



Guide for quality-promoting aspects in medicine and biomedicine

prepared by the "Quality in Clinical Research" working group
of the DFG's Permanent Senate Commission on Key Questions
in Clinical Research

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The following guidelines are intended to provide orientation for applicants, reviewers and review boards as to which aspects of quality assurance may be relevant to DFG proposals in medicine and biomedicine. The recommendations and questions listed as examples aim to help enhance the quality of research projects and the replicability of the results obtained, as well as raise awareness of quality-promoting aspects in the review and evaluation of proposals.

For applicants:

You are recommended to present the essential information on quality-promoting aspects for your project as concisely and coherently as possible in the proposal description¹ in the work programme. Please note that there are specific subsections in the proposal guidelines on the relevance of gender and/or diversity, ethical framework conditions, animal research² and the handling of research data. More detailed information on these points can be provided in the relevant subsections.

For reviewers and review boards:

You are recommended to address the project's specific quality-promoting aspects both when writing the review³ and when evaluating the proposal in the review board, thereby acknowledging the applicants' efforts to take appropriate measures to ensure the quality of the project and the insights gained through the research. For this reason, contributions relating to the quality of research should be taken into account when assessing applicants' research output.

¹ See the Proposal Preparation Instructions for Research Grants – 54.01 Proposal Preparation Instructions – Project Proposals [04/20]

<https://www.dfg.de/foerderung/programme/einzelfoerderung/sachbeihilfe/index.html>

² See the guide issued by the DFG Permanent Senate Commission on Animal Protection and Experimentations https://www.dfg.de/download/pdf/dfg_im_profil/geschaeftsstelle/publikationen/handreichung_sk_terversuche.pdf

³ See 10.20 General Guidelines for the Written Review [09/19] https://www.dfg.de/formulare/10_20/10_20_de.pdf

Choice of research model, datasets/biospecimens used and use of research infrastructures:

1. Why did you choose this model system, this data source or this theoretical approach in connection with the research question? What are the advantages and disadvantages of the model or approach? Are there gender-related and/or other factors that should be taken into account when choosing the model system, data or theoretical approach in relation to the research question? Does the choice of model, data or theoretical framework, especially in human or animal studies, require any ethical or legal framework conditions to be taken into account? When choosing an animal model, was a check carried out according to the 3Rs principle as to whether the model is suitable from the point of view of scientific validity?
2. Is there evidence of the quality and specification of the biospecimens, organisms or research data used that confirms they are appropriate to the research question?
3. Do you require technical, methodological or organisational research infrastructures in order to implement your research project? Are there any local structures whose services or available expertise might improve the project's feasibility and quality assurance? Are data sets or biosamples already available which should therefore not be collected again?

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

4. Have you planned a confirmatory or exploratory approach for your research, and what were the determining factors in making this choice? Would the integration of a replication study be useful in order to secure key prior assumptions or important interim results? Is registration of the study required? Does the project involve a clinical trial?
5. Can the anticipated research conclusions and outcomes actually be derived based on the statistical planning? Are the selected number of cases or repetitions sufficient for this purpose? What sources of bias do you see and how do you deal with these? How do you plan to deal with missing values? What advice and support did you draw on in selecting and presenting the statistical approach?
6. Were there any circumstances relating to the ethical requirements for animal and subject welfare that influenced your statistical planning?
7. What are the main data sets and/or biosamples that your project will generate? In which (recognised) research infrastructures, such as certified biobanks, collections or research data repositories, are the data sets and/or biospecimens to be made available after completion of the project (e.g. relevant NFDI consortia)? Are there any restrictive ethical or legal circumstances that prevent publication in this way and how will you deal with these? Will any costs be incurred for the use of the structures that are to be taken into account when applying for funding?

What are the risks of bias in your research question, planning, implementation and analysis strategy? What approaches are envisaged or implemented in order to avoid such bias (e.g. blinding, randomisation or statistical approaches)? This is particularly relevant

to research projects that involve extensive multimodal datasets (e.g. imaging and/or omics analyses).

Overarching aspects that can indirectly impact on the quality of research projects:

8. Can you name research measures that provide concrete added value in terms of the quality aspects of the question addressed (e.g. a systematic review; a replication study; participation in standard formation processes or the establishment of guidelines, the development and expansion of research infrastructures or the management of a clinical trial)?
9. Are the roles sufficiently clear-cut in terms of responsibilities within the project and results publication in the course of the project? This question is particularly relevant to collaborations that are relevant to project implementation and in the case of projects that help establish academic careers.

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