IACUC should consider asking Hodges to carry out a pilot study, with veterinary oversight, to test the monitoring system and to allow the IACUC to review how he is addressing any welfare issues. The review of the pilot study data by the team (IACUC, veterinarians and researcher) should allow for the development of a monitoring strategy that allows the experiment to be carried out while ensuring that the rats' welfare is protected. Once the study is approved, periodic monitoring of the research records by the IACUC will provide continued assurance that the welfare needs of the animals are being addressed.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

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RESPONSE

Clarity for humane intervention points

Michael W. Brunt, MSc, RMLAT, CMAR

Efficient and clear communication is of particular importance when principal investigators, attending veterinarians (AVs) and IACUCs are determining humane intervention points and adequate monitoring procedures for animals participating in research protocols. Hodges' elaborate remote monitoring and drug-delivery mechanism was shown to be effective through validation at his previous institution. But an action plan for unexpected events that might occur during the monitoring period has not been adequately defined.

The AV would be the ideal person to develop this action plan in collaboration with Hodges. The *Guide for the Care and Use of Laboratory Animals*[1] states, "The primary focus of the veterinarian is to oversee the well-being and clinical care of animals used in research, testing, teaching, and production. This responsibility extends to monitoring and promoting animal well-being at all times during animal use and during all phases of the animal's life." In this situation, definition of humane intervention points will be critical. Once specific clinical risks are identified (e.g., high or low blood glucose concentrations, high or low heart rate, etc.), limits must be set to determine when euthanasia will be required. If Hodges plans to use remote monitoring systems, then he should be expected to return to the facility immediately to treat or euthanize any animals reaching these humane intervention points.

Hodges' "one-man operation" may not be appropriate for extended monitoring periods. The IACUC, the AV and Hodges should identify the adverse events that are most likely to be seen, the experimental time points at which they are likely to be seen and the level of pain or distress expected to result from these. This information may be available from previous studies, enabling Hodges to carry out a risk assessment to determine an appropriate monitoring interval that will allow early detection and prompt resolution of the majority of adverse events. If the information is unknown, then Hodges should carry out a pilot study to identify the most critical time period for animal monitoring, as well as the incidence and severity of adverse events. Once a plan has been approved by the IACUC, post-approval monitoring should be implemented in the early stages of study execution, and the observations of this monitoring should be used to determine whether adjustments should be made to the monitoring protocol to ensure that animals are not experiencing unnecessary pain or distress. This should be a collaborative effort between the IACUC, the AV and the investigator.

Although Hodges' monitoring device represents a refinement to one aspect of post-surgical monitoring, the IACUC's concerns surrounding humane intervention points are also valid. This scenario represents on opportunity for Hodges and the IACUC to work together to improve animal well-being and build trust within the Great Eastern University community. A collegial, cooperative and consultative approach is needed in this situation to exploit the benefits of Hodges' monitoring procedures and alleviate the concerns of the IACUC.

1. Institute for Laboratory Animal Research. *Guide for the Care and Use of Laboratory Animals* 8th edn. (National Academies Press, Washington, DC, 2011).

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RESPONSE

Proceed, but cautiously

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Members of an IACUC are generally familiar with reviewing protocols that test new technologies such as surgical instruments and implants. For studies involving untested devices, IACUCs will typically require intensive monitoring and early endpoints to minimize any potential pain or distress experienced by the animals used. Novel monitoring equipment and technologies used to assess at-risk animals warrant additional caution during IACUC review. Hodges is on a technological cutting edge by proposing use of indwelling cannulas, electrodes and a camera to monitor and infuse his diabetic rats remotely using a smart phone. Although this is a laudable goal, the study design does not address certain factors that need to be considered by the IACUC.

The *Guide for the Care and Use of Laboratory Animals*[1] states that the IACUC should evaluate the criteria and process for timely intervention during the protocol review process. Monitoring procedures and humane endpoints should be based on the specific parameters of the individual protocol.

If Hodges or other appropriate personnel, such as animal care staff or other technical staff, can respond to adverse events or other developments within a reasonable time-frame, then off-site monitoring may be feasible. But without the ability to intervene as necessary, monitoring alone will accomplish nothing. Removing animals from the study does not adequately resolve welfare concerns. If Hodges means removal from the study to include euthanasia, then the capability for remotely initiating appropriate euthanasia should be considered.