

**POLICY: Reporting Requirements for Pilot Studies and Category E (USDA Pain/Distress) Protocols**

<b>Objective:</b>	Define additional reporting on specific animal use and health studies
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<b>Date:</b>	February 24, 2025

**I. Scope**

Additional reporting requirements apply for all animal care & use protocols that involve either or both of the following:

- A pilot study (or studies) or pilot study as a phase of experimentation.
- A study classified as USDA pain/distress Category E (entirely or in part).

The report informs the IACUC periodically of experimental results and any possible consequences (either intended or unintended) affecting animal health or well-being so that arising issues during experimentation can be addressed and resolved.

**II. Reporting Requirements for 90-day Reports**

1. The reporting requirements are listed on the initial protocol approval certification letter.
2. The 90-day reporting period starts at the initiation of the study (i.e., start of the first set of experiments).
3. The PI will notify IACUC / ORPI (cc'ing the IACUC Chair, Attending Veterinarian, and Vivarium) by email 1-2 weeks prior to initiation of work to confirm the start date.
4. The PI will submit the report prior to the 90-day deadline.

**NOTE: Untimely reporting will trigger a protocol review and potential remedial actions.**

**III. Information to be Included in the 90-day Report**

1. The original goal of the study (cut/paste from the protocol).
2. The total number of animals used to date.
3. A summary of experimental results/outcomes thus far.
4. A summary of animal health outcomes, including unexpected or adverse events.
5. The investigator's own interpretation of results and outcomes.
6. A discussion addressing pertinent changes (if any) in:
  - future experiments
  - and/or the goals of the study
7. Documentation regarding whether the study is complete/finished or not.
8. For pilot studies continuing beyond 90 days, estimated time to completion.

***NOTE: PIs are strongly advised to consult with the Attending Veterinarian during report preparation to ensure that documented animal health outcomes are in line with veterinary and animal care staff observations.***

**IV. IACUC Review of Category E studies and pilot studies Reports**

1. All reports are submitted to the Office of Research Protections and Integrity / IACUC Office and will be forwarded to IACUC for review.
2. The IACUC may:

- deem (by a vote of a quorum of members at a convened meeting) that the study is progressing as expected and exempt from additional 90-day reporting OR
  - request a subsequent 90-day report for further review OR
  - ask for clarification and further information regarding the study before making a determination regarding further reporting.
3. Any IACUC member may request clarification and further discussion of the report at the next convened meeting. If no member requests a follow-up discussion, then the report will be filed per regulations.
  4. The Principal Investigator will be informed of any decisions made and/or any follow-up information requested by the Committee.

**V. Adverse Events or Non-compliance**

If an adverse event or non-compliance occurs at any time within the approved protocol period, it will be documented per [SOP: Reporting Non-Compliance, Adverse Events](#). Following appropriate PI, Vivarium, AV, and IACUC action(s), and resumption of the study, 90-day report requirements will continue or resume.

**Revision History**

Approved March 21, 2011

Revised May 19, 2014; March 27, 2017

Re-approved March 23, 2020

Administrative changes September 19, 2022

Revised September 25, 2023

Revised February 24, 2025