



Any individual with animal care and use concerns should confidentially report their findings to one of the following individuals immediately:

Dr. Melinda Hollingshead

Chair, NCI at Frederick
ACUC (301-846-5608)

Dr. Jatinder Gulani

NCI at Frederick Attending
Veterinarian (301-846-5577)

Dr. Craig Reynolds

NCI at Frederick Institutional
Official (301-846-1302)

I would like to ensure that all NCI at Frederick investigators and animal users are aware of our regulatory responsibilities in regards to the humane care and use of animals in biomedical research. All individuals working with live animals are responsible for the well-being of animals under their care. Furthermore, all Principal Investigators are responsible for the care and condition of animals that are utilized under their approved Animal Study Proposal. If an animal is neglected and/or experiences adverse effects resulting in harm or death (including accidents) you are responsible for notifying the [NCI at Frederick Animal Care and Use Committee Office](#) of the incident immediately for investigation. Failure to do so may result in the suspension of your animal use privileges. This is a re-emphasis of the Frederick National Lab's commitment to enforcing the requirements of PHS Policy.

In accordance with Public Health Service Policy, the NCI at Frederick is required to investigate and report to the NIH Office of Laboratory Animal Welfare (OLAW) circumstances in relation to the following:

- a) Serious or continuing noncompliance with the [PHS Policy](#);
- b) Serious deviation from the provisions of the [Guide for the Care and Use of Laboratory Animals](#); or
- c) Suspension of an activity by the Frederick National Lab Animal Care and Use Committee.

To assist institutions in determining what, when, and how situations should be reported OLAW recently issued the [Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane and Care Use of Laboratory Animals](#). Any of the incidents listed below (in accordance with this guidance) must be reported to the NCI at Frederick Animal Care and Use Committee as quickly as possible (preferably within 24 hours). The ACUC is responsible for investigating and recommending, if appropriate, prompt reporting to OLAW.

- Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- Conduct of animal-related activities without appropriate ACUC review and approval;
- Failure to adhere to ACUC-approved Animal Study Proposals;
- Implementation of any significant change to ACUC-approved Animal Study Proposals without prior ACUC approval;
- Conduct of animal-related activities beyond the expiration date established by the ACUC;
- Chronic failure to provide space for animals in accordance with recommendations of the *Guide*;
- Participation in animal-related activities by individuals who have not been appropriately trained;
- Failure to monitor animals post-procedurally as necessary to ensure well-being;

- Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- Failure to ensure death of animals after euthanasia procedures;
- Failure of animal care and use personnel to carry out veterinary orders (e.g., treatments).

If you are uncertain about whether an incident or activity should be reported, please report it. Any of the individuals highlighted in the introduction box may be contacted for confidential reporting. Reprisal for reporting concerns is prohibited by law. Again, it is imperative that the ACUC be notified of any animal welfare concerns to ensure prompt investigation in accordance with NCI at Frederick [Guidelines for Investigating and Reporting Animal Welfare Concerns](#) to determine if OLAW reporting is required. As required, the NCI at Frederick will enforce the requirement to report animal care and use concerns to OLAW. Thank you for your cooperation and commitment to ensure humane animal care and use at the NCI at Frederick.

Sincerely,

Craig Reynolds
Institutional Official

Additional Information

What is the PHS Policy?

"Requires institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities conducted or supported by the Public Health Service."¹

What is the Guide for the Care and Use of Laboratory Animals?

"The purpose of the *Guide* is to assist institutions in caring for and using animals in ways judged to be scientifically, technically, and humanely appropriate. The *Guide* is also intended to assist investigators in fulfilling their obligation to plan and conduct animal experiments in accord with the highest scientific, humane, and ethical principals."²

What is the NIH Office of Laboratory Animal Welfare (OLAW)?

The Office of Laboratory Animal Welfare is responsible for: (1) developing and monitoring, as well as exercising compliance oversight relative to PHS Policy on Humane Care and Use of Laboratory Animals involved in research conducted or supported by any component of the Public Health Service; (2) coordinating appropriate PHS regulations, policies, and procedures both within PHS and in coordination with other Departments and Agencies in the Federal Government; and establishing criteria for and negotiation of Assurances of Compliance with institutions engaged in PHS-conducted or supported research using animals; (3) conducting programs of clarification and guidance for both the Federal and non-Federal sectors with respect to the use of animals in research; and directing the development and implementation of educational and instructional programs and generates

educational resource materials; (4) evaluating the effectiveness of PHS policies and programs for the humane care and use of laboratory animals; and (5) serving as liaison to Presidential, Departmental, Congressional, interagency, and non-governmental Commissions and Boards established to examine issues pertaining to laboratory animal welfare in research and exercises leadership in identifying and addressing such issues.³

Who is the Institutional Official?

Dr. Craig Reynolds, Director of Scientific Operations at the NCI at Frederick, has been designated as the Institutional Official. Dr. Reynolds is responsible for ensuring that the NCI at Frederick is in compliance with the requirements of the PHS Policy.

What is the Animal Care and Use Committee?

The ACUC is appointed by the Institutional Official to oversee the Frederick National Lab's animal program facilities and procedures. The committee must consist of at least one veterinarian trained in laboratory animal science, one practicing scientist with experience in research involving animals, one member whose primary concerns are in a nonscientific area, and one individual that is not affiliated with the institution. The committee must consist of at least five members (currently, the NCI at Frederick ACUC has 10 members) and a single member is eligible to fulfill one or more of the requirements. The ACUC functions are as follows:

- Review the animal care and use program and inspect animal facilities on a semiannual basis;
- Review concerns involving the care and use of animals;
- Make recommendations to the Institutional Official regarding any

- aspects of the institution's animal program, facilities, or personnel training;
- Review, approve, require modification, or withhold approval of PHS supported animal activities (the Committee fulfills this responsibility by reviewing Animal Study Proposal, annual review, and modification submissions on a monthly basis); and
- Be authorized to suspend activities involving animals.

Additional Questions or Concerns?

Please contact the NCI at Frederick Animal Care and Use Committee Coordinator at 301-846-7544 if you have any questions or concerns in regards to animal-related activities.

Please also refer to the NCI at Frederick Animal Care and Use Committee website for the latest guidelines, forms, newsletters, and other pertinent information relating to animal care and use at <http://web.ncifcrf.gov/rtp/lasp/intra/acuc/fred/main.asp>

References

- ¹ PHS Policy at <http://grants.nih.gov/grants/olaw/references/phspol.htm>
- ² The Guide for the Care and Use of Laboratory Animals at http://www.nap.edu/catalog.php?record_id=12910
- ³ The NIH Office of Laboratory Animal Welfare at <http://grants.nih.gov/grants/olaw/olaw.htm>