

## How to improve scientific validity and animal welfare: guidelines for animal research

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Concerns about the justification for animal research are not new. However, in the last 30 years we have witnessed increasing criticism from scientists themselves. This concern focused initially on the superficiality of the descriptions of animal models in publications, then continued with a drive to harmonise (and in some areas standardise) animal models, and was followed by today's debate on validity, replicability and translatability. Requirements to categorise the severity of procedures in connection with harm-benefit assessments have added yet another dimension to the debate.

There is now a plethora of guidelines for animal research, particularly for reporting animal experiments. Some of these have been endorsed by large numbers of journals, with varying effects. The question remains as to whether these cover all aspects governing the quality of preclinical research. In addition, scientists' perception of guidelines, and their willingness to demonstrate more than symbolic compliance, has been debated. Evidence exists of even more serious weaknesses, such as failure to follow key principles (mentioned in many guidelines) which are designed to reduce bias and increase animal welfare.

There is no doubt that the current debate about what has been coined the "reproducibility crisis" has served a useful purpose in questioning established practice and paving the way for a more enlightened, thorough and quality-controlled approach by scientists, particularly in academia. Hopefully, this process has also contributed to a greater understanding of the sum of factors that influence the validity of data from experimental animals, as well as the animals' welfare, from birth onwards. This understanding is essential if an honest harm-benefit assessment is to be achieved.

Currently, the debate tends to revolve around the "mathematical" aspects of experimental design and statistical analysis – areas which are actually the easiest to address. Weaknesses in internal validity can, however, result from events throughout the animals' lifetime. Many of these are "softer" issues, whose solution requires close collaboration between scientists and the animal facility, not least with the technical staff caring for and conducting procedures. Early involvement of all these stakeholders enables a realistic assessment of the facility's standard and competence to be made, with sufficient time to decide whether it is feasible to perform the study, and if it is, to refine husbandry methods and experimental procedures, if necessary.

The PREPARE guidelines for planning animal experiments, and associated website (<https://norecopa.no>), were developed in collaboration with scientists and other stakeholders attending courses in Laboratory Animal Science, with the aim of attending to these issues.

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