used, and use of research infrastructures:

1. Why did you choose this model system, data source, or theoretical approach to pursue the research question? What are the advantages and disadvantages associated with the model or approach? With regard to the research question, are there sex- or gender-related and/or other factors that need to be considered in choosing the model system, data, or theoretical approach? Especially when it comes to human or animal studies, are there ethical and/or legal aspects to consider when choosing a model, data, or a theoretical framework? When choosing an animal model, has it been assessed in terms of the 3Rs principle whether the model is well-suited for achieving scientific validity?

2. Is there evidence to confirm that the quality and specification of the biosamples, organisms, or research data used are appropriate for the research question?

3. Do you require technical, methodological, or organizational research infrastructures to carry out your research project? If applicable, are there structures in place whose services or available expertise could improve the feasibility and quality assurance of the project? Are data sets or biosamples already available and thus do not have to be newly collected?

Type of study, statistical planning, and use, analysis, and storing of data sets:

4. Do you plan to use a confirmatory or exploratory course of action for your research approach, and what played a critical role in that decision? Would the integration of a replication study be useful to corroborate key initial assumptions or important intermediate results? Does the study need to be registered? Is it a clinical trial?

5. Can the anticipated scientific statements and results actually be derived on the basis of the statistical planning? Are the selected sample size or replicates sufficient for this purpose? What sources of bias do you see and how do you address them? How do you plan to deal with missing values? What advice and assistance did you seek in selecting and presenting the statistical approach?

6. Were there circumstances related to ethical requirements for the welfare of experimental animals and human subjects that influenced your statistical planning?

7. What key data sets and/or key biosamples will your project generate? In which (recognized) research infrastructures, such as certified biobanks, sample collections, or research data repositories, will the data sets and/or biosamples be deposited after completion of the project (e.g. relevant NFDI consortia)? Are there any ethical or legal circumstances that pose an obstacle to this study and how do you address them? Are there any costs associated with using the structures that should be taken into account when applying for funding?

What are the risks of bias in your research question and in your planning, execution, and analytical strategy? What approaches are planned or used to avoid bias (e.g. blinding, randomisation, or statistical approaches)? This is particularly relevant for research projects involving large multimodal data sets (e.g. imaging and/or omics analyses).

Overarching aspects that may have an indirect impact on the quality of research projects:

8. Can you name research activities that represent a concrete added value with regard to quality aspects of the question being addressed (e.g. a systematic review; a replication study; involvement in the creation of standards or the establishment of guidelines, in the development and expansion of scientific infrastructures, or in the conducting of a clinical trial)?

9. Are roles sufficiently clear in terms of responsibilities in the project and results published over the course of the project? This question is particularly relevant with regard to collaborations that are relevant for carrying out the project and with regard to projects that serve as the basis for scientific careers.

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