

Comments to Proposed Guidance Regarding Significant Changes to Ongoing Animal Activities

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Section A.

- “..that have the potential to increase the level of pain or distress of the animal AND includes all changes that involve anesthesia, analgesia, sedation, or euthanasia”; **Is this an “and” statement? Would it apply to changes limited ONLY to anesthesia, analgesia, sedation, or euthanasia? For example, if the procedure(s) and pain category do not change and the veterinarian approves a change to the anesthetic, sedative or analgesic regimen to provide better pain relief, would this still be a major modification? What about a change in euthanasia method that is still compliant with current AVMA guidelines?**
- “in frequency, interval, type, number, or anatomical location of:
 - procedures; and
 - substances delivered to the animal”. – **Would this include a change such as from IP to SC (or vice versa) in rodents?**

Section C: **Would changes of correction of typographical errors, or grammar; and/or contact information updates mean there is going to be a new type of approval allowed? Would protocols requiring these types of administrative changes be considered Approved? Modifications Required (In) to Secure Approval or something else?**