UNIVERSITY OF NORTH CAROLINA CHARLOTTE

Animal Care and Use Program

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

Objective:	To define studies where additional reporting on animal use and health is warranted
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Scope

Additional reporting requirements will apply for all animal care & use protocols that 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 either 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 or well-being. It will serve as a basis for dialog between the PI and Committee as to addressing and resolving animal health or well-being issues as they arise during experimentation.

Reporting Requirements by Type of Study

Pilot Studies

Protocols that will consist only of a pilot study or series of pilot studies, as well as protocols that propose a pilot study as part of the total experimentation, typically only one report will be due to the IACUC. Because it is likely that most pilot studies will be concluded by 90 calendar days after initiation, the IACUC expects 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 determined by the initial approval date. If a pilot study has not concluded within 90 days' time, the investigator will submit an interim report at the 90-day mark, and then submit a report at the end of each 90-day period.

Category E Studies

The Office of Research Protections and Integrity will request from investigators reports at intervals of every 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 and approval certification letter. The initial 90-day reporting period will be determined by the initial approval date; subsequent reports will follow every 90 days thereafter.

Content to be Included in each Report

A report will 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 or well-being beyond what was anticipated; and
4. The investigator's own interpretation of results and outcomes.

NOTE: Because animal health information is being reported, it is strongly recommended that PIs 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.

Even if experimentation has not yet begun during an inclusive report period, a report submission is still required by the due date to confirm that experimentation has not begun and to give an estimated timeframe of when experimentation is expected to commence.

Review of Reports by the IACUC

All reports are submitted to the Office of Research Protections and Integrity, which will be responsible for forwarding the report to the IACUC for review.

The IACUC will review each report, and any member of the Committee has the right to request that the report be discussed further in the next convened meeting.

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