

The Trustees of Columbia University in the City of New York
(Exclusive of its Health Science Campus)
and Barnard College

**ASSURANCE OF COMPLIANCE WITH PHS POLICY ON HUMANE
CARE AND USE OF LABORATORY ANIMALS**

The Trustees of Columbia University in the City of New York (exclusive of its Health Sciences Campus) and Barnard College, hereinafter referred to as the institution, hereby give assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy."

I. Applicability

This Assurance is applicable to all research, research training, experimentation, biological testing, and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the subgranting or subcontracting of a PHS-supported activity by this institution. "Institution" includes the Morningside Heights Campus of Columbia University and Barnard College.

II. Institutional Policy

- 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 make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all 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 in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. Institutional Program for Animal Care and Use

- A. The lines of authority, and responsibility for administering the program and ensuring compliance with this policy are:

1) The institutional official authorized to sign the Assurance is the Provost of Columbia University hereinafter referred to as Provost. He is the individual ultimately responsible for administering the animal care and use program at the institution and for ensuring compliance with the PHS Policy. He reports to the President of Columbia University.

2) The Provost has delegated administrative oversight of the institutional animal care and use program to the Office of Projects and Grants, whose Executive Director reports to him through the Executive Vice Provost. The Executive Director of the Office of Projects and Grants serves as an ex-officio member of the Institutional Animal Care and Use committee. She is also responsible for coordinating communications between the institution and government agencies concerning procedures for animal research or use and projects involving animal research or use at this institution.

3) The Director of the Institute of Comparative Medicine (ICM) is responsible for all management, veterinary and administrative aspects of the laboratory animal resources at the institution. The Director of the ICM is the Attending Veterinarian and a member of the Institutional Animal Care and Use Committee. He reports, administratively, to the Provost for this institution.

4) In each of our four departmental animal care facilities (Site A, Site B, Site C and Site D) there is a Faculty Coordinator responsible for all aspects of the operation of that facility. In the Site A facility, a Laboratory Director reports directly to the Faculty Coordinator for animal care matters. Reporting to that Director is an Animal Facility Manager who is directly responsible for the care of the animals. In Sites B, C and Site D facilities the Animal Caretakers report directly to the Faculty Coordinators and are similarly directly responsible for the care of the animals. Each Animal Caretaker has various students (graduate, undergraduate, or work-study) whom he or she oversees as they perform the various research projects with the principal investigators and researchers.

These arrangements are presented schematically as Attachment 1.

5) The Institutional Animal Care and Use Committee (IACUC or the Committee) oversees and evaluates the institution's animal program, procedures and facilities through review of proposed uses of animals in research, testing, or education; inspection of facilities and animal activity areas; submission of reports to responsible institutional officials; ensuring the appropriate training of personnel using or caring for animals; establishment of mechanism for receipt and review of concerns involving the care and use of animals at the institution. The Chair of the IACUC is appointed by the President of Columbia University and routinely reports on Committee matters to the Executive Director of the Office of Projects and Grants. Members of the IACUC are appointed by the President of Columbia University and serve at his pleasure.

- B. The qualification, authority and percentage of time contributed by the veterinarians) who will participate in the program are:

Dr. Dennis F. Kohn, DVM, Ph.D., is the attending veterinarian. Dr. Kohn is an ACLAM (American College of Laboratory Animal Medicine) Diplomate and has had over 35 years of experience in laboratory animal medicine and directing animal resource programs. He has been the Director of the Institute of Comparative Medicine, Health Sciences Division of Columbia University and attending veterinarian for the institution since 1986. As attending veterinarian for the institution, Dr. Kohn has the authority for implementing and maintaining husbandry and veterinary care programs that are consistent with all federal, state and local laws, regulations and guidelines. This authority is through the Office of the Columbia University Provost. Approximately 5% of his time involves participation in the animal care and use program at this institution.

Jennifer Kalishman, DVM, Senior Clinical Veterinarian, Institute of Comparative Medicine, completed a 3 year postdoctoral fellowship in comparative medicine at the University of Washington in 2000 and was a clinical veterinarian at the University of Washington Regional Primate Center prior to joining the veterinary faculty at Columbia University in 2001. Alan Herron, DVM, Chief-Section of Comparative Pathology, Institute of Comparative Medicine, joined the veterinary faculty in 2001 after being a faculty member in the Department of Pathology, University of Miami Medical School for 15-years. Both veterinarians report to Dr. Kohn and will each spend about 5% of their time in support of the animal care and use program at this institution.

The veterinarians are responsible for developing and implementing training programs. The principles and recommendations of the Guide and all the other pertinent regulations and proper techniques are to be conveyed to faculty,

staff, and students who are involved with animal research under a training and continuing education program.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the compositional requirements set forth in section IV.A.3.b of the PHS Policy. Attached (as Attachment No.2) is a list of the names, position titles and earned degrees, specialties and institutional affiliations of the IACUC chairperson and members.

D. The IACUC will:

1 Review at least once every six 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 evaluations are:

The IACUC utilizes the semi-annual meeting to re-examine and discuss the institution's "Elements of Institutional Program for the Care and Use of Laboratory Animals". The items/programs evaluated and discussed are as follows:

- a. Institutional Animal Care and Use committee appointed – properly constituted committee meets at least twice a year to inspect facilities and programs.
- b. Veterinary care – Provided for all animal care problems and for facility inspections, animals inspected regularly, procured properly, proper quarantine, species separated.
- c. Technical personnel for animal care – for both technical and husbandry support.
- d. Special training programs for research, student, and technical.
- e. Special training and/or guidelines for the use of hazardous agents.
- f. Personnel hygiene – laboratory facilities, supplies, clothing provided as needed.
- g. Health Program – physical examinations and medical and work history plus immunization schedule.
- h. Monitoring of physical restraint provided – avoidance of prolonged restraint, devices are suitable to size and shape of animals restrained.
- i. Proper use of anesthesia and analgesia
- j. Surgery and postsurgical care provided in proper aseptic fashion
- k. Euthanasia – Is it carried out by trained personnel using acceptable practices?

- l. Do facilities meet guidelines specifications regarding corridors, doors, windows, floors, drains, walls, ceilings temperature and humidity controls, ventilation, lighting, storage areas, noise control, adequate sanitation facilities.
 - m. Proper husbandry observed for cage size and housing, social environment, space recommendations, temperature and humidity, ventilation, illumination, food, bedding, water, sanitation, waste disposal, vermin and identification and records.
 - n. Living conditions of animals to be used are appropriate for their species
 - o. Living conditions of animals contribute to their health and comfort.
 - p. Satisfactory program of disease prevention (including surveillance of animals) is in place.
2. Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are:

Inspection of all facilities will be made at least every six months by a subcommittee of the IACUC. More frequent inspections will be made if conditions so warrant. The inspection report, recommendations and concerns will be prepared by the IACUC and forwarded to all committee members and the Provost of Columbia University through the Office of Projects and Grants, which provides support services to the IACUC and which reports to the Provost. Copies of any recommendations for improvement of the facilities will also be sent to those individuals responsible for the upkeep of those facilities. Appropriate follow-up will be made to ensure a response to those recommendations

Several members of the IACUC committee, accompanied by the veterinarian, will conduct the semiannual inspection of the facilities utilizing the Guide as a basis. The checklist includes making sure that each facility has/have:

- a. Met the guidelines specifications regarding corridors, doors, windows, floors, drains, walls, ceilings, temperature and humidity controls, ventilation, lighting, storage areas, noise control, adequate sanitation facilities.
- b. Maintained proper animal husbandry for cage size and housing, social environment, space recommendations, temperature and humidity, ventilation, illumination, food, bedding, water, sanitation, waste disposal, vermin and identification of records.
- c. Living conditions for the animals to be utilized, which are appropriate for their species.
- d. Living conditions for animals to be utilized, which contribute to their health and comfort.

- e. A satisfactory program of disease prevention (including surveillance of animals) is in place.
 - f. Protocols in place for activities that involve surgery, which include appropriate provision for preoperative and postoperative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents (i.e., mammals higher on the evolutionary scale than rodents) will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents and lower animals do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures.
3. Prepare reports of its evaluations, as set forth in the PHS Policy, section IV.B.3 and submit reports to the Provost of Columbia University.

The IACUC process for developing reports and submitting them to the Institutional Official is:

At least once every six months, the IACUC will prepare a report describing the nature and extent of Columbia's adherence to the Guide and the PHS Policy. The report will identify specifically any departures from the Guide and the PHS Policy and the reasons for such departures. The report will distinguish significant deficiencies from minor deficiencies. Where program and/or facility deficiencies are noted, the report will contain a reasonable and specific plan and schedule for correcting each deficiency. When recommendations as to the solution of specific problems are made, such solutions will be included in the report. A copy of this report will be sent to the Provost of Columbia University. Annual reports of the IACUC evaluation will be maintained and made available to OLAW upon request.

4. Review concerns involving the care and use of animals at this institution. The IACUC procedures for reviewing concerns are:

Any concerns involving the care and use of animals at this institution can be brought directly to the IACUC (through any of its members) or to the IACUC through the Office of Projects and Grants at Columbia or the Grants Office at Barnard College. The IACUC will investigate all concerns and forward any recommendations to the appropriate authority (attending veterinarian, departmental chairpersons, researcher, etc.). The IACUC will also respond to

the individual reporting any concern, if the call is not anonymous. 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 Executive Director, Office of Projects and Grants and the Provost of Columbia University.

5. Make written recommendations to the Provost of Columbia University regarding any aspect of this institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are:

Any recommendations concerning departures from the Guide and the PHS Policy and any other issues concerning the institution's animal program, facilities or personnel training identified in the course of the IACUC's semiannual review of the institution's animal care program and inspection of animal facilities are included in the semiannual reports. Between such reports, pressing issues and the IACUC's recommendations for dealing with them are brought to the Executive Director, Office of Projects and Grants and, if necessary, referred in writing to the Provost.

6. Review and approve, require modifications to (to secure approval) or withhold approval of those activities related to the care and use of animals, as set forth in the PHS Policy, IV.C; The IACUC procedures for protocol review are:

- I) The Office of Projects and Grants at Columbia University and the Grants Office at Barnard College are the central facilities on each campus for the receipt and submission of proposals to all funding agencies. These offices, through their personnel, will ensure that all proposals (non-competing and competing) which propose the use of vertebrate animals will contain the following information prior to their submission to the funding agency:

- a. Identification of the species and approximate number of animals to be used;
- b. Rationale for involving animals, and for the appropriateness of the species and numbers to be used;
- c. A complete description of the proposed use of the animals;
- d. Assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- e. A description of any euthanasia method to be used.

- II.) The institution will ensure that its on-line RASCAL PropTrak Form (Proposal Tracking System Form) or a Proposal Routing Sheet has been completed and approved by the designated department official(s) when vertebrate animals are to be utilized. Both the hard copy and electronic forms request information about whether vertebrate animals will be utilized. When vertebrate animals are to be used, all investigators complete the institution's on-line RASCAL Animal Care Protocol Form.

The designated individual in the Office of Projects and Grants at Columbia University, who lends administrative support to the Committee, goes on-line daily to check for newly submitted protocols for the Committee's approval. Please see below the Approval Process once the submitted protocol has been inspected for completeness.

- a) The on-line system specifies the information necessary for the principal investigator's protocol to be reviewed by the Committee. A copy of the on-line Protocol Review Summary Form is attached (Attachment No. 3). On the first page of the form the investigator is asked to classify his/her use of vertebrates in the protocol into one of the following pain categories.

- (1) activities that involve little or no pain, distress, or discomfort;
- (2) activities that involve momentary or slight pain, distress, or discomfort;
- (3) activities that involve significant but unavoidable distress or discomfort; and
- (4) activities that potentially involve severe pain or the use of endangered species

- b) Review Process for Protocol Submissions: (Pain Category 1 or 2)

Protocols indicating a pain category of 1 or 2 are assigned and reviewed by two designated members of the IACUC. One of the reviewers is a veterinarian on the committee. The designated reviewers are sent an email (via the RASCAL system) which indicates that a protocol has been submitted for review and they have been designated as the reviewers. The remainder of the IACUC members receive e-mails indicating that this protocol is available for their inspection and who on the committee has been assigned the responsibility for review. All Committee members can then log on to the secure web site to review the protocol. Any IACUC member may request full IACUC review of any protocol. In the absence of a request for full IACUC review, protocol approval is issued when the designated reviewers have so noted their approval in the RASCAL system. The IACUC requires the veterinarian's approval as a condition for committee approval. Approval may be given for a maximum period of

three-years, subject to annual review as described in section 6. II. d), below.

c) Review Process for Protocol Submissions (Pain Category 3 or 4)

Protocols indicating a pain category of 3 or 4 are distributed for a full review to all IACUC members via the RASCAL system. The members receive e-mails indicating that full Committee review is required for a proposal to receive approval. All Committee members then log on to the secure web site to review the protocol. Full reviews are held at a convened meeting where a quorum of members is present. The IACUC requires the veterinarian's approval as a condition for committee approval. Approval may be given for a maximum period of three-years, subject to annual review as described in section 6. II. d), below..

d) Review Process for On-going Activities (Years 2 and 3)

Protocols being reviewed in years 2 and 3 of an on-going activity are distributed via the RASCAL system to a veterinarian who is a member of the Committee for review and approval, if appropriate. All remaining members of the IACUC Committee are e-mailed via the RASCAL system that a protocol has been submitted for an on-going activity and can then log on to the secure web site to review the protocol. Any IACUC member may request full IACUC review of any protocol. In the absence of such a request, protocol approval is issued upon approval by the veterinarian-reviewer.

- III) Protocols are distributed with the proviso that no member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g. is personally involved in the project). However, this individual may provide information requested by the IACUC. A Committee member who has a conflicting interest may not contribute to the constitution of a quorum.
- IV) Notice of approval, disapproval, or required modifications will be forwarded to the designated individual in the Office of Projects and Grants. If a response by the principal investigator is required in order for a decision to be made, the administrative individual will so request and follow up on its receipt in accordance with the IACUC timetable. This individual will notify the principal investigators, the IACUC, and the proposed funding agency of the IACUC decision to approve or withhold approval of the animal protocol. If the IACUC decides to withhold approval of a protocol, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

- V) The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of a protocol or vote with the IACUC.
- VI) Protocols will be re-reviewed when it is determined that substantive changes have been made, such as:
 - a. the use of substantially greater or fewer animals
 - b. a change in species
 - c. a change of type of procedure (i.e., from those involving little or no pain, distress or discomfort to one involving some greater degree of pain, distress or discomfort)

- 7. Review and approve, require modifications to (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities, as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in an ongoing research project are:

The procedures set forth in Item 6, above apply.

- 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 modifications required to secure IACUC approval, as set forth in the PHS Policy in section IV.C.4. The IACUC procedures to notify investigators and the institution of its decision regarding protocol review are as follows:

Principal Investigators with protocols which are approved by the IACUC committee are notified via e-mail (utilizing the RASCAL system) and hard copy of their approval. Both the e-mail and letter state the protocol's approval date, its number and the period for which the approval is valid.

Principal Investigators whose protocols have not been approved by the Committee are notified via e-mail. The e-mail states that the Committee has not approved their protocol. The Principal Investigator is made aware of what additional information is required to receive committee approval.

Copies of the IACUC correspondence letters are maintained by the institution.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C.1-4. at least once every three years. The IACUC procedures for continuing review are:

Notification of receipt of a protocol eligible for continuing review is sent to all IACUC members. Any IACUC member may request full IACUC review of any proposal. If full review is not requested, the protocol is sent to a member of IACUC who is a veterinarian for review and approval as detailed in 6 above. Notice of approval, disapproval, or required modifications will be forwarded to the designated individual in the Office of Projects and Grants. If a response by the principal investigator is required in order for a IACUC decision to be made, the administrative individual will so request and follow up on its receipt in accordance with the IACUC timetable. This individual will notify the principal investigators, the IACUC, and the proposed funding agency of the IACUC decision to approve or withhold approval of the animal protocol. If the IACUC decides to withhold approval of a protocol, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

10. Be authorized to suspend an activity involving animals, as set forth in the PHS Policy in section IV.C. 6. The IACUC procedures for suspending an ongoing activity are:

The IACUC is authorized to suspend an activity by the following procedures:

- a. When the IACUC learns of the possibility that an activity previously approved is not being conducted in accordance with the applicable provisions of the Animal Welfare Act, the Guide, this Assurance or IV.C.1.a-g of the PHS Policy, it will immediately 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 IACUC, to which the principal investigator and any other parties who may be responsible are 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 a majority vote of the quorum present.
- b. Notification of any suspension is sent to the principal investigator and any other party the IACUC has determined is responsible, with copies to the Provost of Columbia University and the Executive Director, Office of Projects and Grants.. The Provost of Columbia University, in

consultation with the director of the ICM, the chair of the IACUC and the Executive Director, Office of Projects and Grants, shall review the reasons for suspension, take appropriate corrective action, and report that action to OLAW.

- E. The individuals authorized by this institution to verify IACUC approval of those sections of applications and proposals related to the care and use of animals are the senior staff members of the Office of Projects and Contracts and the IACUC Administrator.
- F. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is as follows:

Health Care Program

The University is committed to the humane care and use of laboratory animals as defined by The Public Health Service's Policy for the Humane Care and Use of Laboratory Animals. The University is also committed to maintaining the health of its workers and staff involved in the care and use of experimental animals.

On Columbia's Morningside campus (and Barnard College) there are animal care facilities in which faculty and staff work with small animals (rodents, birds, amphibians) in experiments. These individuals are carrying on work in the departments of Psychology and Biology at Barnard and Columbia. They, typically, spend 25% or less of their time working in animal research.

To assess and maintain the health of individuals working with animals on the Morningside campus and Barnard College, the University Health Service will offer the following program to all individuals concerned.

- I. Health Assessment through self-administered history, and a physical examination, if indicated.
 - A. The history questionnaire will be distributed to and collected from all employees working with animals.

Special emphasis has been placed on:

- general health
- prior occupational exposure to animals
- history of allergies
- adequate immunizations (e.g., tetanus at 10 year intervals or as needed based upon exposure risk)
- history of trauma or injuries

- tuberculin testing annually with nonhuman primate contact
 - B. A Health Service nurse practitioner or physician will perform a physical examination as indicated on those individuals whose questionnaire responses suggest an animal related problem or general health concern.
- II. The Health Service will maintain records on all employees involved in work, which requires the use of laboratory animals.
- For any minor problem of injury or illness in which laboratory animals or equipment may play a part, individuals should report to the Health Service for examination and treatment.
- For severe injury and illness that may require immediate specialized or intensive care, individuals should seek care at the nearest hospital emergency room (St. Lukes Roosevelt being the closest such facility). Following this, individuals should report the nature of the injury or illness to Columbia University Health and Related Services.
- After being seen at the Health Service, such individuals will not return to work until cleared by the Health Service to do so. An employee incident involving laboratory animals or equipment used with animals will result in a report being placed in that individual's Health Service record and a copy being sent to the appropriate supervisor.
- III. Employees involved with handling experimental animals will receive regular follow-up at the Health Service. Each year within one month of their anniversary date they will be asked to complete an interval history form and to submit this to the Health Service for review. Significant responses indicating possible problems with regard to experimental animals will result in an examination at the Health Service, and follow-up as indicated.
- IV. The University's Health and Safety Office will provide health education to all present and future employees working with animals. This will acquaint all such employees with the hazards of their work, and will stress prevention and laboratory safety.
- V. The University's Health and Safety Office will monitor conditions in the laboratories involved with animals, and will respond to any specific problems or concerns regarding the use

and maintenance of laboratory animals with respect to occupational hazards.

- G. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed therein, and the average daily inventory, by species, of animals in each facility is appended as Attachment No 4.
- H. The training or instruction available to scientists, animal technicians and other personnel involved in animal care, treatment, or use is:

The Institute of Comparative Medicine offers biweekly lectures and wet labs to all personnel listed on animal protocols. These sessions are for faculty, staff and students located at the Health Sciences Campus, Morningside Campus and Barnard College. The lecture covers regulatory issues, review of IACUC responsibilities, institutional responsibilities of faculty and others who use animals on campus, alternatives, bio methodology, techniques and policies for sterile surgery, anesthesia, analgesia and euthanasia; institutional policies for purchasing of animals; and the names of key resource faculty and staff within the Institute of Comparative Medicine. Wet labs are required for all individuals identified by the IACUC as lacking or possessing minimal experience with the species of animal to be used in the animal protocol. It is available to others who wish to reinforce their skill level. The wet labs are instructed by experienced and AALAS certified veterinary technicians who provide hands-on training in proper animal handling and restraint, methods for blood collection and drug administration, anesthesia and euthanasia.

The course stresses the necessity of minimizing the number of animals used in valid research and of minimizing animal distress. Investigators are told to ask themselves questions like: is it truly necessary to use animals to test this scientific hypothesis and is the knowledge gained worth the cost? They are also asked to consider if the number of animals utilized is the minimum needed to obtain meaningful results. Emphasis is placed on using the most appropriate species and designing experiments to avoid, as much as possible, any discomfort or pain to the animals. Investigators involved with animals are trained to have this awareness in all stages of animal research: conceptualization, planning, conduct, and evaluation.

In addition to this formal session, investigators are informally trained and instructed in the proper methods of reducing distress and discomfort, minimization of animal numbers, and the use of the appropriate species each time they have a protocol reviewed by the IACUC. The protocol review is an interactive process. Investigators who submit protocols which appropriately address these issues receive protocol approval; those whose protocols are deficient do not receive approval. However, they do receive feedback on how

to modify their protocol (and hence the way they look at the problem) to meet acceptable guidelines. This process is, by its nature, educational.

IV. Institutional Status

As specified in the PHS Policy at IV.A.2 as Category 2, all of this institution's program and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be re-evaluated by the IACUC at least once every six months, in accord with IV.B.1. and 2. of the PHS Policy, and reports prepared in accord with IV.B.3. of the PHS Policy. All IACUC semiannual reports will contain a description of the nature and extent of the institution's adherence to the Guide. Any departures from the Guide will be identified specifically and reasons for such departures 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. Semi-annual reports of the IACUC evaluation will be submitted to the Provost of Columbia University. Semi-annual reports of IACUC evaluations will be maintained by this institution and made available to OLAW upon request. The most recent semiannual report to the IACUC is attached (Attachment No. 5).

V. Record-keeping Requirements

- A. The institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto as approved by 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 given or withheld.
 4. Records of semi-annual IACUC reports, recommendations (including minority views) as forwarded to the Provost of Columbia University.
 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 three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OPRR or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

A. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:

1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance or any changes in IACUC membership. If there are no changes to report, this institution will submit a letter to OLAW stating that there are no changes.
2. Notification of the dates that the IACUC has conducted its semi-annual evaluation of the institution's program and facilities (including satellite facilities) and submitted the evaluation to the Provost of Columbia University.

B. The IACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing non-compliance 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.2 and VI.B, above, shall include any minority views filed by members of the IACUC.

VIII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official:

Name: Jonathan R. Cole, Ph.D.
Title: Provost
Address: 205 Low Memorial Library
Columbia University
116th Street and Broadway
New York, NY 10027
Phone: (212) 854-2403

Signature: _____
Date: _____

B. PHS Approving Official:

Name: _____
Address: Office of Laboratory Animal Welfare
Division of Assurances
National Institutes of Health
RKL1, Suite 1050-MS7982
6570 Rockledge Drive
Bethesda, MD 20892-7982

Signature: _____
Date: _____

C. Effective date of Assurance: _____

D. Expiration date of Assurance: _____