Is there a requirement for postapproval monitoring?

The Guide for the Care and Use of Laboratory Animals

- "Continuing IACUC oversight of animal activities is required by federal laws, regulations, and policies." Ch. 2
- "Surgical outcomes should be continually and thoroughly assessed to ensure that appropriate procedures are followed and timely corrective changes are instituted." Ch. 4

PHS Policy

- Requirement for semiannual IACUC visit to labs in which surgical manipulations are performed on animals. IV.B.2.
- "Institutions are responsible for oversight of all animal-related activities regardless of how long or where the activity occurs." grants.nih.gov/grants/olaw/faqs.htm#prorev_1
- "Monitoring of animal care and use is required, though neither the PHS Policy nor the Guide explicitly address or require specific or separate post approval monitoring (PAM) procedures to compare the practices described in approved protocols and SOPs against the manner in which they are actually conducted." grants.nih.gov/grants/olaw/faqs.htm#instresp_6
- “Describe the processes the IACUC uses for monitoring of ongoing activities and continuing review of previously approved protocols.” grants2.nih.gov/grants/olaw/sampledoc/assursmp.htm #9

OLAW and USDA

- "If an institution fails to establish ongoing monitoring systems to ensure that the actual animal work being conducted is the same as that which the IACUC approved, this also contributes to noncompliance in some cases." grants.nih.gov/grants/olaw/LabAnimal.pdf

The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching

- “… IACUC, to monitor the care and use of agricultural animals in agricultural research and teaching activities.” Ch. 1 and 2
- “…monitor the humane and appropriate use of animals in agricultural research and teaching…” Ch. 1
- “The written procedures … must be monitored regularly …” Ch. 1

USDA Animal Care's Research Manual

- The Inspector is responsible for conducting a thorough inspection of the IACUCs monitoring of protocol activity. Section 6.3.1
- Review medical records to determine that animals with painful/distressful procedures received the proper pain/distress relieving drugs, if applicable. Section 6.3.1
- Determine if all of the animal holding, housing, and use areas are inspected. Section 6.2.4

www.aphis.usda.gov/ac/researchmanual