

GUACUC Guidelines for Amendment Requests and New Protocol Submissions

Expedited Administrative Reviews include:

- 1) Change in source of funding
- 2) Addition/Substitution of a qualified student or technician
- 3) Addition of a qualified faculty collaborator
- 4) Addition/Change of grant title

Minor Amendments Category can include:

- 1) Addition of another strain of the same animal species (strain without known phenotypic abnormalities)
- 2) Change in sex of animal to be used
- 3) Small increase in animal numbers (approx. 20%) (limit of 3 requests per 3 year protocol approval period)
- 4) Need to repeat an approved experiment on the same protocol
- 5) *Addition of sample collection times
- 6) *Additional noninvasive sampling
- 7) Addition of a non-survival procedure (*i.e.* a single terminal experiment with no recovery from anesthesia)
- 8) Addition of a new or related compound/diet (if there are no known adverse clinical effects – copy of reference articles required showing no adverse effects) (e.g. change from oral delivery to in the feed)

* provided the total volume collected is within institutional standards for the specified species.

Significant Amendments Category (requires full committee review) can include:

- 1) Change in principal investigator (with or without change/addition of procedures and/or with or without change/addition of qualified personnel)
- 2) Large increase in animal numbers (over 20%)
- 3) Addition of survival surgery
- 4) Addition of painful procedure
- 5) Unanticipated marked increase in clinical signs or proportion of animal deaths
- 6) Addition of a new or related compound/diet (if there are known adverse clinical effects)
- 7) Adding a new cell line
- 8) Modifying a survival surgery to a multiple survival surgeries (if surgical procedure is already approved and needs to be repeated, or if required for an approved device replacement/repair)
- 9) Change/Addition of a species (mice, rats and aquatics only)
- 10) Addition of new multiple survival surgeries (mice, rats and aquatics only)
- 11) Multiple significant amendments on a single protocol may require submission of a New Protocol Application.

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New Protocol Submission will be required:

- 1) Change in purpose or specific aim of the study
 - 2) Initial protocol was a pilot or feasibility study
 - 3) Addition of unalleviated pain or distress procedure to an approved Class I/II protocol
 - 4) Change/Addition of a species (USDA regulated species - *list below*)
 - 5) Additional of multiple survival surgeries (USDA regulated species - *list below*)
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Expedited Administrative Review – Conducted by the GUACUC administrator and reviewed/approved by full committee at the monthly meeting.

Minor Amendments - Amendments may be expeditiously reviewed by the Chair and a Vet and will be presented for full GUACUC review at the next scheduled monthly meeting. During the initial review, the Chairman and/or Veterinarian may refer the amendment for full committee review.

Significant Amendments – Amendments would be reviewed by the full committee or, if warranted, may be reviewed by the designated member review process.

New Protocol Submission – The amendment process is not applicable. A new protocol must be submitted for full GUACUC review

USDA Regulated Species include: hamsters, guinea pigs, ferrets, rabbits, dogs, cats, nonhuman primates, marine mammals and warm blooded animals used in research, testing and experimentation.

Excluded are birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses not used for research purposes, and other farm animals (e.g. livestock, poultry) used or intended for use as food or fiber, for improving animal nutrition, breeding management or production efficiency.

References

The IACUC Handbook, 2nd edition, Eds. Silverman, Suckow, Murthy, CRC Press, 2007.

Animal Welfare Act and Animal Welfare Regulations, United States Department of Agriculture, Animal and Plant Health Inspection Service, August 2002.