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ANIMAL WELFARE COMPLIANCE

Is a laparoscopic serial liver biopsy considered 'major' animal surgery?

Reader Question: We would like to use laparoscopic procedures to obtain serial biopsy samples from an animal's liver before introduction of an infection agent, and again at two intervals after infection. A member of our Institutional Animal Care and Use Committee (IACUC) says the biopsy penetrates the body cavity, so it's "major" surgery. That's not my reading of guidelines from the Office of Laboratory Animal Welfare (OLAW), which says the body cavity must be exposed and/or the biopsy must "substantially" impair the animal physically or physiologically. Who is right?

Expert Comments:

The simple answer is that it is indeed a "major" procedure because, based on the information you've given, your IACUC has made that determination. According to this statement from OLAW, the IACUC has discretion to classify a surgery as major or minor, following OLAW guidelines:

“OLAW would consider the IACUC, in its review of the unique circumstances of the research activity, as the determiner of whether the procedure is major or minor. From the description of the proposed procedures, they are related components of a research project and would be permitted by the Animal Welfare Act regulations [9 CFR, Part 2, Section 2.31 (d)(1)(x)] and the Guide for the Care and Use of Laboratory Animals if determined to be major procedures and approved by the IACUC.”

OLAW's guidelines to help IACUCs decide whether to classify a procedure as major or minor include the following:

- The PI must provide a detailed description of the procedure, along with anticipated or actual consequences, to the IACUC.
- The IACUC determines if the surgical procedures only penetrate the body cavity but don't expose it.
- The IACUC then determines if the procedure produces substantial physical or physiological impairment.

- If the answer to both IACUC determinations is No — i.e., it doesn't expose the body cavity and, No, it won't cause substantial physical or physiological impairment — then the IACUC may classify the surgery as "minor." If the answer to either question is "Yes," it must be considered a "major" operative procedure.

While your IACUC determined the procedure is major surgery, it might have to reclassify the procedure based on the actual clinical outcome. And whether it's classified as major or minor, the IACUC will have to make sure you employ appropriate pain relief, sterility, and peri-operative monitoring.

Comments by a professor of comparative medicine at a major university in the Northeast

To view the full article with reader comments, please visit: <http://www.principalinvestigators.org/no-17-is-a-laparoscopic-serial-liver-biopsy-considered-major-animal-surgery/>