



实验动物科技资讯

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《探索科技伦理与动物实验革新·资源与工具推介》之七

科学进步与伦理责任的平衡,始终是人类文明发展的重要命题。在生命科学和医药科学研究蓬勃发展的历史进程中,实验动物为人类福祉做出了不可替代的贡献。然而,如何以尊重生命的态度对待这些沉默的伙伴,如何在科研创新与动物保护之间构建可持续的伦理框架,是全球科学界和政策制定者共同面临的挑战。

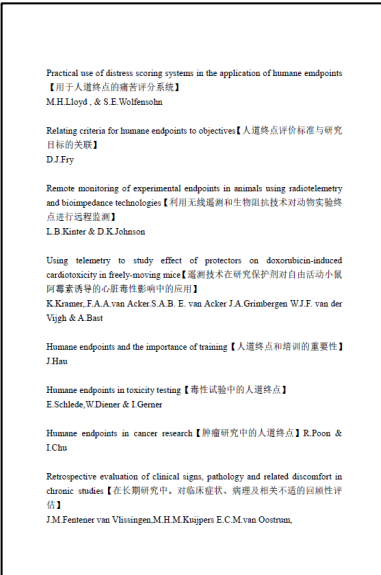
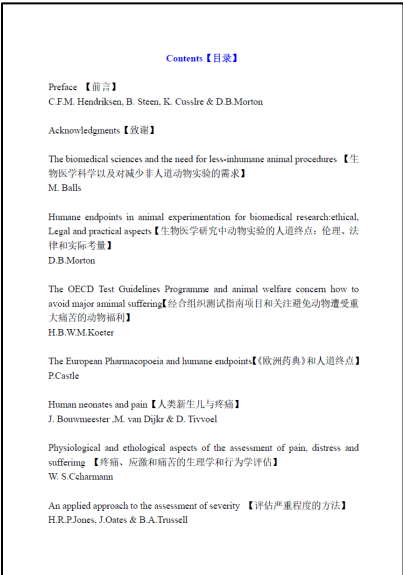
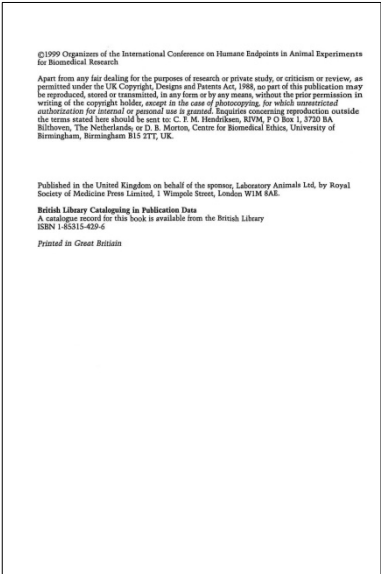
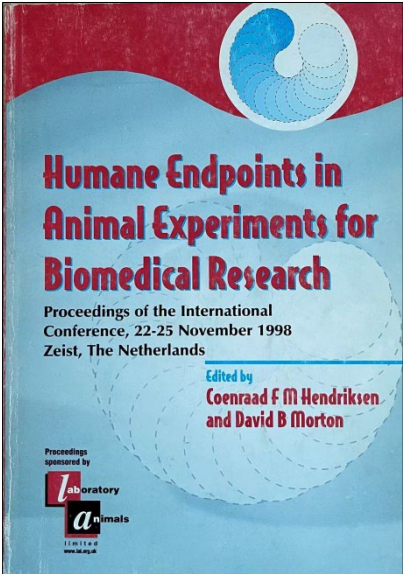
自 2022 年《FDA 现代化法案 2.0》和 2024 年《FDA 现代化法案 3.0》的发布,2025 年美国 NIH 和 FDA 又先后出台了一系列政策,并启动了与之相呼应的“实验动物研究补充计划”(Complement-ARIE)和“替代方法验证网络”(VQN)项目,加速推进 NAMs,通过对传统动物模型和动物实验技术的补充与完善,使生物科学研究更加高效和有效。与此同时,欧盟委员会也于 2025 年 7 月发布了最新“欧洲化工行业行动计划”,并决定自 2026 年起逐步淘汰化学品安全评估中的动物实验。

为了使广大的实验动物科技工作者方便和及时了解有关实验动物福利伦理研究和动物实验替代方法研究的常用工具,借助有关工具获取当下的最新研究进展和研究成果,为科技工作者能够结合自己的研究方向有针对性的进行探索,在解决自己工作中遇到的实际问题的同时,也从不同的侧面和层面推进实验动物福利伦理和动物实验替代方法研究的发展,《实验动物科技资讯》将不定期的推出有关书籍、论文、期刊和网站的介绍,为推动我国实验动物福利和动物实验伦理工作的深度发展、了解和掌握国际上 NAMs 的最新研究动态,以及我国相关政策和标准要求提供有关信息和数据。

专栏编辑

论文集《生物医学研究中动物实验的人道终点》产生于 1998 年 11 月 22-25 日在荷兰 Zeist 举办的国际会议。虽然时间过去久远，但是这次会议在国际上是一个深入探讨动物实验人道终点的里程碑式会议。论文集阐述了动物实验人道终点的意义和基本内容，特别关注了生物技术产品中应用动物实验人道终点开展研究和质量评价的重要性。为此，推荐给实验动物科技工作者，可作为今后开展相关工作的参考。

专业书籍推介



The need to refine the notion of reduction 【“减少”概念的完善】 A.K.Hansen, P.Sandoe,O.Svendsen,B.Forsman & P.Thomson The re-use of animals for research-a humane endpoint 【动物重复利用作为人道终点】 J.M.Feistner van Vlassingen Summary of the workshops	Preface In 1959, Russell and Burch introduced the concepts of replacement, reduction and refinement (the Three Rs) as a starting point for the humane treatment of laboratory animals. They stated that scientists should continually examine their research for possibilities of replacing the use of higher animals by lower organisms or non-biological materials, to reduce the number of animals used, or to refine the scientific procedures so that any suffering, discomfort or pain endured by the animals was the minimum necessary for achieving the scientific objective. The importance of this approach is that there is a real possibility that by upholding these ethical principles there will be, at the same time, an improvement in the scientific quality of the research. Today, the 'Three Rs' are accepted concepts within the scientific community and they form the basis for existing legislation on animal experimentation. Until relatively recently, the highest priority has been given to the R of replacement as being the most effective way to improve animal welfare. However, it is increasingly being recognized that replacement is also the most difficult R to achieve. Our knowledge of the fundamental physiological and pathophysiological processes needed for the development of in vitro methods is still very limited. Even when there appears to be a successful replacement in vitro method, acceptance of it is often hampered by a lack of sound validation data and, therefore, it can be expected that large numbers of animals will continue to be used. This emphasizes the need to concentrate on the R of refinement. Many sorts of animal procedures may cause severe pain and discomfort to the animals. In 1997, according to Dutch statistics, they formed about 19% of all experiments; and in the UK about 2% of project licences were banded as substantial (the difference between the UK and The Netherlands may well represent a difference in the categorization of certain scientific procedures). The severity is often related to the	endpoint being used, and endpoints such as lethality in safety testing (e.g. tests of vaccine potency and acute toxicity) as well as in the research and development of new medicines (e.g. models of infection and cancer) are not uncommon. If refinement is taken seriously by the scientific community, then it should start with these types of experiments. From 23-25 November 1998, a conference was held in Zeist (The Netherlands) to discuss the possibilities and opportunities for the implementation of humane endpoints. It was attended by about 100 delegates from industry, regulatory bodies, animal welfare organizations and academia (来自工业界、监管机构、动物福利组织和学术界约 100 名代表参加了会议。) The purpose of the conference was to bring together those with expertise in various areas of biomedical research to present their latest research results with an emphasis on practical implications. (会议旨在汇集和展示来自生物医学研究各领域专家的最新研究成果和实际意义。) Each paper has been peer reviewed before publication in this volume. During the conference, important issues relating to the recognition and assessment of adverse effects in animals, and the determination, validation, implementation and acceptance of humane endpoints were addressed (会议期间, 讨论了与动物不良反应的识别和评估、人道终点的确定、验证、实施和接受等重要问题。) Papers were presented on new techniques, new approaches and new strategies using non-invasive methods, as well as on the training of observers and the use of recently developed remote sensing devices. (论文涉及使用非侵入性方法的新技术、新方法和新策略, 以及观察员的培训和最新开发的遥感设备的使用。) One of the outcomes of the conference was that it showed that humane endpoints could only be evaluated on a study-by-study basis. (本次会议成果之一就是: 人道终点只能基于逐项研究进行评估。) Input is required from the scientist commissioning the work and processing the data, and also from others involved, such as laboratory animal scientists, animal welfare officers, veterinarians, regulators, and especially the
animal care and technical staff involved in the day-to-day care of the animals. Humane endpoints are part of a dynamic process, influenced by scientific developments as well as by animal welfare concerns as they evolve with time. (人道终点是一个动态过程的一部分, 受科学发展以及动物福利问题的影响, 这些问题会随时间而演变。) It is very likely, therefore, that what we consider to be humane today will not be in the future, and so we need to strive constantly to develop less-inhumane endpoints, and to continually re-assess and re-evaluate the endpoints in animal experiments. (因此, 我们今天认为“人道”的终点很可能在未来不再被视为“人道”, 因此我们需要不断努力开发更少人道的终点, 并持续重新评估和评价动物实验中的终点。) For that reason we hope that this conference will be the first of many. Coenraad F. M. Hendriksen Bjorn Steen National Institute of Public Health and the Environment (RIVM) Bilthoven, The Netherlands Klaus Cussler Paul-Ehrlich-Institut, Langen, Germany David B. Morton Centre for Biomedical Ethics, University of Birmingham, UK Organizing Committee of the International Conference on Humane Endpoints in Animal Experiments for Biomedical Research		