

RESPONSE

IACUC complacency

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Replacement of animal procedures with non-animal alternatives is perhaps the most compelling component of Russell and Burch’s ‘3 Rs’¹. A search for alternatives is mandated for procedures causing more than momentary or slight pain or distress² and, if found, use of that alternative is expected unless exclusion of its use is justified by the Principal Investigator (PI) and approved by the IACUC. The decision by Martex’s upper management to continue limited rabbit testing for a short time longer is not the problem and may have been a wise decision. The problem lies with the complacency of the IACUC in accepting the decision without question and allowing the rabbit testing to continue, even on a smaller scale, without IACUC review and approval. Such inaction and indifference is contrary to Principle III of the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*³. Unjustified use of animals with knowledge of and accessibility to a validated alternative invites dissonance and is indefensible. The animal rights groups appear to be on solid ground as they cited evidence of Martex breaking the law and needlessly using animals in a potentially painful procedure.

Although Martex could wait until the USDA comes to a decision, a proactive approach is required to demonstrate the company’s genuine concern for the welfare of the animals in their charge. The IACUC should insist that all use of rabbits for pyrogen testing cease immediately. If the company feels that limited rabbit testing is still necessary, a formal written justification and detailed testing schedule should be submitted for IACUC consideration. Rabbit testing can resume only after IACUC approval. Alternatively, the company could decide to discontinue use of the rabbits permanently and henceforth use only the LAL test for Baluride, a much more prudent choice, if feasible.

Martex’s IACUC and upper management were probably influenced by the pressures associated with “the success of the company riding on Baluride.” Although not intentional, ensuring the success of their product may have overshadowed animal welfare considerations. Concurrent rabbit and LAL testing while they investigated any potential regulatory, technical, or legal problems seems to be an adequate justification for delaying a complete conversion to the alternative. However, the PI’s scientific justification, and therefore approval, for using the rabbit pyrogenicity test for Baluride was no longer applicable as soon as the LAL test was validated for Baluride. Continuous vigilance by the IACUC to ensure regulatory compliance is paramount to running a first-rate animal care and use program that will stand up to public scrutiny.

1. Russell, W.M.S. & Burch, R.L. *The Principles of Humane Experimental Technique* (Methuen and Company, London, 1959).
2. 9 CFR Subchapter A – Animal Welfare, §2.31(d)(1)(ii).
3. Research Animal Committee. *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training III* (Office of Science and Technology Policy, Washington, DC, 1985).

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RESPONSE

IACUC must review

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The mandate to consider alternatives is enshrined in the Animal Welfare Act¹. The IACUC is also federally mandated to “[r]eview, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received...²” Therefore, the USDA has no reason to become involved in what is essentially an IACUC function, unless the Committee fails to review the procedure at all.

Although reviewing protocols apart from the scheduled process is likely to be disruptive to research, the IACUC certainly has the authority to make this demand. According to the AWARs, “[t]he IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually³.” Additionally, Martex is not required or obligated to conduct the research even though the IACUC has previously approved it⁴.

Action must be taken by the PI and the IACUC. An amendment with a justification for the continued use of rabbits should be

A word from USDA

In response to the issues raised in this scenario, the United States Department of Agriculture, Animal and Plant Health Inspection Service, Animal Care (USDA, APHIS, AC) offers the following clarification and guidance:

The Animal Welfare Act requires research facilities to consider alternatives (replacement, reduction, refinement) to procedures likely to produce pain or distress in any experimental animal. Testing a product in rabbits for the presence of pyrogens could certainly fall under this requirement. This procedure was initially justified by the PI and approved by the IACUC, and should be reviewed at appropriate intervals (annually is a minimum standard; it can be done more often) to determine whether the justification continues to be adequate, especially upon validation of the LAL test.

When USDA is presented with a complaint regarding animal welfare, we are obligated to determine its legitimacy. This may include conducting an unannounced inspection, reviewing records, and having discussions with appropriate facility personnel. Any action taken in response to the complaint would be based on our findings.

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