North South University

Office of Research-NSU

Animal Care and Use Research Policy (2019)

Preamble

North South University (NSU) recognizes the value of live vertebrate animal research as it contributes to human interests in biomedical progress and technological innovations in medicine and public health. At the same time, it is to be understood that NSU faculty, staff, and students who are involved in animal research have professional responsibilities in the humane care and use of non-human animals both in research and in teaching.

The Bangladesh government is concerned to assure animal welfare and protection of animals against cruelty that includes physical, chemical or environmental torture or killing with unnecessary cruelty, while permitting use of animals in research having a "bona fide scientific purpose," notwithstanding a minimal definition of 'animal' as "any domestic or captured animal." (Cruelty to Animals Act, 1920; Animal Welfare Act, April 2016) Further, international standards and periodical scholarship on animal welfare speak to the opportunities, complexities, and obligations that researchers have when engaging in experiments with animals. These include collaborative attention to guiding principles such as those from the Council for International Organization of Medical Sciences and The International Council for Laboratory Animal Science (CIOMS/ICLAS, 2012) and the Nuffield Council on Bioethics (NCB).

Thus, e.g., the Nuffield Council on Bioethics (NCB) addressed the importance of identifying those features in animals that are of moral concern. Thereby, it is important to understand how these features should be taken into account in moral reasoning about the humane care and use of animals in research. This holds for all animals that are subjects of biomedical and/or behavioral research relative to human interests in basic science, applied science, and testing of pharmaceutical and non-pharmaceutical grade compounds and devices. Such features, the NCB opines, include the possession of life, moral status as sentient beings that feel pleasure and pain, have varied degree of cognitive capacity, are sociable within their species, and are capable of flourishing in their natural environment. (Nuffield Council on Bioethics, 2005)

Similarly, CIOMS/ICLAS has updated its *International Guidelines for Biomedical Research Involving Animals*, providing an "international benchmark" pertinent to countries with emerging research. These Guidelines remind researchers that (a) all decisions "regarding the welfare, care, and use of animals should be guided by scientific knowledge and professional judgment, reflect ethical and societal values, and consider the potential benefits and the impact on the well-being of the animals involved;" (b) "Animals should be used only when necessary and only when their use is scientifically and ethically justified" according to the three principles of "Replacement, Reduction and Refinement." 'Replacement' concerns a bona fide assessment of "alternative methods, such as mathematical models, computer simulation, *in vitro* biological systems, or other non-animal (adjunct approaches)." (c) "The nutritional, microbiological, and general health status as well as the physiological and behavioral characteristics of the animals should be appropriate to the planned use as determined by scientific and veterinary

medical experts and/or the scientific literature." (d) "The heath and welfare of animals should be primary considerations in decisions regarding the program of veterinary medical care to include animal acquisition and/or production, transportation, husbandry and management, housing, restraint, and final disposition of animals, whether euthanasia, rehoming, or release. Measure should be taken to ensure that the animals' environment and management are appropriate for the species and contribute to the animals' well-being." (e) "The welfare, care, and use of animals should be under the supervision of a veterinarian or scientist trained and experienced in the health, welfare, proper handling, and use of the species being maintained or studied....Animal health and welfare should be continuously monitored and assessed with measures to ensure that indicators of potential suffering are promptly detected and managed. Appropriate veterinary care should always be available and provided as necessary by a veterinarian." (f) "[There] is a moral imperative to prevent or minimize stress, distress, discomfort, and pain in animals, consistent with sound scientific or veterinary medical practice." (g) "Endpoints and timely interventions should be established for both humane and experimental reasons...established before animal use begins, should be assessed throughout the course of the study, and should be applied as early as possible to prevent, ameliorate, or minimize unnecessary and/or unintended pain and/or distress."

Relative to morally relevant features of animals such as those identified above, standards of due care are generally implemented to underscore and assure (a) refinement of experimental techniques in research protocols to reduce animal suffering through painful and/or distressing procedures (e.g., "appropriate sedation, analgesia, anesthesia, non-pharmacological interventions, and/or other palliative measures developed in consultation with a qualified veterinarian or scientist"); (b) reduction of numbers of animal subjects used in experiments to what is warranted by research goals and objectives within the time frame of a given protocol, and (c) replacement of live animals with other experimental procedures wherever possible (Russell and Burch, 1959)—all of which conduces to professional scientific and ethical assessment of relative benefit to humans and harm to animals that are subjected to experimental investigations.

Accordingly, university researchers are expected to comply with generally recognized standards of due care, including having properly regulated animal facilities, animal housing, standard operating procedure for procurement and import/export of animals to/from NSU facilities, adequate bio-security and bio-containment pertinent to animal screening, quarantine, or decontamination related to disease control and surveillance, proper maintenance of animal colonies, conditions for environmental enrichment of housed and caged animals, control of biological specimens used in laboratory experimental procedures on animals, proper use of pharmaceutical and non-pharmaceutical grade compounds and/or devices on animals, and due veterinary review and oversight pertinent to animal food intake and acceptable methods of euthanasia.

To this end, Office of Research-NSU develops this animal care and use policy along with an NSU Animal Care and Use Committee (IACUC) that is responsible for assuring due compliance of all university faculty, staff, and students involved in live animal research. (The policy herein articulated is an adaptation of reasonably applicable standards operative in the USA, in this case those of the University of Illinois

at Urbana-Champaign, as updated to 2017.) The NSU IACUC is expected to assure compliance with this university policy and any and all national laws and regulations governing the care and use of animals in teaching and research at NSU facilities.

IACUC Membership

The IACUC members shall be appointed by the Vice Chancellor in the capacity of Institutional Official (IO) or by the Vice Chancellor's designee, in consultation with the Director, Office of Research-NSU. The members of the IACUC shall include the following:

- 1. At least two veterinarians, preferably having training and/or experience in laboratory animal science and medicine;
- 2. Five practicing scientists from the NSU core health and life science faculty who are experienced in research involving vertebrate animals;
- 3. Two NSU faculty whose primary interests are not in a health and life-science discipline;
- 4. Two individuals who have no NSU affiliation and who may contribute a community perspective

IACUC General Responsibilities

The IACUC shall, under the direction of the Chairperson,

- 1. Review and inspect all animal research facilities on campus at least once every six months as part of institutional and public assurance of human use of animals.
- 2. Review and approve research protocols submitted by NSU researchers that involve live animal research in campus facilities.
- 3. Review and evaluate all proposed programmatic activities and/or changes in research protocols.
- 4. Take corrective action and otherwise suspend any and all research activities that do not comply with standards of due care as stipulated by the IACUC and as expected by public law and/or university policy and regulations.
- 5. Review any complaint, whether the source is internal or external to NSU, or allegation of misconduct in the humane use and care of animals involved in teaching and research.
- 6. Maintain all records involving IACUC review of research protocol and related communications with principal investigators and university authorities.
- 7. Submit monthly reports on its regulatory activities to the Director, Office of Research.
- 8. When warranted, submit recommendations for improvements in operational facilities and procedures to the Director, Office of Research.

IACUC Protocol Review Responsibilities

All research involving animal care and use in NSU facilities must be evaluated by the IACUC. The IACUC's procedures of protocol review should include:

1. Pre-review of submitted documents for completeness according to IACUC's protocol content requirements

- 2. Primary review by a designated IACUC member
- 3. Primary review by a designated veterinarian
- 4. Verification of mandatory (a) animal care and use training and (b) occupational health and safety training of all research personnel listed in the protocol documents
- 5. Review by a quorum of the IACUC, including one of the following decisions: (a) approval; (b) require modifications of the protocol and re-submittal; (c) disapprove. A quorum is a simple majority of the membership, and must include at least one committee veterinarian and one non-affiliated member.
- 6. Written notification of decision to the PI
- 7. Signature agreement from the PI that thereby constitutes authorization to proceed with research activities

The timeline for approval/disapproval of a properly submitted research protocol should take no more than six weeks, dependent on the IACUC's schedule of meetings, the PI's responsiveness to IACUC queries, and quorum review requirement after primary reviews have been completed. A Pre-review by IACUC staff should take no more than two days; a new protocol review approximately four weeks; a renewal protocol review approximately four weeks; minor amendments to protocol approximately two days; major amendments to protocol approximately four weeks; full committee quorum review at the IACUC monthly meeting. All IACUC approvals are for a maximum of three years, although it is to be understood that the IACUC will conduct mandatory annual reviews of research activities to assure compliance with policy and regulation. Where research continues beyond the initial three year approval period, the designated principal investigator is expected to submit a new proposal/protocol for IACUC review and approval prior to the expiration of the current protocol.

Researcher Responsibilities

Any and all NSU faculty designated as principal investigator (PI) in an animal research protocol is required to prepare and submit a proper research protocol to the IACUC for review and approval of proposed research before initiating any research activities. A research protocol normally includes the following information:

- 1. Research project overview identifying research goals and objectives
- 2. List of animal species, sources of procurement, and pertinent identifying information
- 3. Rationale for the animal species listed and numbers of animals to be procured
- 4. Description of planned use of the listed animals
- 5. Description of care and use facilities, including how assurances are warranted for biological, chemical, and/or radiation safety when pertinent to the research protocol
- 6. Description of veterinary care to be provided, surgical procedures, minimization of pain, methods of euthanasia, disposal of euthanized animals, etc.
- 7. Identification of all funding sources (intramural and/or extramural) and amounts over budgeted time frame
- 8. Identification of all personnel participating, including description of relevant qualifications and experience
- 9. Identification of animal care and use training and occupational health and safety training to be provided to all research personnel listed (such training

understood to be mandatory for all personnel prior to initiation of research activities)

Policy Updates

Under the authority of the Vice Chancellor, the Director, Office of Research-NSU, reserves the right to update, revise, and amend animal care and use policies and procedures when warranted by institutional authority and/or governmental regulatory developments. When updated, revised, or amended, the policy document shall show the effective date of approval. Earlier versions of the policy shall be archived by the Office of Research-NSU and otherwise remain available for reference.

References

- 1. "The Cruelty to Animals Act, 1920," Legislative and Parliamentary Affairs Division, Ministry of Law, Justice and Parliamentary Affairs, 2010, http://www.bagheera.com/wp-content/uploads/es_laws/Bangladesh_-
 _THE_CRUELTY_TO_ANIMALS_ACT.pdf
- 2. University of Illinois at Urbana-Champaign, Office of the Vice Chancellor for Research, Illinois *Institutional Animal Care and Use Committee (IACUC)*, http://research.illinois.edu/regulatory-compliance-safety/iacuc.
- 3. Nuffield Council on Bioethics, *The Ethics of Research Involving Animals* (London, 2005)
- 4. Council for International Organization of Medical Sciences (CIOMS) and The International Council for Laboratory Animal Science (ICLAS), *International Guiding Principles for Biomedical Research Involving Animals*, December 2012, http://iclas.org/wp-content/uploads/2013/03/CIOMS-ICLAS-Principles-Final.pdf
- 5. D. DeGrazia, *Taking Animals Seriously: Mental Life and Moral Status* (Cambridge: Cambridge University Press, 1996)
- 6. W. Russel and R. Burch, *The Principles of Humane Experimental Technique* (London: Methuen, 1959)