Response to May Protocol Review

To the Editor — I read with interest the responses to Jerald Silverman's IACUC challenge published in the April issue of Lab Animal (May issue of Lab Animal Europe) and am in agreement with Bill Greer and Lauren Dandridge's pithy response. In the described scenario, a veterinary school IACUC's initial review requested details of a NIH grant-funded trial of a novel anti-neoplastic drug in dogs. For the study, clinical limb amputation would be carried out before the study's blinded comparison of the new drug with the school's standard post-amputation carboplatin regimen. The IACUC members conducting the pre-review considered the protocol to be sufficiently described, except for details regarding the amputation procedure. The lead investigator remonstrated that the amputation would be carried out in accordance with the school's clinical standard and as such was outside IACUC remit.

The regulatory context is somewhat different here in Europe, specifically here in the UK.

At first glance, the project would not be the subject of UK laboratory animal legislation, the Animals (Scientific Procedures) Act 1986 (ASPA). The ASPA exempts clinical trials because clinical procedures, however unpleasant, are invariably intended to be in the subject's individual interest; hence, the project would not need to be referred to the ASPA institutional review process. Instead, the funder would obtain a (Veterinary Medicines Regulations) Animal Test Certificate. I infer that the manufacturer and study operator would negotiate the detail sought with the UK competent authority, the Veterinary Medicines Directorate, on the basis of extant protocols for this clinical application and class of drug, rather than with the Home Office, the UK competent authority for the ASPA.

It would be ridiculous to assume nil interaction between the amputation and subsequent chemotherapy in the study design, and unethical to limit clinical decision-making to foster case recruitment. Recruitment conditions will be defined for a range of surgical procedures and perioperative pharmaceuticals used in the amputation, and the level of detail that is recorded. As surgical procedures and anesthesiology evolve, inevitably any trial is a snapshot of current clinical practice.

However, ASPA institutional review would also be needed if the study were to include any non-clinical protocol, such as piggyback sampling for an unrelated scientific purpose. Obviously, the scale of the detriment can only be defined and justified for ASPA licensing in the context of the clinical protocol.

Whether or not an unconsenting, uninformed subject of a clinical procedure can truly be described as a patient—that is another question! ❐

H J Price
Former ASPA Named Veterinary Surgeon.
e-mail: hprice321@btinternet.com

Published online: 24 September 2018
https://doi.org/10.1038/s41684-018-0159-8