UH IACUC

Policy for Tracking Protocol Renewals

I. Policy Statement

The purpose of this policy is to ensure IACUC protocols are reviewed and approved according to required time intervals for various Federal and grant award agencies.

- 1. The Office of Laboratory Welfare (OLAW) and the United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA APHIS) require animal use protocols to be reviewed and approved at least once every three years. All animal use protocols must be submitted for full committee review at a convened meeting. This review is sometimes called a de novo review because the protocol receives the same scrutiny by the committee as if it were a brandnew submission.
- 2. Animal use protocols that utilize grant funding from the Department of Defense (DOD) are required to be reviewed and approved at least once annually. Protocols utilizing funding by the Department of Veterans Affairs (VA) are required to reviewed at least annually if they involve USDA-regulated species.

II. Guidance and Procedures

- 1. The Compliance Office utilizes Topaz to generate lists of protocols and their corresponding renewal dates.
- 2. The Office of Research Compliance Office sends courtesy reminders to Principal Investigators (PI) when protocols are due for renewal at the next monthly meeting.
- 3. The Compliance Office works with the Office of Research Services to obtain a list of protocols that utilize DOD and/or VA funding and ensure reminders are sent for annual renewals when required. Pls must submit a complete, **Annual Renewal Form** in Topaz for these protocols. Additionally, a de novo review is required every 3 years for these protocols.
- 4. Pls on protocols that do not utilize DOD/VA funding for USDA-covered species receive renewal reminders every three years. Pls must submit a complete **Original Protocol Form** in Topaz for these renewals for a de novo review.
- As part of continuing review, PIs on protocols that do not utilize DOD/VA funding for USDA-regulated species receive reminders to submit annual progress reports annually as an IACUC requirement. PIs must submit an abbreviated, **Annual Progress Report Form** in Topaz.
- 6. Annual progress reports are reviewed and approved using Designated Member Review (DMR) and/or Veterinary Verification and Consultation (VVC).

- 7. All facilities with active protocols continue to be inspected by the IACUC on a semi-annual basis.
- 8. The Post Approval Monitoring (PAM) Coordinator conducts random audits and visits in addition to semi-annual IACUC inspections for those projects that utilize animals in Pain Category E. The PAM Coordinator may also visit facilities to follow up on incidents and/or deficiencies noted in inspections.
- 9. ORS is provided with IACUC approval letters for protocols upon request. Approval letters include either annual or triennial expiration dates, depending on the type of project funding. ORS is *not* made aware of progress report due dates as these are not protocol expiration dates.

Reference: USDA APHIS

https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/sa_by_date/sa-2021/sa-11/cures-act-awa

OLAW https://olaw.nih.gov/faqs - /guidance/faqs?anchor=question613

VHA Handbook 1200.07 § 8.g. (Annual Review of Proposals) and 8.g.(1) (First and Second Annual Review of Protocols)[Page 28] was rescinded by VHA Office of Research and Development Chief Veterinary Medical Officer in April 2020 (accessible at: https://www.research.va.gov/programs/animal_research/

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