

Name: Animal Colony/NYS Institute for Basic Research [A168]

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Recd
Code A168

NEW YORK STATE DEPARTMENT OF HEALTH
WADSWORTH CENTER
LABORATORY ANIMAL WELFARE PROGRAM
EMPIRE STATE PLAZA, P.O. BOX 509
ALBANY, NEW YORK 12201-0509

2019 RENEWAL APPLICATION
FOR APPROVAL FOR USE OF LIVING ANIMALS

SECTION I - GENERAL LABORATORY/INSTITUTION INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
Laboratory/Institution Name: Animal Colony/NYS Institute for Basic Research	
Address 1: 1050 Forest Hill Road	
Address 2:	
City, State, Zipcode: Staten Island, NY 10314-6399	
County: Richmond	
Telephone Number: 718-494-5157	
Fax Number: 718-698-0896	
E-mail Address: richard.carp@opwdd.ny.gov	melissa.a.nashat@opwdd.ny.gov

RECEIVED
OCT 21 2018
FACILITIES MANAGEMENT
10/23/18

SECTION I - GENERAL LABORATORY/INSTITUTION INFORMATION

Ownership:

- ☐ Corporation ☒ Government ☐ Individual ☐ Not For Profit ☐ Partnership
☐ Other: _____

Facility Type:

- ☐ 2 Year College ☐ 4 Year College ☐ Clinical or Environmental Lab
☐ Hospital ☐ Medical School ☐ Product Testing Lab
☐ Public Health Lab ☒ Research & Development Lab ☐ Veterinary School
☐ Other: _____

SECTION II - PROGRAM INFORMATION

Animals (Check all that apply):

- | | | | |
|---|--------------------------------------|---|--------------------------------------|
| <input checked="" type="checkbox"/> Mice (genus mus) | <input type="checkbox"/> Hamsters | <input type="checkbox"/> Fish | <input type="checkbox"/> Sheep/Goats |
| <input type="checkbox"/> Mice (wild or other) | <input type="checkbox"/> Guinea Pigs | <input type="checkbox"/> Cats | <input type="checkbox"/> Cattle |
| <input checked="" type="checkbox"/> Rats (genus rattus) | <input type="checkbox"/> Rabbits | <input type="checkbox"/> Dogs | <input type="checkbox"/> Swine |
| <input type="checkbox"/> Rats (wild or other) | <input type="checkbox"/> Small Birds | <input type="checkbox"/> Non-Human Primates | <input type="checkbox"/> Poultry |
| <input type="checkbox"/> Other: _____ | | | |

Are you currently housing live animals at your institution? ☒ Yes ☐ No

If you are not currently housing live animals, do you anticipate having live animals in your facility during the next 12 months?* ☐ Yes ☐ No

*LAWP permits are issued to those institutions that maintain living animals for teaching and/or research and have the appropriate programs and facilities to properly and humanely care for those animals.

Does your laboratory/institution have an Animal Care Committee? ☒ Yes ☐ No
(If Yes, attach a copy of the Committee members)

Since your last application, have there been any changes in your animal care and use procedures (i.e. feeding programs, disease control, environmental management, humane care, euthanasia)? ☒ Yes ☐ No
(If Yes, please explain) (See changes attached)

Note: Any procedures that require the withholding of feed and water or exposing the animals to adverse or unusual conditions should be documented in your animal use protocols and approved by your IACUC.

Living animals are used for (Check all that apply):

- | | |
|---|---|
| <input type="checkbox"/> Diagnostic Procedures | <input type="checkbox"/> Education/Teaching Demonstrations |
| <input checked="" type="checkbox"/> Experimentation | <input type="checkbox"/> Farm Production |
| <input type="checkbox"/> Public Display | <input type="checkbox"/> Public Health/Disease Surveillance |
| <input type="checkbox"/> Other: _____ | |

Are animals used in studies with human infectious agents? ☐ Yes ☒ No
(If Yes, attach a copy of your procedures for processing medical waste generated by the animals)

Registration/Accreditation Type:

- | | | |
|--|--|--|
| <input type="checkbox"/> AAALAC Accredited | <input type="checkbox"/> USDA Registered | <input checked="" type="checkbox"/> None |
| <input type="checkbox"/> Other: _____ | | |

SECTION III - PERSONNEL INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
Laboratory/Institution Person In Charge (Name): Carp, Richard I.	Melissa A. Nashat
Title: Research Scientist	Research Scientist
Telephone Number: 718-494-5157	
Work Hours: MON: 9:00 am to 5:30 pm TUE: 9:00 am to 5:30 pm WED: 9:00 am to 5:30 pm THU: 9:00 am to 5:30 pm FRI: 9:00 am to 5:30 pm	Work Hours: Mon: 10:00 a.m. to 6:30 p.m. Tue: to Wed: 10:00 a.m. to 6:30 p.m. (alternate week) Thu: 10:00 a.m. to 6:30 p.m. Fri: to Sat: to Sun: to

CURRENT DATA	INDICATE CHANGES HERE
Veterinarian in Charge (Name): Carp, Richard I.	Melissa A. Nashat
Title:	Clinical Veterinarian
Telephone Number: 718-494-5157	
Work Name/Address (if different from laboratory/institution):	
Work Hours: MON: 9:00 am to 5:30 pm TUE: 9:00 am to 5:30 pm WED: 9:00 am to 5:30 pm THU: 9:00 am to 5:30 pm FRI: 9:00 am to 5:30 pm	Work Hours: Mon: 10:00 a.m. to 6:30 p.m. Tue: to Wed: 10:00 a.m. to 6:30 p.m. Thu: 10:00 a.m. to 6:30 p.m. Fri: to Sat: to Sun: to

SECTION III - PERSONNEL INFORMATION

CURRENT DATA	INDICATE CHANGES HERE
Contact Person (Name): Carp, Richard I.	Harry C. Meeker
Title: Research Scientist	Animal Facility Supervisor
Telephone Number: 718-494-5157	718-494-5155
	harry.meeker@apwdd.ny.gov
Work Hours: MON: 9:00 am to 5:30 pm TUE: 9:00 am to 5:30 pm WED: 9:00 am to 5:30 pm THU: 9:00 am to 5:30 pm FRI: 9:00 am to 5:30 pm	Work Hours: Mon: 9:00 a.m. to 5:30 p.m. Tue: 9:00 a.m. to 5:30 p.m. Wed: 9:00 a.m. to 5:30 p.m. Thu: 9:00 a.m. to 5:30 p.m. Fri: 9:00 a.m. to 5:30 p.m. Sat: to Sun: to

- ☒ Attach a list of all full-time and part-time animal care staff which includes the following information:
Name, Full-Time or Part-Time, Title and Education Level (Highest).
- ☐ No additional staff.

SECTION IV - ATTESTATION

I have read the Administrative Rules and Regulations concerning the use of living animals and understand that I am fully responsible for all work involving the use of living animals. I understand that the Certificate of Approval is not transferable and the New York State Department of Health (the Department) shall be advised promptly if the individual, in whose name approval has been granted, ceases to be in charge. The facility(ies) will be operated according to all applicable laws, rules and regulations.

I understand that by signing this application form I agree to cooperate with any investigations conducted by the Department to verify or confirm information given or any other investigation conducted in connection with animal welfare in any facility identified in this application. If additional information is requested, I will provide it.

In signing this application, I hereby certify that the information I have given the Department as a basis for obtaining or retaining a certificate of approval is true and correct. As information changes, I will promptly notify the Department. Further, I understand that filing a false instrument constitutes a crime under the Penal Law of the State of New York.

Melissa M. Asht Clinical Veterinarian
 Signature, Laboratory/Institutional Officer

Title

10/18/18
 Date

SECTION V - ADDITIONAL SITES WHERE LIVING ANIMALS ARE LOCATED

CURRENT DATA	INDICATE CHANGES HERE
Site [003] Name: Animal Colony/Institute for Basic Research	
Address 1: 1050 Forest Hill Rd.	
Address 2:	
City, State, Zipcode: Staten Island, NY 10314-6399	
Site Telephone Number: 718-494-5157	
Site Fax Number:	
Site E-mail Address:	melissa.a.nashat@opwdd.ny.gov
Contact Person (Name): Carp, Richard I.	Melissa A. Nashat

ATTACHMENT 2
October 2018

SECTION III - Animal Care Staff

NAME	FULL/PART TIME	TITLE	EDUCATION (Highest)
Feng Lu	Full	Animal Caretaker	High School
Hui Fen Li	75%	Animal Caretaker	High School
Lee Hendricks	Full	Animal Caretaker	High School
Daniel Boyd	Full	Animal Caretaker	High School

SECTION II - Institutional Animal Care & Use Committee Members

Name	Degree/ Credentials	Position Title	PHS Policy Membership Requirements
David Bolton	Ph.D.	Chairman	Scientist
Maureen McCole	College	Administrative Assistant	Non-Scientist
Fred J.Kieras	Ph.D.	Research Scientist III	Scientist
Jeffrey H. Goodman	Ph.D.	Research Scientist IV	Scientist
Kathryn Chadman	Ph.D.	Research Scientist III	Scientist
Adam Golabek	Ph.D.	Research Scientist IV	Scientist
Carl Dobkin	Ph.D.	Research Scientist V	Scientist
Fumio Someki	Ph.D.	Assistant Professor in Educational Studies	Non-Scientist, Community Member
Harry Meeker	M.S.	Research Scientist II	Scientist, Animal Colony Supervisor
Wen Hu	M.D., Ph.D.	Research Scientist III	Practicing Scientist, experienced in research involving animals.
Cheng-Xin Gong	M.D.	Research Scientist VI	Practicing Scientist experienced in research involving animals.
Melissa Nashat	D/M, Ph.D., Daclam	Research Scientist IV	Clinical Veterinarian

Section II Program Information: Changes to IBR IACUC Policy

In response to the violation from NYS DOH received on June 25, described as "Pharmaceutical grade anesthetics are required for survival surgery. Please discontinue the use of tribromoethanol [Avertin] for survival surgery unless there is specific scientific justification for its use."

The IBR IACUC has enacted the following plan.

1. The veterinarian has prepared non-pharmaceutical grade substance guidelines.
2. The guidelines were approved by the IACUC on August 23, 2018.
3. Any use of Avertin for non-survival acute procedures or for procedures approved with scientific justification on Animal Study Protocols will continue to be approved by the IACUC in accordance with proper Avertin reconstitution, storage, and administration practices.
4. The IACUC has notified investigators of the change in IBR policy (IACUC) on August 28 via email. A discussion with information regarding alternative anesthetic options was held on September 10.
5. The IACUC will facilitate the process of Animal Study Protocol modifications that will be required to amend for use of alternatives in anesthesia.
6. The veterinarian will prepare training guidelines for changes in inhalant anesthetic use and will train staff converting from Avertin to inhalant anesthesia.



*IBR IACUC Guidelines for the use of non-pharmaceutical grade
substances in laboratory animals*

Purpose

These guidelines describe IBR's expectations for the use of non-pharmaceutical grade substances in vertebrate animals. These guidelines serve to compel investigators to be compliant with federal and state regulations. Policy #3 of the USDA Animal Care Resource Guide states, "Pharmaceutical grade compounds are to be used whenever available. Non-pharmaceutical-grade substances should only be used in regulated animals after specific review and approval by the IACUC. The IACUC should develop a consistent evaluation process which includes but is not limited to the scientific justification and the availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone is not sufficient justification for using a non-pharmaceutical-grade substance." OLAW agrees with the USDA's position and recognizes that "it is frequently necessary to use non-pharmaceutical-grade substances such as investigational substances, veterinarian- or pharmacy-compounded substances, and/or Schedule I controlled substances to meet scientific and research goals." New York State Department of Health enforces the USDA and OLAW positions on non-pharmaceutical grade substances for laboratory animals used within New York State.

Applicability

These guidelines apply to all animal-based research that fall under the IBR IACUC's jurisdiction. The document applies to all personnel who administer substances to animals in the context of research. Personnel should be appropriately qualified and trained to perform animal research and administer substances. All research on animals should be done in accordance with an IACUC-approved animal study protocol (ASP).

Definitions

Pharmaceutical grade substance (PGS) or compound: a drug, biologic, or reagent (including test articles, fluid therapy, medications, vehicles, and diluents) which is approved by the Food and Drug Administration (FDA) for use in a specific species at a specific dose for a specific purpose. PGS must meet chemical purity standards that have been established by a recognized pharmacopeia, such as the United States Pharmacopeia/National Formulary or the British Pharmacopeia. If all components of a mixture are pharmaceutical grade, then the entire substance is considered a PGS. If a substance is sterile, it should be indicated.

of prepared compounds is required. Compounds placed in multi-use vials should be labeled with the identity of the substance, concentration or activity, the date of preparation, the expiration date, and the initials of the individual who prepared the substance. Reconstituted compounds should be discarded before degradation occurs. If expiration dates of multiple components are known, then the expiration date for the reconstituted substance is the earliest expiration date of any ingredient. If stability is unknown, the compound should be prepared fresh prior to each use. Manufacturer recommendations for preparation and storage should be considered. Inspection of NPGS on IACUC-approved ASPs may be done on semi-annual IACUC visits.

Example scientific justifications

- PGS is not available from a veterinary or medical supplier in any form.
- PGS is not available from a veterinary or medical supplier in the necessary concentration for appropriate scientific investigation.
- Available PGS is not appropriate for the specified route of administration (for example, the pH of the prepared substance is irritating upon injection).
- PGS contains unwanted fillers/diluents/vehicles/preservatives that may inhibit research or may impact research outcomes.
- PGS compounds have been demonstrated to have known unwanted effects on measured outcomes substantiated by data or published reports.
- In some cases, NPGS such as anesthetics including Avertin, can be used in terminal procedures when scientifically justified and if it is in an IACUC-approved ASP. In this case, the NPGS must be prepared and stored properly, must be administered in a sterile manner, and must be within its expiration date.
- Demonstration that an NPGS has improved ramifications for animal welfare, such as reduced mortality of an anesthetic, can be obtained by performing a validation pilot study. A validation pilot study must compare an NPGS to a PGS to demonstrate that the NPGS is safe, with reduced adverse effects, and produces improved scientific results over the PGS. A validation pilot study must be approved by the IACUC, and in most cases would be performed at the PI's expense. A pilot study may include investigation of different dosages or routes, different animal strains, gross pathologic assessment, histologic assessment, clinical pathologic assessment, comparisons of morbidity and mortality and/or documentation of any adverse effects. The veterinarian should be consulted regarding preparation and execution of a pilot study.

Resources

A list of PGS and biologics is available from the FDA database:

<https://www.fda.gov/Drugs/InformationOnDrugs/default.htm>

The Orange Book is the reference for FDA-approved human drugs.

<https://www.accessdata.fda.gov/scripts/cder/ob/>

The Green Book is the reference for FDA-approved veterinary drugs.

<https://www.fda.gov/animalveterinary/products/approvedanimaldrugproducts/default.htm>

References



Institute for Basic Research in Developmental Disabilities (IBR)

ANDREW M. CUOMO
Governor

KERRY A. DELANEY
Acting Commissioner

JOSEPH J. MATURI
Acting Director

September 27, 2018

Mr. Bruce Patrick

Dear Mr. Patrick:

I want to personally thank you for having served on the Institutional Animal Care and Use Committee (IACUC).

Your many years of service are greatly appreciated.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Joseph J. Maturi".

Joseph J. Maturi
Acting Director

cc: Dr. David Bolton

The research division of the Office for People With Developmental Disabilities (OPWDD)

NYS Institute for Basic Research in Developmental Disabilities

1050 Forest Hill Road, Staten Island, NY 10314 | Tel: 718-494-0600 | Fax: 718-494-0833 | www.opwdd.ny.gov/institute-for-research

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 06/29/2021



Institute for Basic Research in Developmental Disabilities (IBR)

ANDREW M. CUOMO
Governor

KERRY A. DELANEY
Acting Commissioner

JOSEPH J. MATURI
Acting Director

September 27, 2018

Dr. Cheng-Xin Gong
Research Scientist 6
Institute for Basic Research
1050 Forest Hill Road
Staten Island, NY 10314

Dear Dr. Gong,

I am delighted to appoint you to serve on the Institutional Animal Care and Use Committee (IACUC) of the Institute for Basic Research for a term effective immediately. I know the Committee will benefit from your participation.

Dr. David Bolton continues to serve as the Chair of the IACUC and Ms. Maureen McCole continues to serve as the Administrative Assistant to the Committee. Dr. Bolton or Ms. McCole will contact you regarding upcoming meetings and provide you with additional information regarding the Committee.

I genuinely appreciate your service to the Institute.

Sincerely yours,

Joseph J. Maturi
Acting Director

cc: Dr. David Bolton

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NEW YORK
STATE OF
OPPORTUNITY.

Institute for Basic Research in Developmental Disabilities (IBR)

ANDREW M. CUOMO
Governor

KERRY A. DELANEY
Acting Commissioner

JOSEPH J. MATURI
Acting Director

September 27, 2018

Dr. Wen Hu
Research Scientist 3
Institute for Basic Research
1050 Forest Hill Road
Staten Island, NY 10314

Dear Dr. Hu,

I am delighted to appoint you to serve on the Institutional Animal Care and Use Committee (IACUC) of the Institute for Basic Research for a term effective immediately. I know the Committee will benefit from your participation.

Dr. David Bolton continues to serve as the Chair of the IACUC and Ms. Maureen McCole continues to serve as the Administrative Assistant to the Committee. Dr. Bolton or Ms. McCole will contact you regarding upcoming meetings and provide you with additional information regarding the Committee.

I genuinely appreciate your service to the Institute.

Sincerely yours,

Joseph J. Maturi
Acting Director

cc: Dr. David Bolton

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