and processes, but it alone should not be relied upon to serve this need.

Appropriate strain choice is as important as appropriate species choice from the standpoint of scientific integrity and ethics: one must always match the model to the scientific question being posed. Determination of appropriate strain choice to best fit the science is most effectively left to the investigator and the veterinary consultant involved in the preparation of a protocol for the IACUC's review (section 2.31 (d)(1)(B))[1]. The development of specialized strains of research animals into more refined disease models has had effects on animal welfare, some predicted and some unintended. Investigators, research animal veterinarians and animal care technicians have had to increase their knowledge of strain-specific clinical effects in order to optimally monitor the health status of the animals and to intervene in order to prevent unnecessary pain and distress. Strengthening this aspect of the pre-submission veterinary consultation would be a more efficient use of institutional programmatic resources.

The IACUC in turn must be provided sufficient information in the animal protocol about the known and possible health effects of an investigator's preferred mouse strain, and the endpoints for which staff must monitor, to fulfill its role in assessing whether animal pain and distress will be minimized and appropriately mitigated. The IACUC also can provide an objective opinion when the veterinarian and the investigator cannot agree upon a specific strain during the review of the protocol itself.

Protocols as documents serve a specific purpose, as different from monthly billing invoices and weekly animal censuses as they are different from grant applications. I would caution institutional management personnel to think carefully about relying too heavily on the IACUC protocol as the sole document upon which the entire animal program pivots.

1. Animal Welfare Act and Regulations. 9 CFR, Chapter 1, Subchapter A.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals (US Department of Health and Human Services* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).

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RESPONSE

Change to ensure compliance

Thea McCready, BA

I agree with the statement that "noncompliance is noncompliance," which is why I feel that Great Eastern University's IACUC should change the protocol form to list animal strains instead of species alone. Noncompliance is a serious offense and should be avoided at all costs. Although the change may be perceived as extraneous work by the researchers now, it could help to ensure that investigators maintain protocol compliance. Protocol noncompliance may still occur, but it is within the IACUC's purview to put in place a method to safeguard investigators by minimizing the potential for noncompliance. By specifying animal strains and strain numbers, researchers will give the IACUC the information it needs to conduct a thorough review of proposed activities. The provision of this information also allows less opportunity for errors in procurement and animal use, thus lessening the chances for inadvertent noncompliance.

The Animal Welfare Act regulations[1] (AWARs, §2.31.e.1; §2.31.e.2), the Public Health Service *Policy on Humane Care and Use of Laboratory Animals*[2] (IV.D.1.b) and the *Guide for the Care and Use of Laboratory Animals*[3] (the *Guide*) state that IACUC proposals should include a rationale for involving animals, identification of the animal species involved and its appropriateness for the proposed use and the approximate number of animals to be used. Additionally, §2.31.e.3 of the AWARs[1] requires that IACUC proposals include "a complete description of the proposed use of the animals." Although the regulations do not specifically state that the IACUC must review and approve the use of a particular strain, these provisions implicitly require investigators to fully address their animal construct as it relates to the proposed experimental design.

The *Guide*[3] states that "while the responsibility for scientific merit review normally lies outside the IACUC, the committee members should evaluate scientific elements of the protocol as they relate to the welfare and use of the animals." Phenotypic assessment is necessary because it directly relates to the research outcomes and must be scientifically justified. Particularly, strain variances can pose the potential for genetically based developmental problems or leave an animal more susceptible to disease. Use of strains with these sorts of characteristics requires an outlined plan for addressing the potential pain and distress that might result from the phenotypic features. Researchers should consult the literature available for assistance in selecting the appropriate animal species and strain, as well as the appropriate control animals. Initial selection of an incorrect strain for the desired research can result in the unnecessary or inappropriate use of animals; therefore, it is critical for the IACUC to assess the proposed phenotype.

Inclusion of the animal strain is a requirement for Department of Defense proposals, as outlined in its Standard Animal Use Protocol Format[4], and its presence as part of the protocol form positively contributes to the concept of best practices within an animal care and use program. IACUCs that strive to be proactive rather than reactive should seriously consider the potential benefits of including strain and number specifications as part of the protocol form.

1. Animal Welfare Act and Regulations. 9 CFR, Chapter 1, Subchapter A.
2. Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986; amended 2002).
3. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).
4. Department of Defense. *Instruction 3216.01. Use of Animals in DoD Programs.* (Department of Defense, Washington, DC, 2010).

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RESPONSE

When strain matters

Bill Moseley, MA, CPIA & Elaine Kim, BS

Great Eastern's IACUC administrator is clearly a professional interested in assisting the IACUC in fulfilling its regulatory