Guidance on Determining Indispensability and Balancing Potential Benefits of Animal Experiments with Costs to the Animals with Specific Consideration of EU Directive 2010/63/EU

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In memoriam
Frau Ulrike Gross

Summary
A concept and practical guidance were developed that seek to balance potential benefits of animal experiments for humans, other animals and the environment against the pain, suffering and distress inflicted on the experimental animals. The aim was to achieve transparent decisions that can be communicated in a concise manner which are accessible for a layperson and in accordance with German national law and EU Directive 2010/63/EU. The steps of the resulting decision process deal with the classification of procedures into the four severity levels, the consideration of humane endpoints, determination of the indispensability of the procedure on the basis of sound scientific arguments, classification into applied or basic research, determination of the probability of success in the case of applied research, and the cost-benefit analysis, culminating in a decision on the approval or denial of the procedure.

Keywords: animal experiments, applications, cost-benefit analysis, Directive 2010/63/EU

EU Directive 2010/63/EU for the protection of animals used for scientific purposes (EU, 2010) requires an authorization procedure for animal experiments that comprises a “comprehensive project evaluation, taking into account ethical considerations in the use of animals”. In EU Member States where such procedures are already in force, implementation practices vary widely. Opinions about how to improve, reform and manage such procedures are numerous and diverse. In particular, there is considerable disagreement on the weight to be given to various criteria on which decisions are to be based. These guidelines are intended to simplify the actual evaluation procedure and to be useful for all persons concerned with the licensing process of animal experiments, not only scientists, but also, e.g., ethicists, animal care attendants and personnel of licensing authorities, who may be scientific laypersons. In addition, in Germany, for example, committee members may be working on a freelance basis. Lengthy analyses may exceed their resources. For these and other reasons (e.g., quality assurance, transparency or later analysis), it is considered necessary to develop a structured, criteria-based guiding protocol to balance potential benefits against the animals’ costs. For this purpose, a concept and practical guidelines were developed that seek to balance potential benefits of animal experiments for humans, other animals, and the environment against the pain, suffering, and distress inflicted on the laboratory animals. Since the authors are committed to the ultimate abolishment of animal experiments but realize that this aim cannot be achieved in the short run, the proposed guidelines are intended to thoroughly scrutinize claims by researchers stating that given animal models faithfully mirror human physiological conditions and will lead to concrete therapies without proper backup from scientific evidence. Experiments based on such invalid claims cannot be expected to result in clinically useful results. They thus lead to a lot of unnecessary sacrificing of animals, which can be avoided by preventing such procedures in the first place. The authors base the guidelines on another assumption concerning the ethical justification of animal suffering in experiments for basic research: research without clearly defined and foreseeable benefits in the form of therapies. The authors believe that such experiments can only be justified if the suffering does not exceed the category “mild”.

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Thus, the aim was to come to transparent decisions that can be communicated in a concise manner, are accessible for a layperson and in accordance with the German law and EU Directive 2010/63/EU. The steps of the resulting decision process are concerned with classifying procedures into the four severity levels, considering humane endpoints, determining the indispensability of the procedure on the basis of sound scientific arguments, classifying procedures into applied or basic research, determining the probability of success in the case of applied research, and the cost-benefit analysis, culminating in a decision on the approval or denial of the procedure.

In order to manage balancing and evaluation of the procedure, the guidelines are kept short and will doubtlessly be considered incomplete by many. The authors acknowledge this and want to underline that the guidelines in the present form are intended to be a thought starter and a basis for further discussion.

Further information on the guidelines see Lindl et al. (2012a,b).

References


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