Animal Care and Use Program Policy

Reporting Requirements: Protocols Using Pilot Studies, Categorized As USDA Pain/Distress Category E

**Objective:**
To describe types of studies where additional reporting on animal use and health is warranted

**Author:**
Office of Research Protections and Integrity

**Approved:**
03/21/2011; revised 05/19/2014; 03/27/2017; 3/23/2020

**Scope**
Additional reporting requirements will apply for all animal care/use protocols which involve either or both of the following:

- A pilot study or pilot study as a phase of experimentation;
- Designation of pain/distress Category E (for both designation for an entire study, or for a specific experiment/phase of a study);

The purpose of the report will be to inform the IACUC periodically of experimental results and any possible intended/unintended consequences affecting animal health/well-being. It will serve as a basis for dialog between the PI and Committee on how to address and resolve animal health or well-being issues as they arise during experimentation.

**Reporting Requirements by Type of Study**

**Pilot Studies**

For protocols which will consist only of a pilot study or series of pilot studies, as well as protocols which propose a pilot study as part of its total experimentation, typically only one report will be due to the IACUC. Since it is likely that most pilot studies will have concluded by 90 calendar days after initiation, the IACUC would expect the report due at that point in time. Information about reporting requirements and timelines will be noted on the initial protocol approval certification letter. The 90-day mark will be set by the initial approval date. If a pilot has not concluded within 90 days’ time, the investigator will submit an interim report at the 90-day mark, and then would submit the final report at the end of the next 90-day period.

**Category E Studies**

The Office of Research Protections and Integrity will request from investigators reports at intervals of 90 calendar days until the study/study phase is complete. Reports will be due no later than the 90-day mark. Information about reporting requirements and timelines will be noted on the initial protocol approval certification letter. The initial 90-day reporting period will be set by the initial approval date; subsequent reports will follow every 90 days thereafter.
Content to be Included in a Report and Review of Reports by the IACUC

A report would briefly cover the following:

1. The total number of animals used to date;
2. A summary of experimental results/outcomes thus far;
3. A summary of animal health outcomes, particularly any unexpected or adverse events compromising animal health/well-being beyond what was anticipated; and
4. The investigator’s own interpretation of results/outcomes.

Since animal health information is being requested, it is strongly recommended that PIs consult with the Attending Veterinarian during report preparation to ensure that reported animal health outcomes are in line with veterinary and animal care staff observations.

Even if experimentation has not yet begun during an inclusive report period, a report is still required to be submitted by the due date simply stating that experimentation has not begun along with an estimated timeframe of when experimentation is expected to commence.

All reports are to be submitted to the Office of Research Protections and Integrity, which will be responsible for forwarding the report to the IACUC for review. Only if an investigator has a currently existing Category E study can the report be filed as part of the annual renewal form.

The IACUC will review reports initially in an expedited manner, however any member on the Committee reserves the right to request that the report be further discussed in the next available convened meeting.