

Columbia University  
Assurance # D16-00003 (A3007-01)  
**ANIMAL WELFARE ASSURANCE**  
in accordance with the PHS Policy for  
Humane Care and Use of Laboratory Animals

I, Deborah F. Stiles, B.A., J.D., as Vice President for Research Operations and Policy and named Institutional Official for animal care and use at Columbia University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

**I. Applicability of Assurance**

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing and related activities ("Activities") involving live vertebrate animals supported by the Public Health Service (PHS), the Department of Health and Human Services (HHS), the National Science Foundation (NSF) and/or the National Aeronautics and Space Administration (NASA) and conducted at this Institution. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority: Columbia University; Columbia University Irving Medical Center (including the College of Physicians and Surgeons, the College of Dental Medicine, the Mailman School of Public Health, the School of Nursing and the Radiological Research Accelerator Facility (RARAF)); Columbia University - Morningside Heights campus (including Lamont-Doherty Earth Observatory); and Columbia University – Manhattanville campus.

B. The following other institution is also included: Barnard College.  
Barnard College does not have animal facilities where research involving animals will be conducted using PHS, HHS or NSF funds.

**II. Institutional Commitment**

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in Activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for Activities involving animals (the "Program") according to the *Guide for the Care and Use of Laboratory Animals* (Guide).

- E. This Institution agrees to ensure that all performance sites engaged in Activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the Activities have Institutional Animal Care and Use Committee (IACUC or the "Committee") approval.

### III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the Program and ensuring compliance with the PHS Policy are as follows:

See the organizational chart included in VIII. below.

- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the Program are as follows:

- 1) Director (the "ICM Director") of the Institute of Comparative Medicine ("ICM"), Attending Veterinarian ("AV")

Name: Brian Karolewski

Degrees: VMD, PhD, DACLAM

AVMA accredited veterinary school or equivalent: University of Pennsylvania School of Veterinary Medicine

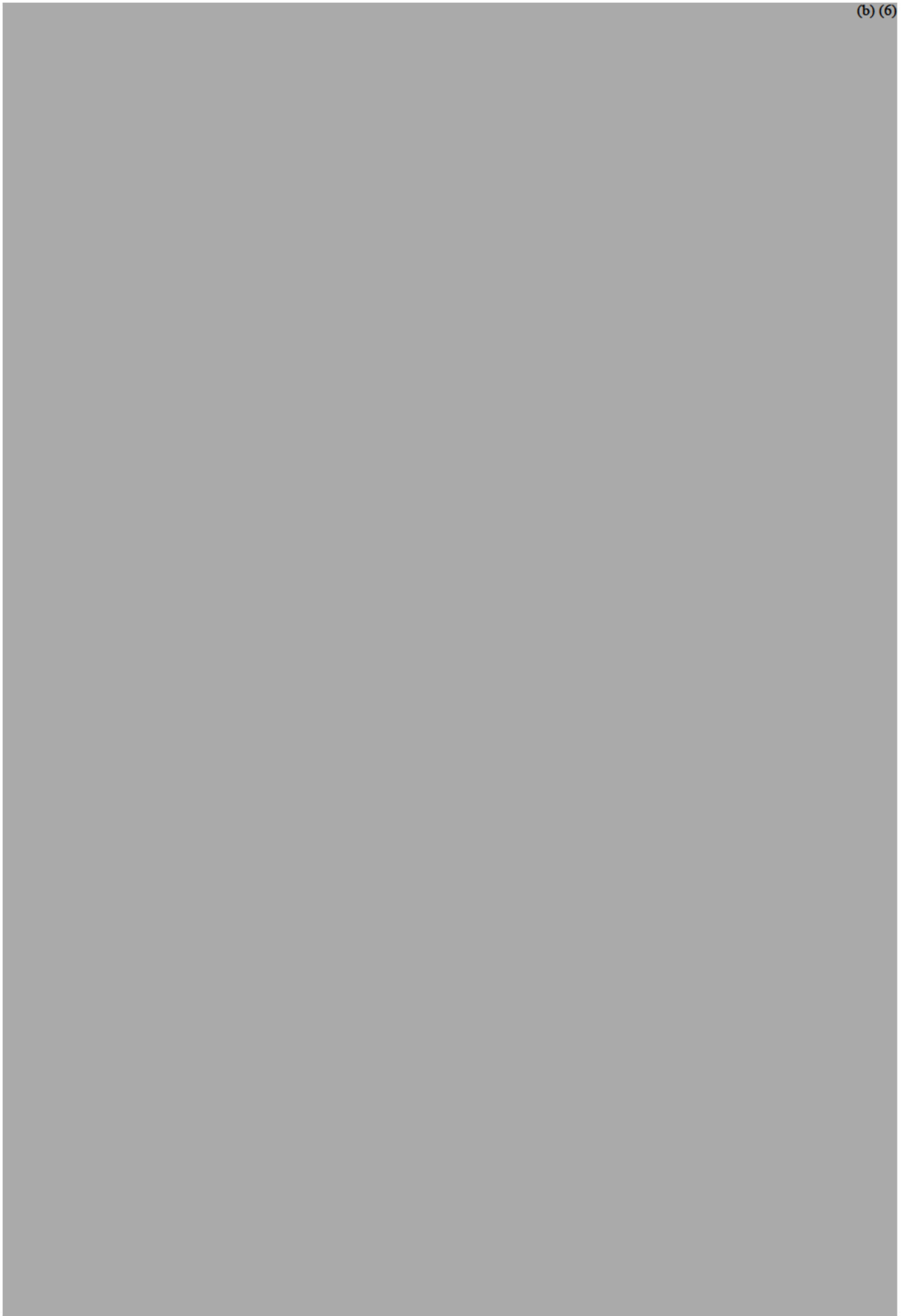
Training or experience in laboratory animal medicine or in the use of the species at the institution: Diplomate of the American College of Laboratory Animal Medicine (ACLAM) with greater than 24 years of experience in laboratory animal medicine.

Authority: The ICM Director/AV, Dr. B. Karolewski, has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. He implements the PHS Policy and the recommendations of the Guide, and works closely with the IACUC to ensure that the animal resources of the Institution and all animal research conducted at the Institution are in compliance with all pertinent Federal, State, and city laws, regulations, policies and guidelines.

Time contributed to Program: The position of Director is a full-time position. One hundred percent of the Director's time is committed to directing the service, teaching, training, and research Activities of the ICM.

(b) (6)

(b) (6)



(b) (6)

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b.

Section IX. of this document includes a list of the chairperson and members of the IACUC with their names, degrees, profession, titles or specialties, and institutional affiliations.

- D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The IACUC reviews the Program at least once every six months. All IACUC members are given the opportunity to participate in the review. This review is conducted by at least two IACUC members utilizing the OLAW Program Review Checklist template, followed by a review during a convened meeting of a quorum of the IACUC. The review is based on the PHS Policy, the *Guide*, and the United States Department of Agriculture (USDA) Animal Welfare Act Regulations. Information for the review is gathered from inspections of the facilities (which occur at least once every six months), review of any outside agency inspection reports, review of IACUC membership and activities, discussions and communications with the ICM Director and other ICM veterinarians concerning the program for animal care and use, review of compliance monitoring data, review of animal welfare/compliance investigations conducted during the reporting period and review of departures from the *Guide*.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

The IACUC inspects all animal facilities (including satellite facilities and surgical sites) at least once every six months using the *Guide* and the USDA Animal Welfare Act Regulations as the basis for evaluation. Inspections are conducted by at least 2 members of the IACUC. All IACUC members are given the opportunity to participate in the inspections. If any recommendations are made with respect to the animal facilities managed by the ICM, written correspondence with proposed correction dates stating these recommendations and proposed dates are sent to the Director and Associate Director of the ICM as well as the Facilities Operations Manager. For all animal laboratories and satellite facilities, notice of any deficiencies is sent to the responsible investigator with proposed correction dates.

- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

The IACUC prepares a report of each of its semiannual evaluations resulting from the Program review and inspections described in Sections III.D.1 and 2 above. Reports are prepared in the format suggested by OLAW. Each report describes the nature and extent of the Institution's adherence to the Guide, the PHS Policy and the USDA Animal Welfare Act Regulations and any departures from those documents, stating the reasons therefor. Departures from the Guide are identified according to OLAW guidance. These departures are tracked during the protocol review process and the IACUC staff utilizes reports from the electronic protocol review system to prepare the departures list for the semiannual review. Any departures not covered in the protocol review process are reported to the IACUC by the veterinary staff and others are detected during the semiannual Program review. All are compiled by the IACUC staff and included in the semiannual report. If the IACUC identifies departures from the PHS Policy or the Guide that are not approved by the IACUC, they are considered noncompliance and will be promptly reported to OLAW. The report distinguishes significant deficiencies, if any, from minor deficiencies, and contains a reasonable and specific plan and schedule for correcting such deficiencies. A significant deficiency is one that is or may be a threat to the health or safety of the animals. All deficiencies that do not meet that criteria are considered minor. The report is signed by a majority of the IACUC members and includes any minority views. Each report is submitted to the IO.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:
  - a. Any person, including any University employee, student, volunteer or member of the general public may report concerns involving the care and use of animals. Concerns may be reported anonymously. All ICM personnel and members of the research community receive training on reporting of animal welfare concerns. Signs describing the procedures are posted in the animal facilities. Concerns may be submitted to ICM personnel, IACUC members or IACUC staff members in person, via phone or email, or via the IACUC Concern Hotline phone number. The Hotline number is listed on the IACUC's website, displayed in the ICM animal facilities and displayed during orientation sessions. The procedures include a mechanism for anonymity, compliance with applicable whistleblower policies and nondiscrimination against the concerned/reporting party, and protection from reprisals.
  - b. Submitted concerns are forwarded to the IACUC Chair, the AV and the Executive Director of the Office of the IACUC. The IACUC Chair appoints an investigative group to conduct an investigation. Members of the group are chosen to avoid any conflict of interest. The investigative group reports the results of its investigation to the IACUC for review and appropriate action. In all instances, if the complainant identifies him/herself, he/she will be notified of the outcome of the investigation. The IACUC is kept apprised of the status of the investigation until its completion.
  - c. All actions taken are documented. The IACUC Chair will forward any IACUC recommendations to the appropriate authority (i.e., the ICM Director, a departmental chair, the principal investigator, etc.). If the matter cannot be resolved through the auspices of the IACUC and the relevant authority, and if it is deemed of sufficient concern, the matter will be referred by the IACUC to the IO.



- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

Any recommendations concerning departures from the Guide and the PHS Policy and any other issues concerning the Institution's Program, animal facilities or personnel training identified in the course of any semiannual review by the IACUC are included in the IACUC's semiannual report. Between such reports, pressing issues and the IACUC's recommendations for dealing with them are referred in writing to the IO.

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

- a. No Activity involving animals may occur at this Institution unless a protocol relating to such Activity has been approved by the IACUC in accordance with the procedures set forth below. To implement this policy, all animals are ordered through the ICM, and the ICM will not order animals unless the investigator/user can provide an IACUC-approved protocol number for the specified animal Activity.

- b. The Institution collects, maintains and processes information relating to the Institution's research by means of a web-based computer system, called RASCAL. The animal care module of this computer system requires each investigator involved in research using laboratory animals to submit a Columbia University Animal Care Protocol Datasheet (a "Protocol Datasheet") that summarizes certain information. On the first page of the Protocol Datasheet, the investigator is asked to classify his/her use of vertebrates in the protocol into one of the following categories (a "Pain/Distress Category"):

- (1) Activities that involve only breeding, conditioning or holding of animals ("Category B");
- (2) Activities that involve momentary or slight pain, distress or discomfort ("Category C");
- (3) Activities that involve more than momentary or slight pain, distress or discomfort for which appropriate anesthetic, analgesic or tranquilizing drugs or other methods are used to relieve pain/distress ("Category D"); and
- (4) Activities that involve more than momentary or slight pain, distress or discomfort for which the use of appropriate anesthetic, analgesic or tranquilizing drugs would adversely affect the procedures, results or interpretation of the research ("Category E").

- c. The IACUC administrative staff sorts the completed Protocol Datasheets into two groups (Categories B and C, and Categories D and E).

At the end of each week, a list (the "Weekly Protocol List") of all protocols that have been received during the week is provided to each member of the IACUC. The Weekly Protocol List gives the following information with respect to each protocol: the protocol title; the principal investigator; the department; the funding agency; the species to be



used; the quantity of animals requested; the Pain/Distress Category; whether surgery is involved; the location of the proposed research; keywords used in the search for alternatives to painful procedures and a brief description of the proposed research. Copies of the completed Protocol Datasheets are available to all IACUC members via the web-based computer system. Any member of the IACUC may obtain full Committee review of any protocol included on the Weekly Protocol List by requesting such review (a) for protocols in Categories B and C, prior to the close of business on the Wednesday following the distribution of the Weekly Protocol List and (b) for protocols in Categories D and E, at or before the meeting of the protocol review subcommittee at which the protocol will be discussed. Additionally, any member may request full Committee review of any protocol while the protocol is under review. In any event, IACUC members will have a minimum of two business days to request full Committee review of any protocol.

- d. Unless full Committee review is requested, all protocols are reviewed using a designated member review process, conducted by a single member of the IACUC designated by the Chair of the IACUC (the "Designated Reviewer"). For protocols in Categories B and C, the review by the Designated Reviewer includes consultation with a member of the IACUC staff who is also a member of the IACUC. For protocols in Categories D and E, the review by the Designated Reviewer includes consultation with one of two protocol review subcommittees of the IACUC, each of which includes at least one veterinarian of the ICM. Each protocol review subcommittee meets once per month to discuss research proposals and advise the Designated Reviewer assigned to each protocol.
- e. Following the Designated Reviewer's consultation with a member of the IACUC staff who is also an IACUC member (for protocols in Categories B and C) or with the applicable protocol review subcommittee (for protocols in Categories D and E), the Designated Reviewer approves, requires modifications in to secure approval or requests full Committee review of the protocol. Protocol approval by this designated member review process requires both the expiration of the time period provided to all IACUC members to request full Committee review (without any such request having been received) and the approval of the Designated Reviewer, and is effective only after both have occurred.
- f. If full Committee review is requested, the Committee will meet at a convened meeting at which a quorum is present to review and approve, require modifications in (to secure approval) or withhold approval of the protocol. Approval or withholding approval of any protocol for which full Committee review has been requested requires the affirmative vote of a majority of the quorum present at the meeting. If the outcome of the review is to require modifications to secure approval of the protocol, the Committee will vote either to return the revised protocol for full Committee review or to allow a Designated Reviewer, appointed by the IACUC Chair, to review the revised protocol. For protocols in Categories B and C, the review by the Designated Reviewer includes consultation with a member of the IACUC staff who is also a member of the IACUC. For protocols in Categories D and E, the review by the Designated Reviewer includes consultation with an ICM veterinarian. If the Committee votes to allow designated member review of the revised protocol, the revised protocol will be placed on the Weekly Protocol List when it is submitted, and all members of the IACUC will have the opportunity to obtain full Committee review of the revised protocol by requesting such review prior to the close of business on the Wednesday following the distribution of the Weekly Protocol List. In any event, IACUC members will have a minimum of two business days to request full Committee review of the revised protocol.

- g. No member of the IACUC may participate in the review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.
  - h. A list of all protocols approved by the IACUC is available to the ICM electronically.
- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:
- a. All significant changes are approved by either designated member review or full Committee review in accordance with the procedures described in Section III.D.6. above.
  - b. Significant changes include but are not limited to the following:
    - (1) A change in the overall aims or objectives of the study;
    - (2) A change which may involve an increase in the levels of pain, distress and/or discomfort or degree of invasiveness;
    - (3) A change from non-surgery to surgery, from minor to major surgery, from non-survival to survival surgery, or from single to multiple survival surgery;
    - (4) An increase greater than 10% in the number of animals required for protocols involving the use of mice, rats or fish;
    - (5) Any increase in the number of animals required for protocols involving species other than mice, rats and fish;
    - (6) A change in the genus or species of animals used;
    - (7) The addition of the use of hazardous agents in animal procedures;
    - (8) A change in anesthetic agent(s) or the use or withholding of analgesics;
    - (9) A change in the method of euthanasia;
    - (10) A change in the principal investigator;
    - (11) A change in or addition of a location outside the ICM facilities that is used for animal experimentation; and
    - (12) A change that impacts personnel safety.
- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC

procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The Office of the IACUC through the RASCAL animal care module generates a letter to each principal investigator who has submitted a protocol notifying him/her of the action of the Committee with respect to such protocol. When the decision is to withhold approval of an Activity, or to require modifications to secure approval, the letter includes a statement of the reasons for the decision and the investigator may respond to the Committee in writing or in person. Following such a response, or if no response is received from the investigator, the Chair of the IACUC also notifies the IO in writing if the Committee decides to withhold approval of an Activity. A list of the protocols approved by the IACUC under the procedures set forth in Section III.D.6 above is sent to the IO at least once a month and is also available to them at all times via the RASCAL system.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by the PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4. at least once every three years. The IACUC procedures for conducting continuing reviews are as follows:
  - a. Each investigator whose protocol has previously been approved by the IACUC pursuant to the procedures set forth in III.D.6 above is required to submit a Columbia University Protocol Continuation DataSheet (a "Protocol Continuation DataSheet") to the IACUC prior to each anniversary of the date of such approval. The purpose of the Protocol Continuation Datasheet is to enable the IACUC to review the Activities under the protocol on an annual basis. Failure to submit a Protocol Continuation Datasheet on a timely basis will result in automatic expiration of the approval of the Activities under the protocol on the anniversary date, and submission of a new protocol is then required to obtain IACUC approval to continue such Activities.
  - b. Upon receipt of a Protocol Continuation Datasheet, the administrative staff of the IACUC will include the protocol continuation and the information described in Section III.D.6.c above in the Weekly Protocol List provided to each member of the Committee. Copies of the completed Protocol Continuation Datasheets are available to all IACUC members via the web-based computer system. Any member of the IACUC may obtain full Committee review of the proposed continuation of Activities under a protocol by requesting such review prior to the close of business on the Wednesday following the distribution of the Weekly Protocol List, or at any time until the review of the protocol continuation has been completed. In any event, IACUC members will have a minimum of two business days to request full Committee review. Unless full Committee review has been requested, each Protocol Continuation Datasheet is reviewed by a Designated Reviewer appointed by the Chair. For protocols in Categories B and C, the review by the Designated Reviewer includes consultation with a member of the IACUC staff who is also a member of the IACUC. For protocols in Categories D and E, the review by the Designated Reviewer includes consultation with a veterinarian of the ICM. Approval of the continuation of Activities under a protocol by this designated member reviewer process requires both expiration of the time period provided to all IACUC members to request full Committee review (without such request having been received) and the approval of the Designated Reviewer, and is effective only after both have occurred.
  - c. Activities under each protocol must be reviewed de novo by either designated member review or full Committee review at least once every three years, using the procedures set

forth in III.D.6. above. The de novo review is completed prior to the expiration date of the protocol.

- d. Post approval monitoring is conducted by the IACUC office staff. Monitoring includes semiannual inspection finding follow up, announced and unannounced laboratory monitoring visits conducted outside the semiannual inspection process, follow up to incidents of noncompliance, and formal monitoring via meetings with investigators and their staff members.
- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:
- a. When the IACUC learns of the possibility that an Activity is not being conducted in accordance with the applicable provisions of the PHS Policy, the Animal Welfare Act, Animal Welfare Act Regulations, the Guide or this Assurance, it will promptly undertake an investigation into the relevant facts and circumstances. The results of that investigation are discussed at a convened meeting of a quorum of the full Committee to which the principal investigator and any other parties who may be responsible may be invited to present any additional information and to respond to questions from the Committee. Following the discussion, the IACUC will vote to determine what, if any, action, including possible suspension, is appropriate. Suspension of any previously approved Activity requires the affirmative vote of a majority of the quorum present.
  - b. Notification of any suspension is sent by the IACUC to the principal investigator and any other party the IACUC has determined is responsible, with copies to the IO. The IO, in consultation with the IACUC, the Director of the ICM, the Chair of the IACUC and the Executive Director of the Office of the IACUC, will review the reasons for the suspension, take appropriate corrective action and report that action to the Office of Laboratory Animal Welfare ("OLAW") of the National Institutes of Health (the "NIH").
- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:
- 1) The objectives of this Institution's occupational health and safety program are achieved through appropriately training all personnel to understand the hazards associated with their job duties and work area, and how those risks are mitigated through institutional policies, engineering controls, work practices and personal protective equipment. Development, implementation and monitoring of the program involves input from trained occupational health professionals, including a physician with medical expertise in zoonotic diseases. The Columbia University Environmental Health and Safety Office is responsible for monitoring the overall occupational health and safety program.
  - 2) All personnel at risk (e.g., investigators, visiting faculty, research technicians, students, ICM veterinarians, veterinary technicians and husbandry technicians, IACUC staff and members) are enrolled in an Occupational Health Program (the "OHP"). Enrollment in the OHP is mandatory. The OHP includes a baseline risk assessment medical evaluation and periodic medical evaluations specific to animal use as determined in the protocol review process or, in the case of ICM employees, as required by the nature of their employment. Counseling is given by health care providers during baseline and periodic visits and when injuries are reported. Summer students who do not attend the University are enrolled in the OHP. Their own medical health care provider completes a medical attestation form (questionnaire and vaccination history) which is assessed by the individuals who perform the medical



evaluations referenced above. The attestations are approved and the individuals enrolled in the OHP if it can be determined the individuals fulfill all the Columbia requirements.

- 3) Hazard identification covers experimental hazards and hazards intrinsic to animal care and use, with training on occupational health and safety topics such as zoonoses, allergies, special precautions to be taken during pregnancy and illness or immune suppression. Special emphasis is placed on general health, prior occupational exposure to animals, a history of allergies, adequate immunizations (e.g. tetanus at 10 year intervals or as needed based upon exposure risk, history of rabies exposure and vaccine), history of animal-related injuries and tuberculin skin testing/Quantiferon-TB testing, as appropriate, for those who have contact with nonhuman primates. Tetanus vaccination or prophylaxis is offered to employees, if necessary. Tuberculosis screening is conducted on a yearly basis for all ICM staff (veterinarians, veterinary technicians, and husbandry technicians) and researchers/lab personnel working with nonhuman primates. Counseling is given by health care providers during baseline and periodic visits and when injuries are reported. For personnel working with nonhuman primates, counseling regarding specific procedures following a bite/scratch or other injury related to nonhuman primates is reviewed during baseline and periodic visits. The procedures are also listed and discussed in the Macacine herpesvirus 1 computer based training module that all personnel working with nonhuman primates must take. A list of procedures is also available in all bite/scratch kits located in the nonhuman primate areas. During business hours, the Workforce Health and Safety Office at CUIMC performs treatment for bites, scratches, illness or injury. After business hours, the Emergency Room at CUIMC performs treatment. Notice of how and where to obtain health care following bite/scratch, illness or injury is posted in all nonhuman primate rooms, as well as prep rooms, surgery rooms, and cage wash and necropsy areas.
- 4) The Environmental Health and Safety Office ("EH&S") of the Institution establishes and administers the Institution's policies for personal hygiene and personnel protection. The Radiation Safety Office ("RSO") establishes and administers the Institution's policies relating to the use of radioactive substances. Both EH&S and the RSO coordinate their activities with the IACUC in order to minimize the exposure of all members of the ICM staff and research personnel to unnecessary risks. The Associate Director, Biological Safety within EH&S serves as a member of the IACUC.
- 5) All research personnel are advised on procedures to report animal bites, exposure to potential allergens or zoonotic diseases in the mandatory species-specific online training modules provided by the ICM. Research personnel are advised on personal protective equipment (PPE) and physical hazards during the required building orientation session provided by each building's supervisor. Potential dangers in working with and precautions for handling nonhuman primates, PPE, and standard operating procedures for nonhuman primate exposure cases are taught in two mandatory online training modules (the Macaque and Macacine herpesvirus 1 computer based training modules) provided by the ICM. A quiz is given following each training module. An annual refresher course is given. University facility, maintenance, and security personnel receive a lecture on a yearly basis which reviews procedures for working in the animal facility, potential allergens and exposures to Macacine herpesvirus 1. Every effort is made to move animals to different rooms/areas when facility maintenance is occurring to reduce any potential exposure. Summer students and visiting faculty receive the same TB screening and training before permission to work with nonhuman primates is granted.

- 6) As part of the protocol review process, investigators whose animal-related Activities involve the use of recombinant DNA molecules, infectious agents, human blood, human cell lines, hazardous chemicals and/or radioisotopes must complete and submit the appropriate Appendix to the protocol in the RASCAL system. Those completed Appendices are accessible to EH&S and/or the RSO. Each Appendix contains information concerning personal hygiene and safe practices for handling the specific agent(s) or material(s) involved in the relevant research. EH&S and/or the Radiation Safety Officer must approve the applicable Appendix before the IACUC will approve the proposed Activity involving the use of such materials.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

*See the Facility and Species Inventory table provided in Part X. below.*

- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:
- 1) The IACUC ensures that research personnel have knowledge and expertise in procedures proposed via the animal care module, RASCAL. The extent of each individual's experience and expertise, plus protocol roles and responsibilities must be listed in the protocol. Additionally, records of completion of the training program are captured in RASCAL. Those include ICM online training modules, the regulatory lecture, species specific training and rodent wet lab training.
  - 2) The IACUC conducts at least twice weekly face-to-face or virtual (via Zoom) regulatory lectures, as well as extra sessions as required by the research community. Attendance at these lectures is mandatory for any individuals who wish to work with animals at the Institution. These sessions cover requirements of the PHS and U.S. Department of Agriculture (USDA) regulations as well as those of the Animal Welfare Act. General considerations regarding the humane care and use of animals, including research and testing methods to minimize animal numbers required to obtain valid results and to limit pain/distress and a discussion of protocol review, as well as information on submitting animal welfare concerns, are also included in these sessions. After the initial lecture, all animal users must complete an online training module covering the same information at least once every three years.
  - 3) All researchers are also required to complete the ICM introductory course given online. Following this training, researchers take the species-specific online course(s) as appropriate. The species-specific online course(s) is a pre-requisite to the hands-on wet lab training session(s). Researchers housing their animals in a barrier facility must also complete the rodent barrier online course. Prior to obtaining animal facility access, personnel are also required to undergo a building specific orientation session that includes barrier training and information on PPE and physical hazards.
  - 4) The ICM training coordinator along with the veterinary technical staff of the ICM, under the direction of the ICM veterinarians, also conduct a series of wet-lab courses designed to provide practical experience and training in handling the various animal species. Subjects covered during the wet-lab courses include assessment of pain and distress, anesthetic & injection techniques, methods of gauging the depth of anesthesia, methods of blood collection, and appropriate methods of euthanasia. Wet-labs for mouse and rat handling are

mandatory. All researchers who conduct survival rodent surgery must also complete two online courses, one covering rodent surgery and one use of anesthetics and analgesics, once a year. They are also required to attend a hands on rodent surgery training session. For those researchers performing survival stereotaxic surgery on rodents, an additional online course is required to train those individuals on how to maintain sterility while doing this type of surgery.

- 5) Investigators and other scientific personnel are also trained and instructed through the protocol review process in (a) the proper methods of reducing pain and distress; (b) the minimization of number of animals required; and (c) the use of the appropriate species. Protocol review is an interactive process in which the principal investigator and the IACUC enter into a dialogue concerning the care and use of animals in the proposed research project. Such a dialogue is a very effective form of training, since it is conducted on a case by case basis when the investigator is most interested in learning appropriate methods for conducting his/her research. All of the applicable training requirements mentioned above must be completed prior to approval of an IACUC protocol.
- 6) Investigators and other scientific personnel are also trained and instructed, through the post approval monitoring process, in any aspect of the animal care and use program that may be pertinent during monitoring visits.
- 7) Researchers are encouraged to communicate with the veterinarians, the training coordinator and IACUC staff during protocol development and throughout their experiments so that skills and techniques can continuously be enhanced. ICM also invites laboratory animal science speakers throughout the year to give lectures to the researchers on various topics such as nomenclature, breeding strategies, rederivation, and cryopreservation etc.
- 8) There is an extensive training program for animal care technicians. Initially it includes at least two in-house online modules - Introduction to the Institute of Comparative Medicine and rodent barrier training. If the technician will be working with nonhuman primates, specialized training must be completed. Various other modes of training are utilized including videos, lectures, reading assignments, and on the job training. Continuing education opportunities exist for all husbandry technicians through the Metro-NYC American Association for Laboratory Animal Science (AALAS) Branch. All technicians also have access to the AALAS Learning Library and are encouraged to utilize this resource. Support is available for staff to attend seminars and conferences. AALAS certification classes and review sessions are conducted on an as needed basis. Quarterly ICM staff meetings are held to teach and review laboratory animal science topics and standards, as well as research and testing methods to minimize animal numbers required to obtain valid results and limit pain/distress.
- 9) When first appointed, IACUC members are provided orientation and training with the Executive Director of the Office of the IACUC. During orientation, new members receive a packet containing various background materials and resources, including the Animal Welfare Act and regulations, the PHS Policy, the Guide, the AVMA Guidelines for the Euthanasia of Animals, the Institution's approved Animal Welfare Assurance and other materials. IACUC members are encouraged to attend local and national IACUC conferences. Webinars serve as another source of IACUC member training. Training is often provided during monthly IACUC meetings.

#### **IV. Institutional Program Evaluation and Accreditation**



All of this Institution's programs and facilities (including satellite facilities) for Activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to OLAW upon request.

- (1) This Institution is Category 1 — accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

## **V. Recordkeeping Requirements**

- A. This Institution will maintain for at least 3 years:
1. A copy of this Assurance and any modifications made to it, as approved by the PHS
  2. Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations
  3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
  4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Deborah F. Stiles, B.A., J.D.
  5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing Activities reviewed and approved by the IACUC for the duration of the Activity and for an additional 3 years after completion of the Activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## **VI. Reporting Requirements**

- A. The Institutional reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:
1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  2. Any change in the description of the Institution's Program for animal care and use as described in this Assurance

3. Any change in the IACUC membership
  4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's Program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Deborah F. Stiles.
  5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
1. Any serious or continuing noncompliance with the PHS Policy
  2. Any serious deviations from the provisions of the *Guide*
  3. Any suspension of an activity by the IACUC
- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

**VII. Institutional Endorsement and PHS Approval**

<b>A. Authorized Institutional Official</b>	
Name: Deborah F. Stiles, B.A., J.D.	
Title: Vice President for Research Operations and Policy	
Name of Institution: Columbia University	
Address: 535 West 116 <sup>th</sup> Street (b) (4) Low Library, MC 4310 New York, NY 10027	
Phone: (b) (6)	Fax: (b) (6)
E-mail: dfs2102@columbia.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature (b) (6)	Date: 7.14.21

<b>B. PHS Approving Official (to be completed by OLAW)</b>	
<p>Jacquelyn Tubbs, DVM, DACLAM Animal Welfare Program Specialist Office of Laboratory Animal Welfare (OLAW), National Institutes of Health 6700B Rockledge Suite 2500, MSC 6910 Bethesda, MD USA 20892-6910 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163</p>	
<p><b>Jacquelyn T. Tubbs -S</b></p> <p>Digitally signed by Jacquelyn T. Tubbs -S Date: 2021.07.15 07:54:59 -04'00'</p>	
Signature:	Date:
Assurance Number: D16-00003 (A3007-01)	
Effective Date: 07-15-2021	Expiration Date: 07-31-2025

**IX. Membership of the IACUC**

Date: 3-31-21			
Name of Institution: Columbia University			
Assurance Number: D16-00003 (A3007-01)			
<b>IACUC Chairperson</b>			
Name: E. Heidi Jerome			
Title: Associate Professor of Clinical Anesthesiology and Pediatrics			Degree/Credentials: M. D.
Address: (street, city, state, zip code) 630 W 168th Street Box 64 College of Physicians and Surgeons New York, New York 10032			
E-mail: ej91@columbia.edu			
Phone: (b) (6)		Fax: (b) (6)	
PHS Policy Membership Requirements: Scientist			
<b>IACUC Roster</b>			
Name of Member/ Code	Degree/ Credentials	Position Title	PHS Policy Membership Requirements
(b) (6)			Scientist
			Alternate to #7
			Nonscientist
			Alternate to #2
			Scientist
			Member
			Scientist

(b) (6)			Scientist
			Scientist
			Scientist
			Alternate to #13, #19, #22,
13 Brian Karolewski	V.M.D., Ph.D.	Director, Institute of Comparative Medicine	Attending Veterinarian
(b) (6)			Scientist
			Scientist
			Nonaffiliated, Nonscientist
			Scientist
			Nonaffiliated, Nonscientist
			Veterinarian
			Scientist
			Scientist
			Veterinarian
			Scientist
			Scientist
			Scientist

\* = Alternate

**X. Columbia University Facility and Species Inventory**

<b>Site</b>	<b>Gross Square Feet Including Service Areas*</b>	<b>Species</b>	<b>Average Daily Inventory Fiscal Year 2020</b>
(b) (4)	35,485	Fish	15,414
		Mouse	33,459
		Rat	10
		Gerbil	5
		Guinea Pig	5
		Rabbit	18
		Dog	1
		Pig	9
		NHP	60
	278	Mouse	0
	116	Mouse	2
	168	Mouse	10
	12, 711	Mouse	22,038
	183	Frog	8
	8, 289	Mouse	7950
		Rat	3
	181	Mouse	
	5,110	Mouse	9,642
		Rat	140
	7,888	Mouse	14,214
	186	Mouse	35
	154	Mouse	0
	2,340	Salamander	290
		Mouse	1989
		Rat	18
	63	Frog	20
	22	Frog	20
	206	Mouse	5
	180.5	Mouse	29
	1,842	Mouse	14
	350	Mouse	250
		Rat	30

(b) (4)	804	Mouse	1000
		Rat	100
	34	Mouse	2
	19,496	Mouse	22773
		Peromyscus	1136
		Bird	107
		Fish	235
		NHP	112
		Cuttlefish	245

\*Gross square footage includes animal holding space, procedure room space, storage space and cage wash space.



March 25, 2021

Deborah F. Stiles  
Chief Operating Officer  
Vice President for Research Operations and Policy  
Columbia University  
(b) (4) Low Library  
New York, NY 10027

Dear Ms. Stiles,

We at Barnard College appreciate the collaboration between our institutions pertaining to animal research. Our research investigators will continue to submit their protocols involving animal subjects for review and approval by the Columbia University IACUC. We will continue to follow guidance of the Institutional Official (IO) and IACUC of Columbia University.

We wish to continue to be included in the PHS Animal Welfare Assurance for Columbia University in the City of New York, D16-0003 (A3007-01), and we will continue to comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals administered by the National Institutes of Health, Office of Laboratory Animal Welfare. We will also comply with provisions of the *Guide for the Care and Use of Laboratory Animals*, the Animal Welfare Act regulations (as applicable) and the AVMA Guidelines for the Euthanasia of Animals. We will continue to comply with requirements of the Columbia IACUC and IO.

Sincerely,

(b) (6)

