**ICAHN SCHOOL OF MEDICINE at MOUNT SINAI**
**One Gustave L. Levy Place**
**New York, NY 10029-6574**

# ASSURANCE OF COMPLIANCE WITH PUBLIC HEALTH SERVICE POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

The Icahn School of Medicine at Mount Sinai, hereinafter referred to as Institution, hereby gives 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. The Institutional Official (IO) is Eric Nestler, M.D., Ph.D., Nash Family Professor of Neuroscience, Director, The Friedman Brain Institute, Dean for Academic and Scientific Affairs Icahn School of Medicine at Mount Sinai.

## I. APPLICABILITY

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, DHHS, and/or NSF (if applicable). This Assurance covers only those facilities and components listed below.

This Institution includes the following branches and major components: Mount Sinai Medical Center, Mount Sinai Beth Israel, Mount Sinai Brooklyn, Mount Sinai Queens, Mount Sinai West, Mount Sinai St. Luke's, New York Eye and Ear Infirmary of Mount Sinai, Mount Sinai Doctors Faculty Practice, Urgent Care, and the Icahn School of Medicine at Mount Sinai.

## 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 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)*.

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

## 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 illustrated in two diagrams (Appendix I). Dr. Jonathan Cohen, the Attending Veterinarian with program authority and Director of the Center for Comparative Medicine and Surgery (CCMS), reports operationally to Dr. Eric Nestler, the IO. This provides open and direct lines of communication with the IO. Dr. Cohen meets with the IO quarterly to discuss issues related to the animal care and use program. Dr. Cohen reports fiscally to the (b) (6) (b) (6) Dr. Cohen is also a member of the Dean's Leadership Council. Drs. Cohen and Martinelli (IACUC Chair) are also members of the Dean's Research Focus group. These groups meet monthly with senior leadership to discuss the directions of the medical school. Through these interactions the Attending Veterinarian and the IACUC Chair have ample opportunity to address issues affecting the animal care and use program.

**B.** The qualifications, authority and percent of time contributed by the veterinarian(s) who will participate in the program are:

1. Jonathan A. Cohen, DVM, MS, DACLAM, full-time, Attending Veterinarian and Director, Center for Comparative Medicine and Surgery (CCMS); (Tuskegee University School of Veterinary Medicine, Class '2007), 100 percent effort.

(b) (6)

Dr. Cohen holds a DVM degree from the Tuskegee Institute, School of Veterinary Medicine, Tuskegee Alabama (2007). Dr. Cohen is a Diplomat of the American College of Laboratory Animal Medicine since 2011, and has worked with laboratory animals since 2000. His responsibilities include oversight of the Institutional program of Veterinary Care, guidance on enforcement of the *Guide* and Institutional policies, observations and assessments of animal health and welfare, administration of and advice on medical treatments. (b) (6)

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**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 membership meets the compositional requirements set forth in the PHS Policy at PHS: IVA.3.b. The Dean of Basic Sciences and the Graduate School of Biomedical Sciences of the Icahn School of Medicine at Mount Sinai, as the delegated Institutional Official (IO), appoints members of the IACUC. The list of names, degrees, position titles, specialties and Institutional affiliations of the Chairperson and of members of the IACUC is attached (Appendix II). "Other Key Contacts" table is attached (Appendix III).

**D.** The IACUC will:

**1.** Review at least once every six months the Institutional program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program evaluations will consist of the evaluation of: i) IACUC membership and function; ii) IACUC records and reporting requirements; iii) veterinary supervision and veterinary medical care; iv) personnel qualification and training; v) occupational health and training of personnel working with animals. The review will be conducted at a convened IACUC meeting and the detailed evaluation of each area of the programs will be based on the OLAW checklist "Semiannual Program and Facility Review Checklist".

**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. Teams of at least two voting IACUC members accompanied by one of the Veterinarians and by facility supervisors will conduct semiannual facility inspections. All IACUC members will have the opportunity to participate in the inspections. Inspections will follow the OLAW "Semiannual Facility Inspection Checklist, Animal Housing & Support Area" and will include particulars such as the physical plant of the facility (e.g., floors, walls, HVAC, lighting, drainage, etc.), temperature and humidity conditions, general sanitation, cage changing and sanitation, waste and carcass disposal, pest control, environmental enrichment, food storage, feeding schedules. During the visit, animals will also be inspected and the Veterinarian and facility supervisors will be queried about animal health, veterinary care, emergency procedures, and personnel training. Deficiencies will be recorded and classified as minor or significant, the latter representing a potential threat to animal health or safety. In addition, a reasonable time frame will be established in written communications for the correction of significant deficiencies.

Teams of IACUC members accompanied by a Veterinarian will inspect research laboratories where procedures on live animals are conducted. During such inspections, investigators and their staff will be interviewed and informed about deficiencies and will receive recommendation

about corrections and improvements. Deficiencies will be recorded and investigators will be notified in writing with a request to respond with plans for corrective actions. The IACUC and the Compliance Officer will conduct re-inspection of laboratories for compliance with the recommendations. The IACUC will also use these inspections as opportunities for continuing education of investigators and their staff about various aspects of animal care and use including federal, state and Institutional policies, methods and procedures used in animal experimentation, anesthesia, analgesia, permissible methods of euthanasia, and issue related to occupational health and safety. The IACUC Inspectors also distribute useful informational literature.

**3.** Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3 and submit the reports to the IO. At the completion of the semiannual program, and facility review, the IACUC will submit to the IO a written report describing the results of the review of the animal care and use program. The report will address in particular: i) program deficiencies (classified as significant or minor), and plans and schedules for corrections of the deficiencies; ii) deficiencies in animal facilities (classified as significant or minor) and plans and schedules for corrections; iii) any minority view regarding the report; iv) any departure from PHS policies and the *Guide* approved by the IACUC with an explanation of the reason for the departure. The report to the IO will be approved and signed by a majority of IACUC members.

**4.** Review concerns regarding the care and use of animals at the Institution. Any individual may confidentially report any concerns regarding the use of animals at the Institution to the IO, the IACUC Chair, the Director of CCMS, the Dean of the Medical School or the Compliance Office of the Mount Sinai Medical Center. A 24-hour Hotline for *Anonymous Reporting* has been established through the Institutional Compliance Office. The Hotline telephone number is prominently posted at the entrance to all animal facilities. The Hotline operators follow a specific protocol for reporting complaints. As required by the AWA, any reporting person will be protected from all forms of reprisal, harassment or discrimination by maintaining full confidentiality or anonymity. All concerns and allegations of non-compliance will be reported to the IACUC. When deemed appropriate, an IACUC subcommittee appointed by the Chair will conduct an investigation of an incident or allegation of non-compliance. The investigation will be carried out according to specific guidelines outlined in an IACUC policy developed in collaboration with the Institution's Legal Department. The final subcommittee report will be reviewed by the IACUC at a convened meeting and then communicated in writing to the IO. The IACUC report will contain recommendation to the IO for actions that may include sanctions against individual(s) responsible for non-compliance as well as plans for corrective measures. The IACUC will notify promptly OLAW of an impending inquiry. At the conclusion of the process, the IO will provide OLAW with a final report describing the findings of the investigation and of the resolution of non-compliance issues.

**5.** Make written recommendations to the IO regarding any aspect of the Institution's animal program, facilities, or personnel training. Recommendation concerning program changes or animal facilities will generally be contained in the semiannual reports to the IO. At other times, the IACUC will provide written recommendations directly to the IO.

**6.** The outcomes of Full Committee review are, approve, require modifications, or disapproval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. Full committee review will occur during a convened meeting of the IACUC meeting and with a formal vote.

Reviews will be conducted as follows:

All vertebrate animal research protocols will be reviewed in the same manner irrespective of the source of funding, or the species involved in the study. Principal Investigators (PIs) will be required to submit to the IACUC, an on-line application via an online portal called IDEATE, describing the proposed research activities involving vertebrate animals. The IDEATE system is paperless, and receipt, processing, and review of an application are all done entirely online. The application forms are logic-driven and easy to use. The system also records in a database in real time all actions by applicants, by the IACUC office, and by reviewers. A list of weekly applications will be distributed to all IACUC members via email. All members have full access to the IDEATE database, and any committee member may request the full committee review of any protocol. Any unusual concern raised by a member of the Committee will be brought to the attention of the full Committee. Committee members have 10 business days to request a Full Committee Review (FCR) after receipt of the protocol list.

Submitted applications will be screened by the IACUC office for completeness (administrative review only) and then reviewed by designated members or by the full Committee at a convened meeting (FCR). One (or more) IACUC member selected by the Chairperson will conduct designated member reviews (DMR). Designated reviewers will be qualified to conduct the review and shall have the authority to approve, require modification in (to secure approval), or request a full committee review. If a protocol is assigned to more than one reviewer, the reviewers will be unanimous in their final decision, and will be aware of and agree to all the modifications requested by other reviewers. This is facilitated by the IDEATE portal which allows designated reviewers to view each other's comments. Any DMR that is not unanimous will be referred to FCR.

As per current IACUC policy, protocols involving USDA covered species, as well as protocols requiring major survival surgeries (in any species) or involving potential pain or distress to animals or use of hazardous materials will undergo full committee review. IACUC meetings will be conducted only when a quorum of members is in attendance. At such meetings, approval will require a majority vote of the quorum present; when raised, a minority opinion report will be recorded in the minutes. Should conflict of interest arise, members would abstain from the proceedings. Additional reviews by the Institutional Biosafety and Radiation Safety officers, the Institutional Biosafety Committee (IBC), and the Occupational Health physician will be required when hazardous procedures are proposed in a study, such as the use of infectious agents, radionuclides, recombinant DNA, or hazardous chemicals. If substantive modifications are required after FCR, the committee may vote to return the amended protocol to FCR; for less significant changes the quorum of members present may vote unanimously to use DMR procedure. In the latter case, *all* members of the committee would have agreed in advance in writing that the quorum of members present may decide by unanimous vote to use DMR after FCR.

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 as set forth in the PHS policy IV.C. PIs will be required to submit a protocol amendment to the IACUC describing any proposed changes in an ongoing animal protocol. This process is coordinated by the

IDEATE system, which offers an online amendment form associated with the original protocol. This facilitates both the filing and the review of the amendment. Significant changes in an ongoing research projects will include but are not be limited to, i) changes in personnel responsible for carrying out animal procedures, ii) changes in the approved species of animal, iii) any procedural changes that may produce an increase in the levels of pain and/or distress in the animal, iv) addition of surgical procedures, v) use of hazardous materials. Amended proposals will be reviewed according to the criteria described above in section III.D.6.

**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 as set forth in the PHS Policy IV.C.4. PIs will be notified in writing of the committee decisions regarding approval, withholding of approval or request for modification of a protocol. When approval is withheld, the PI will be notified in writing and will be given the opportunity to respond in writing or in person during a convened meeting of the Full Committee. Once a review decision is rendered and recorded in IDEATE, the system will issue automatic e-mail notices to PIs. If modifications are requested, the IDEATE system will release to the PI an editable copy of the application. Approval will be granted if, after review of the revised application, all requested modifications have been entered in the application. A formal letter of approval will be signed by the IACUC Chair and forwarded to the Investigators. Copies of approval letters will also be provided to the Institutional Grants and Contracts Office and to the Finance Department for notification to funding agencies.

**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 at least every 3 years in accordance with the PHS Policy at IV.C. 1-4. Protocol approval will be granted for a period of three years. At the expiration of the approval period, the project will be subjected to a complete *de novo* review as specified in section III.D.6. Triennial renewals for protocols involving USDA covered species will be reviewed by FCR; after FCR, DMR may be used as described in section III.D.6.

During the three-year approval period, irrespective the species involved, oversight of all protocols will be maintained by requiring PIs to submit an annual Progress Report containing the following information: i) a summary of the studies conducted during the previous year, ii) a summary of aims for the upcoming year, iii) a justification for animal numbers, iv) a description of any changes in protocol methodologies and in personnel vi) information regarding adverse events. PIs reporting significant deviations from the originally approved protocol (e.g. greater than 10% increase in animal numbers, adding invasive procedures, additional species), or unexpected adverse events will be required to amend the protocol.

Annual progress reports for non-USDA covered species will be generally reviewed by DMR. Annual Progress Reports of protocols involving USDA-covered species will be reviewed at a convened FCR meeting; after FCR of the Progress report, DMR may be used as described in section III.D.6.

A second method for continuing review will be based on a Post-Approval Monitoring (PAM) program. In general, all animals are routinely inspected daily by CCMS husbandry staff for evidence of illness or injury. Sick animals are reported to Veterinary Medicine technicians and, in turn, to the

Veterinarians. In addition to this routine monitoring, a more intensive observation program will be applied to animals used in protocols that may entail a high risk for morbidity, severe debilitation or mortality of experimental subjects. These protocols, identified by the IACUC during the initial review process, will be placed on a special PAM list. The PAM program has two components:

(1) Vivarium monitoring: Animals used in such studies will be subjected to more intensive inspection and monitoring by CCMS husbandry, Veterinary technicians and Veterinarians. Health reports will be generated monthly and any concerns of animal wellbeing presented to the IACUC by the Veterinarians at convened meetings for review, discussion and decision by the IACUC to require modifications of the protocol. In addition to such flagged protocols, any protocols yielding a large amount of sick reports by CCMS staff will be reported to the IACUC for inclusion in the more intensive monitoring program. Protocols will only be removed from the PAM list after reporting back to the IACUC and securing approval from the committee.

(2) Laboratory monitoring: Un-announced laboratory visits as designated by the IACUC for protocols of concern, as above, will be conducted by the (b) (6)

(b) (6)

**10.** Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. Reports or complaints to the IACUC regarding any animal activity, non-compliance with the AWA, the *Guide* or PHS policy will be promptly investigated. The Chairperson will conduct a preliminary assessment of the allegation. When warranted, an IACUC subcommittee (composed of one veterinarian and one or more committee members) will be established to conduct further investigation. The subcommittee will then report its findings at a convened meeting of the full committee. The IACUC may suspend an activity after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. In such case, the IACUC will report in writing the suspension to the IO of the Mount Sinai School of Medicine, Dr. Eric Nestler. The IO in consultation with the IACUC shall review the reasons for the suspension, take appropriate corrective action, and will promptly provide OLAW with a report on the suspension, a description of the circumstances leading to such action, and the Institutional plan for corrective action.

## E. Occupational Health and Safety program (OHSP)

### 1) Offices responsible for the OHSP.

The OHSP the Icahn School of Medicine at Mount Sinai is under the purview of the Employee Health Services (EHS), the Environmental Health and Safety Office (EHSO), the Radiation Safety Office (RSO) and the IACUC. (b) (6)

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(b) (6) The EHS staff also has Nurse Practitioners and Nurses on staff. The EHSO and RSO have directors and staffers. The Institutional Biosafety Officer, who is also is trained in chemical safety and hygiene, liaises with EHS, the Institutional Infection Control,. The EHS Deputy Medical Director, the Biosafety and Radiation Safety Officers, as

voting members of the IACUC, review protocols and advise the committee on issues related to their specialties.

**2) Program objectives.**

The objectives of the program are to:

i. Assess the if the individual is able to perform essential functions of the job,
ii. Provide a safe and healthy environment for employees and assist them in the maintenance or improvement of their health,
iii. Protect employees from risks associated with contagious diseases, and hazards at the workplace, along with other occupational hazards such as exposure to animals and laboratory environments.
iv. Establish a record of the individual's medical status.
v. Protect animals from risk associated with exposures related to employees.
vi. Comply with all applicable federal, state and local regulations.

**3) Program for Risk assessment and hazard identification.**

**i)** A risk assessment and hazard identification process is embedded in the online IACUC protocols forms. A specially designed *Biosafety Risk Assessment* form is embedded within the main IACUC application form and is required for all protocol submissions. PIs must list and describe in this document all chemical, physical and biological agents used in the protocol, the quantities used and the potential hazards associated with the agent(s).

**ii)** The Radiation and Biological Safety Officers (both are members of the IACUC) review the information and report to the IACUC during the process of protocol review. The Biological Safety Officer also determines if protocols employing biological agents (e.g., infectious agents and recombinant DNA) require clearance by the Institutional Biosafety Committee. The establishment of a risk-specific Standard Operating Procedure (SOP) (with the guidance of safety officers) is required for the use of all materials and substances that may be present a risk to the health of employees. IACUC and institutional policies also requires that such SOPs include descriptions of personal hygiene practices, personal protective equipment (PPE), and proper handling and disposal of the hazardous material not in the laboratory as well as at the site of administration of such materials to animals.

**iii)** Notification of potential risks associated with hazardous materials used in animals is also provided to supervisors of the animal facilities in order to ensure that proper measures (e.g., training, isolation, posting of biohazard risks, PPE) are taken to protect husbandry and animal care providers.

**iv)** The EHS Deputy Medical Director (who is a member of the IACUC) makes recommendations concerning medical clearance of individuals working or potentially exposed to certain hazardous agents (e.g. vaccinia). These recommendations apply to Investigators, their staffs and animal caregivers and husbandry personnel. In such cases, the individual would receive a confidential risk evaluation, information and counseling about the potential health consequences based on exposure to the agents and personalized recommendations on precautions, prophylaxis, vaccines and other recommendations as deemed necessary based on the research protocol. . The institutional Environmental Health & Safety (EH&S) maintains a website, Portal for Education and the Advancement of Knowledge (PEAK), where investigators and their staff may find training modules and best safety practices regarding the use of chemical, biological and radiological hazards.

v) In addition to reviewing IACUC forms for risks assessment, data regarding potential hazards to individual employees are also collected, analyzed (and acted upon if necessary) via an institution-wide program that requires employees to file a yearly health questionnaire. Details about these questionnaires and this program are provided in section 4.

**4) Personnel monitoring program.**

All new employees must have a completed initial health assessment questionnaire prior to the initiation of their employment. Employee Health Service is responsible for following the employee's institutional health compliance through the electronic medical record (EMR). Subsequently, if the personnel is potentially exposed to laboratory animals or laboratory hazards is required to submit a yearly, confidential, HIPAA-compliant annual Occupational Health and Safety Questionnaire. The latter is an online document, which has two main sections: the first is designed to elicit information about the working environment (e.g., animal contact, potential exposure to hazardous materials, etc); the second is a confidential health questionnaire. The Biosafety Officer is responsible for reviewing the first section of the document and conducting a risk assessment. Medical personnel of the Employee Health Service are responsible for reviewing the confidential health questionnaire. The medical information provided includes issues related to zoonoses, allergy, bites, pregnancy status, other potential exposures and risk associated with working with the hazardous agents etc).

**5) Personnel enrollment**

Two general categories of employees must file the questionnaire: i) the first one includes all investigators and laboratory workers *directly* involved in animal research, such as Principal Investigators (PI), co-investigators, post-doctoral fellows, students, laboratory technicians, and all employees of the animal facilities; ii) the second category encompasses non-laboratory personnel that may be exposed to animals or laboratory hazards while performing their duties (Building Services, Security personnel, Engineers etc). Personnel are enrolled in the program via an on-line system based on the Medical Center employee database of a central Institutional repository (named "Sinai Central)". Specialized software enables the system to send automatic yearly e-mail notifications of the pending questionnaires to all listed employees involved in animal related research. In addition, the system will keep sending email reminders until individual employees submit the required questionnaire through the system. Lastly the software allows the Biosafety Officer and medical personnel of the Employees Health Service to generate anonymous reports and statistics (e.g. on bite incidents, scratches, injuries) from data provided in the questionnaire.

Based on the review of the questionnaires, when warranted, the EHS will take necessary appropriate measure to protect the health of individual employees (e.g., medical recommendations for pregnant personnel and those planning to become pregnant, advice to persons decreased immune-systems, prophylactic vaccinations, referral to physicians, recommendations for the modified duty or restrictions at the workplace etc). The Biosafety Officer will also take steps to ensure that personnel are appropriately trained and protected from hazards. These measures would include one- on-one training, visit to the laboratory, contacting supervisors and requiring additional SOPs etc.

The Training and Compliance Coordinator also provides mandatory training for all new animal users. An integral part of the training is a lecture on Occupational health, allergies and zoonoses.

In addition to the above measures, Institutional policy requires Principal Investigators and supervisors to advise their staff about hazards regarding all aspects of safety and health. PI and Supervisors are also responsible for informing individual staffers regarding precautions to take in the event of a pregnancy, illness or if the individual is immunocompromised or referring them to the EHS. Both EHS medical personnel and the Biosafety Officer are also available for confidential consultation to the employees and for counseling on a case-by-case basis.

**5) Special monitoring program for non–human primate users.**

A, separate Occupational Health Program has been developed for animal husbandry staff and investigators working with non-human primates to comply with NIH state and local regulations and requirements. The program is under the purview of the EHS, providing TB testing and follows up. Tetanus vaccination (or booster), measles, mumps and rubella (MMR) as per institutional requirements; Hepatitis B vaccinations are also strongly encouraged for all animal users.

The Veterinary staff of the Vivarium provides specialized one-on-one training to Investigators and their staff. A special training lecture and yearly refreshers concerning zoonotic risks, Herpes B and appropriate responses to exposure to primate bodily fluids or bites/scratches are mandatory for all primate users and their staff. Written instructions on how to deal with these incidents and bite kits are also available in all primate rooms. The expiration dates of the antiseptics and bandages contained in the kits are inspected semiannually.

The Deputy Director of EHS participate in a periodic educational sessions/lectures on health issues related to animal exposures and for non-human primates (NHP). Immediately after application of first aid, injured personnel are instructed to proceed to Employee Health during normal business hours to be triaged and treated as appropriate. After hours or in case of acute or life threatening injury the injured personnel should go directly to the Emergency Department. The Emergency Department follows specific Institutional policies, procedures and reporting requirements on subsequent treatments.

**6) Additional special procedures for emergencies.**

Emergencies such as those due to animal bites/scratches by rodents and species other than primates are referred to Employee Health Service during normal business hours where they are triaged and treated as appropriate. After hours or in case of acute or life threatening injury the injured personnel should go directly to the Emergency Department. Institutional policies require the Principal investigators and supervisors to notify the Biosafety Officer and Human Resources.

In the case of injuries related to human blood or bodily fluid exposure due to needles, sharps, splashes or other injury, the employee must notify the Needle-stick program manager at the EHS and follow the instructions provided Subsequent follow-up in the EHS during routine business hours and Emergency Department following after hours as outlined in Needle stick/BBFE injury protocol and procedure. The Needle stick program manager notifies the Biosafety Officer, Infection Prevention (IP) and Environmental Health and Safety at the Institution about the incident

**7) Health care services**

i) Pre-placement Health Evaluation

This evaluation includes a pre-placement health assessment questionnaire and an examination to determine if the new hire can perform the essential functions of the job with or without accommodation.

ii) Pre-placement testing and Immunization

All CCMS employees are screened for immunity to Measles, Mumps, Rubella, Varicella, Tetanus, Pertussis. If the employee is found to be non-immune to one of these infectious agents they will be offered the appropriate vaccination. It is a condition of employment at the Mount Sinai Health System to have immunity to these infectious agents. If the employee would be working with human blood or blood products, they would also be screened for immunity to Hepatitis B. If they lack immunity to Hepatitis B, they will be offered the vaccine. If they choose not to be vaccinated for Hepatitis B they must sign a declination. Also at the time of the pre-placement exam they will be screened for tuberculosis either by PPD, QFT. In cases of having a documented history of prophylactic treatment, symptom based screening and a Chest x-ray may be required to rule out active tuberculosis.

iii) Annual Examination and Health Screening

A Health Assessment Questionnaire is required for all employees annually. In addition, a history is taken of interim vaccinations for CCMS employees. Persons identified as having medical problems, are referred to their health care provider.

iv) Annual Tests

**Tuberculosis screening tests such as PPD/QFT** is used for of animal care staff and investigators working with non-human primates and other tests if indicated.

**8) Other aspects of the Occupational Health and Safety Program**

i) Working with the Infectious Prevention team.

EHS provides a Fitness of Duty Examination and, if needed, referral to appropriate medical consultants.

ii) Environmental Surveillance.

Members of the Environmental Health and Safety Office of the Mount Sinai Medical Center perform routine inspection for physical, chemical and biological hazards in the workplace.

**F.** 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 of animals, by species in each facility is provided in an attached table (Appendix IV).

**G.** As part of the program for animal care and use, this Institution will provide the following training or instruction to scientists, animal technicians and other personnel involved in animal care, treatment and use:

1."Orientation to the Care and Use of Animals in Research", is the title of the orientation program for all animal users and scientists. The initial component of the orientation has an on-line segment (AALAS Learning Library modules) and a didactic classroom segment, both of which are

mandatory for all new personnel. The IACUC may also require other employees to attend when deemed necessary.

1) **The on-line portion** focuses on (i) federal statutes and regulations (AWA, AWAR), and PHS policies on animal research; species specific husbandry and veterinary topics (ii) Institutional research policies; ethics and methodology of animal research, including sources for information on alternatives to animal use; (iii) anesthesia of laboratory animals; methods to reduce pain and distress; (iv) analgesia and post-operative care of laboratory animals; (v) methods to minimize the number of animals needed in a study; vi) the Three R principle (vii) zoonoses and occupational health and safety; (viii) disease / distress recognition. Each of the required modules has an examination, which personnel must complete. The Training and Compliance Coordinator and the IACUC Associate Director have access to these records, and the Training Coordinator maintains records of such training.

2) **The classroom portion** focuses on institutional policies and procedures: (i) ethics and methodology of animal research; (ii) humane vs. experimental endpoints; (iii); husbandry practices ; (v) occupational health and safety, vi) update on changes in regulation vii) question/answer session. Following the on-line and classroom sessions, anyone with fewer than six months experience with the species they would be working with, are required to participate in a hands-on wet lab, where basic handling, restraint and injection techniques are reviewed. Optional refresher hands-on sessions are made available for experienced technicians and scientists, who wish to brush up on their techniques and/or learn a new one.

3) The final step in the orientation program is a **walk-through** of the Vivaria where animals will be housed. All animal users that will work in the Vivaria and seek access permission are required to attend this final orientation step given by the facility Supervisor of the area. This orientation focuses on the procedures and personnel protective equipment (PPE) specific to that facility. The veterinarians and veterinary technicians also provide special training on a case-by-case basis. Non-human primate users must wear masks, face shields, gloves, gowns, and shoe covers to enter non-human primate rooms. Ferret users must wear masks, gloves, gowns, and shoe covers to enter non-human primate rooms.

2. Veterinarians and veterinary technicians experienced in non-human primate handling provide individual training to non-human primate users. Training stresses the bio-hazards presented by non-human primates, and focuses on methods of handling, sedation and/or anesthesia for handling, the use of protective equipment (e.g., gloves, protective eyewear, masks) and garments, use of bite/splash/scratch kits (available in all areas where non-human primates are used) and procedures to follow in case of accidents (e.g., bites, scratches, exposure to bodily fluids). In addition, all non-human primate users are required to attend (at least every other year or more frequently if necessary) a formal lecture given periodically by one of the veterinarians or the Occupational Health physician on non-human primates and the particular dangers presented by non-human primate zoonoses, (i.e., Macacine HerpesVirus (monkey B virus, endoparasities, bacteria, etc).

**3**. Monthly meetings are utilized as continuing education sessions for animal husbandry personnel. Representatives from various vendors as well as Institutional professionals are recruited to conduct informative instructions and/or discussion. AALAS classes are held weekly for all animal husbandry technicians in preparation for AALAS certification. Staff members are encouraged to

seek certification through re-classification by salary incentives. All new husbandry staff is also required to complete the Orientation to the Care and Use of Animals in Research lecture and online materials, as well as species-specific and general husbandry sections of the Purina Animal Health Course.

**4.** IACUC members training.

The Chair and the IACUC Administrator provide training to newly appointed IACUC members.

A. Orientation

During the orientation session the IACUC administrator provides an overview of:

i) The role of the IO
ii) Rules on the composition of the IACUC
iii) Role of the non-affiliated member
iv) Role of the attending Veterinarian
v) Functions and mandates of the of the IACUC
vi) IACUC institutional policies
vii) IACUC review process
viii) The administrative process of the IACUC office

New members also receive copies of and are encouraged to become familiar with the following documents.

i) The *AWA* and *PHS Policies*
ii) The *Guide*
iii) The OLAW *Institutional Animal Care and Use Committee Guidebook*
iv) The AVMA *Guidelines on Euthanasia*
v) IACUC policies

The new IACUC member is also informed about a number of reference books, publications (e.g. Lab Animal, Ilar Journal) and manuals available in the IACUC Office and In the CCMS Library.
After the orientation session, the new member meets with IACUC Chair for a review of the duties and responsibilities of an IACUC member, and a review of the role of the IACUC in the oversight of the Institutional animal care and use program.

B. Training

The IACUC administrator gives a presentation of the on:

i) The review process as required by federal regulations (designated versus full committee review). In this context, the new member is provided with a copy of the article: Wolff. A. *Correct Conduct of Full Committee and Designated Member protocol Review*, Lab Animal, 2002, 31(No. 9).
ii) Guidelines on the review process (minimization of pain and distress, veterinary care, AVMA guidelines on euthanasia, search for alternatives, the three *R* concept, humane endpoints, justification of animal numbers etc).
iii) Types of review decisions
iv) Semiannual review of the program for animal care and use.
v) Semiannual inspections of animal facilities and research laboratories.
vi) Reporting of concerns
vii) Structure and significance of individual sections if the on line IACUC forms.
viii) Structure and significance of the *Biosafety Risk Assessment* forms regarding animal care and use issue as well as occupational health and safety.

ix) Internal and external Web-based resources (e.g., IACUC, and Occupational Health and Safety, OLAW, NRC, AALAS, SCAW, AAALAC).
x) IACUC policies
xi) Confidentiality of the IACUC-related business.

C) Additional training tools

The IACUC has recently acquired access to the AALAS Learning Library and will also require new members to take the online module entitled "Essentials for IACUC members". The module will also be used for refresher training of current committee members.

## IV. INSTITUTIONAL PROGRAM

As specified in the PHS Policy at IV.A.2, as category 1, all of the Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) since 1965, File number 002. After the most recent AAALAC site visit in April 3rd -5th, 2017 the Institution received Continuing Full Accreditation. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be re-evaluated by the IACUC at least every 6 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 include a description of the nature and extent of this Institution's adherence to 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 evaluations will be submitted to the IO. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

## V. RECORD KEEPING REQUIREMENTS

**A.** This Institution will maintain for at least 3 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 semiannual IACUC reports and recommendations (including minority views) as forwarded to the IO, Eric Nestler, M.D., Ph.D., Dean of Academic and Scientific Affairs, Icahn School of Medicine at Mount Sinai.
5. Records of accrediting body terminations.

**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.** At least once every 12 months (January 1st - December 31st), the IACUC through the IO will report in writing to OLAW by January 31st:

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 the Assurance, or any changes in IACUC membership. If there are no changes to report, this Institution will provide OLAW with written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted evaluations to the IO, Dr. Eric Nestler, MD, Ph.D., Nash Family Professor of Neuroscience Director, The Friedman Brain Institute Dean for Academic and Scientific Affair, Icahn School of Medicine at Mount Sinai.

**B.** The IACUC, through the IO, 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 provision of the *Guide*.
3. Any suspension of an activity by the IACUC.

**C.** Reports filed under VI.A and VI.B (above) shall include any minority views filed by members of the IACUC.

## VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

**A. Authorized Institutional Official**

**Name:** Eric J. Nestler, M.D., Ph.D.
**Title:** Nash Family Professor of Neuroscience
Director, The Friedman Brain Institute
Dean for Academic and Scientific Affairs
**Address**: Icahn School of Medicine at Mount Sinai
Box 1639, One Gustave L. Levy Place, New York, NY 10029
**Phone:** (b) (6)
**Fax:**
**e-mail:**eric.nestler@mssm.edu
**Signature:** Eric Nestler Digitally signed by Eric Nestler DN: cn=Eric Nestler, o=Icahn School of Medicine at Mount Sinai, ou, email=eric.nestler@mssm.edu, c=US Date: 2019.01.10 13:21:11 -05'00'

**Date:** 1 / 10 / 19

**B. PHS Approving Official**

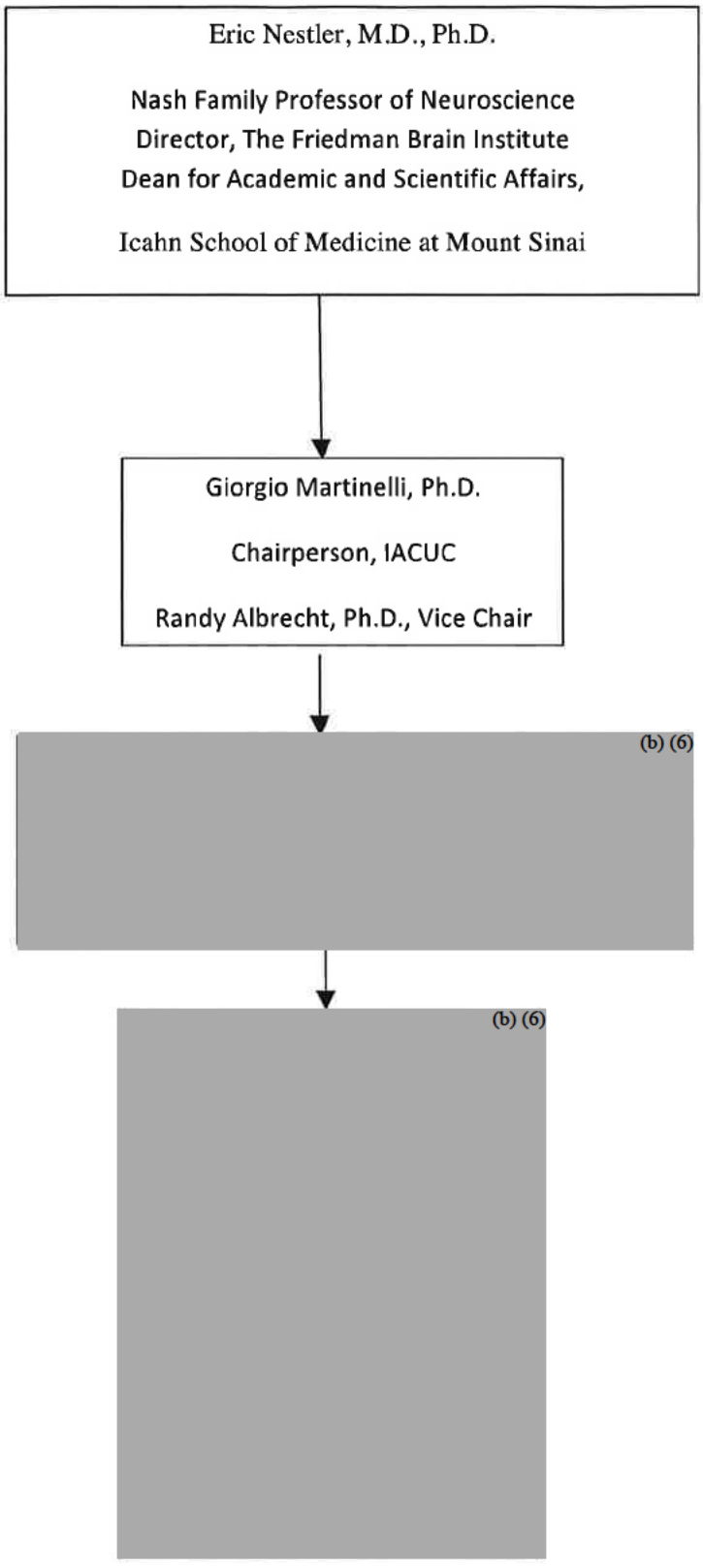
**Name:**
**Title:** **Venita B. Thornton, D.V.M., M.P.H.**
**Senior Assurance Officer, Division of Assurances**
**Office of Laboratory Animal Welfare (OLAW)**
**Address** **National Institutes of Health**
**6700B Rockledge Drive**
**Suite 2500 - MSC 6910**
**Bethesda, Maryland 20892**
**thorntov@od.nih.gov**

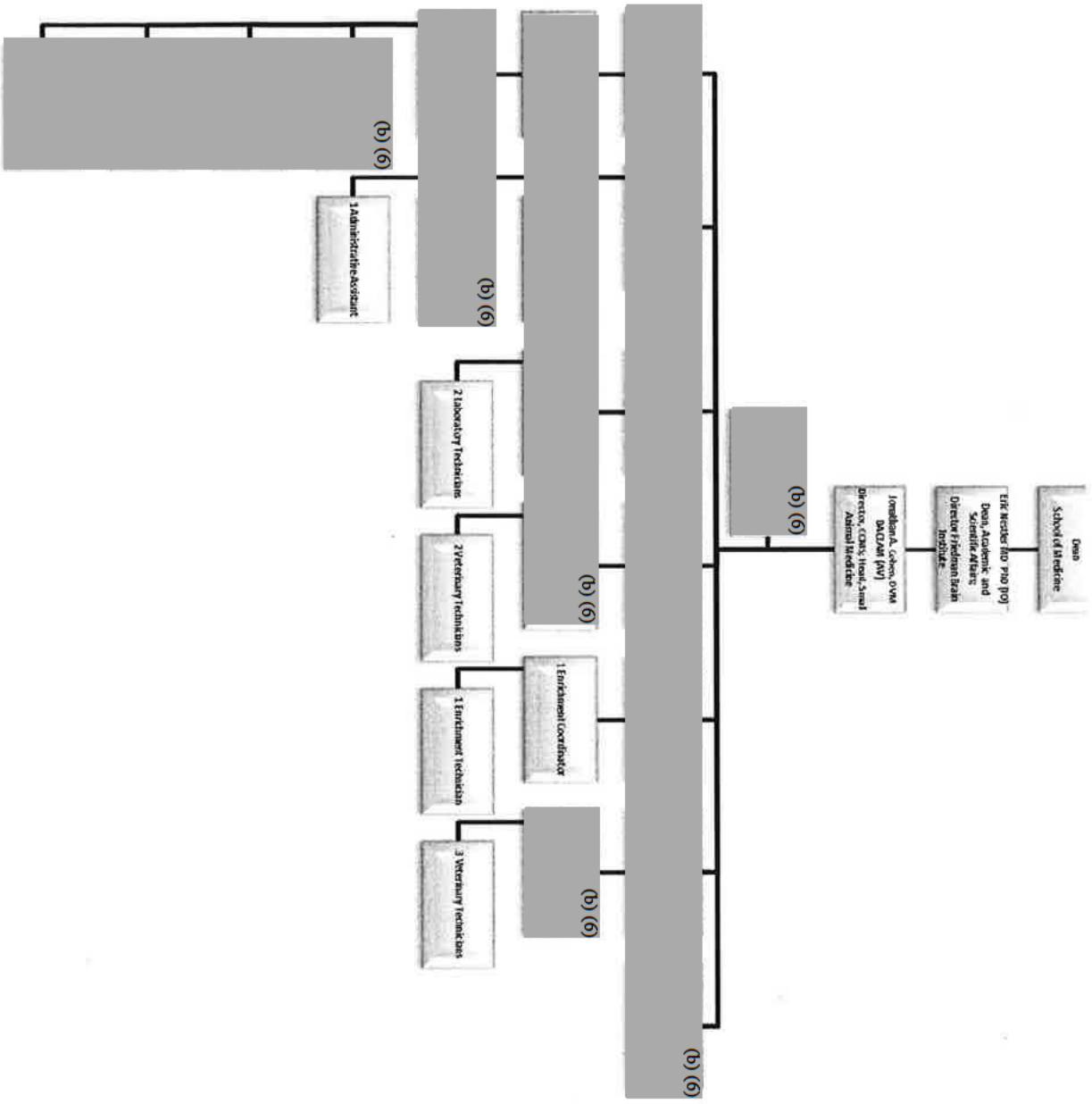
**Phone:** 301/451-4208
**Fax:** 301/402-7065
**Signature:** (b) (6)
**Date:** 01/22/2019

**C.** Effective Date of Assurance: 01/22/2019

**D.** Expiration Date of Assurance: 01/31/2023

## Appendix I






**MI**

**NAME OF INSTITUTION:** Icahn School of Medicine at Mount Sinai

**ASSURANCE NUMBER: A3111-01**

| **Chairperson Name, Title and Degree/Credentials** | **Business Address, Phone, Fax and Email of Chairperson** |
|---|---|
| Name: Giorgio Martinelli, Chairperson, IACUC | Address: Icahn School of Medicine at Mt. Sinai<br>1 Gustave L. Levy Place, Box 1155<br>New York, NY 10029 |
| Degree/Credentials:MS, D.Sc., Ph.D. | Phone: (b) (6) Fax: (b) (6)<br>e-mail: giorgio.martinelli@mssm.edu |

| **Member Name** | **Degree** | **Position Title** | **PHS Policy Membership Requirement**** |
|---|---|---|---|
| (b) (6) | | | Scientist, **Vice -Chair** |
| | | | Scientist |
| | | | Scientist |

| | | | |
|---|---|---|---|
| Jonathan Cohen | DVM, DACLAM | Director, Center for Comparative Medicine and Surgery,<br>Head, Small Medicine, Center for Comparative Medicine and Surgery,<br>Assistant Professor | Veterinarian |
| [redacted] (b) (6) | | | Veterinarian |
| | | | Scientist |
| | | | Scientist |
| | | | Scientist |
| | | | Scientist |
| | | | Scientist |

| | | | |
|---|---|---|---|
| Giorgio Martinelli | DSc., Ph.D. | Research Assoc. Professor-Neurology | **Chair,** Scientist |
| [redacted] | | | Member |
| | | | Scientist |
| | | | Scientist |
| | | | Non-Affiliated Member |
| | | | Ethicist<br>Non-Scientist |
| | | | Ethicist<br>Non-Scientist |
| | | | Scientist |

(b) (6)

| | |
|---|---|
| (b) (6) | Veterinarian |
| | Veterinarian |
| | M.D. |

## Appendix III

### Other Key Contacts

| | |
|---|---|
| **Contact #1** | |
| Name: Giorgio Martinelli, Ph.D. | |
| Title: IACUC Chairperson | |
| Phone: (b) (6) (b) (6) | e-mail: giorgio.martinelli@mssm.edu |
| Icahn School of medicine at Mount Sinai<br>One Gustave L. Levy Place, Box 1155<br>New York, NY 10029 | |
| **Contact #2** | |
| Name: Jonathan Cohen, DVM | |
| Title: Director of the Center for Comparative Medicine and Surgery | |
| Phone: (b) (6) (b) (6) | e-mail: jonathan.cohen@mssm.edu |
| Icahn School of medicine at Mount Sinai<br>One Gustave L. Levy Place, Box 1031<br>New York, NY 10029 | |

## Appendix IV

| Laboratory Unit or Building | Floor | Net Square Feet (Including service area) | Type of Facility |
|---|---|---|---|
| [redacted] | (b) (4) | 19,600 | Modified Barrier & Conv. |
| | | 1, 848 | Conventional |
| | | 20,417 | Modified Barrier |
| | | 25,000 | Modified Barrier, Conventional |

| Species Housed in Unit | Approximate Average Daily Inventory of Species |
|---|---|
| Cat | None |
| Dog | None |
| Fish | 4,000 |
| Frog | 300 |

| | |
|---|---|
| Guinea Pig | 21 |
| Hamster | 7 |
| Monkey | 64 |
| Mouse | 19,740 cages |
| Pig | 30 |
| Rabbit | 96 |
| Rat | 772 |
| Sheep | 3 |
| Chicken | None |
| Ferrets | 20 |