NYU Grossman School of Medicine
An administrative unit of New York University (NYUGSoM)
D16-00274 (A3435-01)

Animal Welfare Assurance for Domestic Institutions

I, Jeremy I. Paul, PhD, Assistant Dean, Basic Science Research Operations, as named Institutional Official for animal care and use at New York University Grossman School of Medicine, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, and/or the National Science Foundation (NSF). This Assurance, which is available to IACUC members upon request, covers only those facilities and components listed below.

The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

A. Animal facilities on the NYU Langone Health and NYU Winthrop Hospital (NYUW) campuses managed by the Division of Comparative Medicine (DCM). The Attending Veterinarian, Jennifer K. Pullium, M.V.B. is the Senior Director of DCM. The program includes five animal facilities located on the NYUGSoM main campus in Manhattan. The animal facilities on the NYU Winthrop campus are managed by the Comparative Medicine Division (CMD). The [redacted] (b) (6)

The NYUGSoM facilities are:
1. Skirball Central Animal Facility (SCAF)
2. Science Building Animal Facility (SBCAF & SBAF)
3. Alexandria Center for Life Sciences West Tower (AWCAF)
4. Kriser Dental School Central Animal Facility (DCAF)

B. The animal care and use program at NYU Winthrop is a covered component. The NYUW facilities are:

1. Research Building
2. 259 First Street

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II. Institutional Commitment

A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.

B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.

D. This Institution has established and will maintain a program for activities involving animals according to the 8th edition of *The Guide for the Care and Use of Laboratory Animals* (*Guide*).

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

III. Institutional Program for Animal Care and Use

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

1. The Institutional Official authorized to sign this Assurance is the Assistant Dean, Basic Science Research Operations. As the Institutional Official, I am the individual ultimately responsible for administering the animal care and use program at NYUGSoM and NYUW and for ensuring compliance with the PHS Policy. I report to the Vice Dean for Science and Chief Scientific Officer who reports to the Dean of the NYUGSoM. A chart describing the lines of responsibility for the Animal Care and Use Program is in Section XI on page 33.

2. The Senior Director of DCM is responsible for management of the veterinary and all Administrative aspects for laboratory animal resources at this institution. The DCM Senior Director is the Attending Veterinarian who reports directly to the Institutional Official. The organizational chart for DCM is in section XII on page 34.

3. The IACUC oversees and evaluates the institution's animal care and use program, procedures and facilities through review of proposed uses of animals in research, testing and education; inspection of facilities and animal activity areas; submission of reports to the Institutional Official; assurance of the appropriate training of personnel using or caring for animals and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at this institution. Members of the IACUC are appointed by the Institutional Official. The Chair of the IACUC is appointed by the Institutional Official and reports on IACUC matters directly to the Institutional Official.

4. The administrative staff of the IACUC is headed by a Director, who reports directly to the Institutional Official. The organizational chart for the administrative office supporting the IACUC is in Section XIII on page 35.

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

1) **Name:** Jennifer K. Pullium, DCM Senior Director, Attending Veterinarian
Degrees: MVB, University College Dublin, 1996; Diplomate American College of Laboratory Animal Medicine (ACLAM), certified 2002; Post-doctoral Fellow at Emory School of Medicine, 2000; Georgia Veterinary Medical License (1998-present); New York State Veterinary Medical License (2008-present)
Training and/or experience in laboratory animal medicine: Associate Professor, Department of Pathology, NYU Grossman School of Medicine since 2009; Associate Professor, Center for Comparative Medicine and Surgery, Mount Sinai School of Medicine 2006; Associate Professor, Department of Genetics and Genomic Sciences, Mount Sinai School of Medicine 2007; Associate Professor, Department of Pathology and Laboratory Medicine and Director of Animal Health and Rodent Quarantine Programs, Emory University School of Medicine. Other professional appointments include American College of Laboratory Animal Medicine Foundation Scientific Director since 2015 and ad hoc grant review member since 2003, Institutional Animal Care and Use Committee Vice Chair, Emory University, 2005, Ad hoc member, Scientific and Technical Review Board (STRB) on Biomedical and Behavioral Research Facilities, Research Infrastructure Division, National Center for Research Resources, NIH since 2005; Over 15 years of primary clinical medicine oversight covering rodents, rabbits, and nonhuman primates.
Authority: Dr. Pullium has direct program authority and responsibility for the Institution's animal care and use program and has access to all animals within the program.
Time Contributed to Program: Dr. Pullium is a full time employee of NYU Grossman School of Medicine contributing 100 percent of her time to the animal care and use program.

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C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached in Section VIII on page 25, is a list of the chairperson and members of the IACUC and names of the Chair and veterinarians, degrees, profession, titles or specialties, and institutional affiliations.

D. The IACUC will:

1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the 8th edition of *the Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

a. Every six months, the IACUC Director, Assistant Director and IACUC Project Coordinator complete a draft version of the semiannual evaluation in a Report to the Institutional Official (RtoIO) based on the OLAW sample semiannual report. This report includes:

- any significant changes that may have occurred in the animal care and use program during the semiannual period;
- a description of the nature and extent of the institution's adherence to PHS Policy, *the Guide* and the AWA. (The report includes any departures from PHS Policy, the *Guide* or the AWA approved by the IACUC, along with the reason for the departure.)
- any deficiencies identified in the animal care and use program
- any deficiencies identified during the semiannual inspection of animal facilities, satellites and animal study areas;
- any minority views, or a statement that there are no minority views to report during the specific semiannual period;
- AAALAC accreditation status; and
- The IACUC roster, with the signatures of a majority of the IACUC members.

b. The draft report is distributed to IACUC members for their review at least one week prior to the Semiannual Program Review IACUC meeting, and is discussed at a convened meeting of a quorum of the members.

c. The NIH Semiannual Program Review and Facility Inspection Checklist is used as a guide during the meeting to discuss the draft report and the entire animal care and use program.

d. The report is approved at the meeting unless there are member concerns that cannot be satisfactorily addressed during the meeting. If there are concerns, the report is not approved until a subsequent meeting after those concerns have been addressed.

e. Approval of this report, including any minority opinions, is made part of the IACUC meeting minutes.

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

a. Every six months, IACUC Specialists schedule multiple subcommittees, each with at least two members of the IACUC, to inspect all animal housing facilities and animal

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study locations. All IACUC members, including non-affiliated community members, are invited and encouraged to participate in inspections.

b. Based on the findings of the inspection teams, the IACUC Specialists prepare draft inspection reports for each location. The reports are distributed to IACUC members for their review at least one week prior to an IACUC meeting. The draft is discussed at the next convened IACUC meeting.

c. Deficiencies cited on the draft IACUC inspection reports are initially classified as either minor or significant. Correction dates are assigned by the IACUC and communicated to responsible individuals. For all deficiencies, the IACUC works with the responsible individual to devise a plan for correction no later than the correction dates assigned by the IACUC. Such plans are communicated to the Institutional Official via the IACUC Semiannual RtoIO, or by other means if more immediate communication is required.

d. The IACUC is informed of progress made in correcting deficiencies at subsequent meetings.

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

As soon as practical after IACUC approval of the Semiannual RtoIO, the final signed report is sent to the Institutional Official. The report is prepared as described in Section 1 and 2 above.

4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

a. Animal welfare concerns or allegations of noncompliance can be reported to any IACUC member, DCM/CMD staff, the AV or IACUC staff member. Individuals wishing to express a concern anonymously can do so by calling the NYU Langone Health 24-hour Compliance Helpline number (1-866-NYU-1212) for reporting concerns about any compliance or ethical issues. Anonymous concerns may also be reported online via the NYU Langone Health Compliance Helpline website.

b. Reporting animal welfare concerns is covered in the institution's orientation for new employees as well as the IACUC orientation session, required for all new staff who will be working with animals. At the same time, employees are informed of the institutional policy against retaliation including discrimination against the concerned reporting party and their protection from reprisals. Information on procedures to report animal welfare concerns are also posted in all animal housing locations and distributed on business cards during orientation and inspections.

c. All reported animal welfare concerns are investigated as soon as possible by the IACUC Chair together with the IACUC Director, Assistant Director and any IACUC member or members that the IACUC Chair may choose.

d. At the discretion of the person leading the initial investigation, the allegation is reviewed by the IACUC either at a specially convened emergency meeting of a subcommittee of the IACUC or at the next scheduled IACUC meeting.

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e. After reviewing the facts of the case and, if necessary, further investigation, the IACUC makes a determination as to how the case should be resolved.

f. As soon as the allegation appears to have some credibility, the Institutional Official is informed and is kept informed of progress as the investigation and deliberations proceed. If warranted, the Institutional Official may assist the IACUC investigation by calling a special meeting of representatives from the Office of Legal Counsel and/or the Office of Internal Audit, Compliance & Enterprise Risk Management as well as the IACUC Chair, Director and Attending Veterinarian to discuss the concern.

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

a. Reporting the committees' recommendations either in the "Semiannual Report to the Institutional Official";
b. In a special IACUC report when deemed necessary or
c. In person when the Institutional Official is in attendance at an IACUC meeting. The proceedings are included in the meeting minutes.

The Institutional Official meets with the IACUC Chair when necessary. The IACUC Director and Attending Veterinarian accompanied by the NYUW Institutional Veterinarian have separate regularly scheduled bi-weekly meetings with the Institutional Official as well as a joint quarterly meeting where the animal care and use program is discussed, including any items of concern.

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

Within the boundary of this Assurance and the PHS Policy, the Chair will make the final determination regarding DMR vs FCR with preference given to more scrutiny in cases where the determination is not clear:

The NYUGSoM IACUC uses three types of review procedures, **Full Committee Review (FCR), Designated Member Review (DMR)** and **Administrative Review** and recognizes three types of animal study protocols:

a. **New Protocols** which may be subject to either full or designated member review;
b. **Annual Review Protocols** proposing the use of USDA-covered species or those protocols required to be reviewed annually by the funding agency automatically subject to designated member reviews;
c. **Three-year Renewal Protocols** which may be subject to either full or designated member reviews.

All protocols are submitted to the IACUC via an electronic protocol and review system. Protocols involving Category D or E procedures on USDA-covered species are pre-reviewed by a DCM veterinarian prior to submission. Upon submission of all protocols, the IACUC

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administrative staff pre-reviews the protocol to check for accuracy, omissions, whether or not all questions have been adequately answered, protocol consistency, confirmation that personnel have completed requisite training, and other non-research information required at the institutional level. Some protocols may also be assigned to EH&S or RS reviewers to be evaluated for the use of potentially hazardous biologicals, chemicals or other materials as well as viral vectors, transgenic animals, and procedures involving radiation or radioactive materials. As part of the ancillary review process, reviewers enter their comments and recommendations and requests for clarifications directly into the electronic protocol submission and review system. After the initial pre-review, comments are summarized by IACUC staff, returned to the PI and subsequent revisions are managed by IACUC staff until all reviewer comments have been addressed.

New Protocols, Annual Review Protocols and Three-Year Renewal Protocols eligible for DMR are placed into a 5 day "grace period." Notification of submissions entering grace period is sent to all members via the electronic system. During this time, no changes may be made to the submission. If no member calls for FCR of the submission, the software allows reviewers to be assigned for DMR. The protocol review proceeds with comments made by the reviewer, summarized by the IACUC office, and answered by the researcher until either approval is granted or the protocol is brought for FCR. Submissions approved via DMR automatically appear as items of notification on the next meeting's agenda. The full submitted protocol is available to all committee members through an electronic protocol submission and review system.

Review process for New Protocols and Three-year Renewal Protocols

The review process for **New Protocols** and **Three-year Renewal Protocols** is essentially identical. New protocols must be submitted on the appropriate NYUGSoM IACUC New Protocol form. Protocols that are to be conducted at other institutions are submitted on the other institution's protocol forms which are attached to the NYUGSoM protocol form and accepted for review by the NYUGSoM IACUC. These protocols must be approved by the other institution's IACUC before submission to the NYUGSoM IACUC. Approvals are valid for three years with two interim annual reviews for protocols involving USDA-covered species or those required to be reviewed annually by the funding agency. All protocols receive ongoing IACUC oversight.

Studies that are to continue beyond the three-year IACUC protocol approval period are considered the same as new protocols. It is recommended that Three-year Renewal protocols be submitted on a current NYUGSoM IACUC Three-year Renewal Protocol form at least six weeks prior to the end of the three year approved period.

New Protocols and Three-year Renewal Protocols may require a full committee review or may qualify for designated member review. Full committee review of New and Three-year protocols only applies to the use of any species owned by NYUGSoM/NYU Langone Health. The following is a description of each process.

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a. Full Committee Review

Protocols requiring Full Committee review include those that:

- Propose the use of USDA covered species in pain categories D or E;
- Involve multiple survival surgical procedures with the potential for substantial pain and/or distress in any species (typically category D);
- Are referred for full committee review by a designated reviewer or at the request of any IACUC member;
- Were initially assigned for designated member review but for which any designated reviewer did not recommend approval or modifications required to secure approval;
- Involve procedures in any species that could be classified as USDA pain category E which includes those that involve but are not exclusively limited to:

    a. Induction or phenotype of anatomic or physiological abnormalities that will result in significant pain or distress including those resulting in disabilities that significantly affect the animal's ability to eat, drink, ambulate, or make normal postural adjustments.
    b. Prolonged physical restraint for periods consistent with more than minimal pain and/or distress.
    c. Application of noxious or stressful stimuli from which escape is impossible.
    d. Procedures or phenotype that cause severe, persistent, or irreversible disruption of sensorimotor organization, e.g., paralysis.
    e. Food and/or fluid restriction intended to produce greater than 15% loss of normal body weight.
    f. Death without benefit of anesthesia including studies that designate "death as an endpoint."
    g. The administration of compounds that may be expected to result in more than minimal pain and/or distress, illness or death, even when death is not the intended endpoint.
    h. Attempts to induce psychotic-like behavior.
    i. Monoclonal antibody production using the in vivo ascites method in mice.
    j. Procedures or phenotype resulting in significant post-procedural pain that cannot be alleviated with analgesics.

Reviewer assignments are made by the Chair after being proposed by IACUC staff. Reviewers are notified of their review assignments via email through the electronic protocol submission and review system. Prior to the meeting at which protocols requiring Full Committee Review are to be discussed, protocols are reviewed by a veterinarian and one scientific committee member who is designated as the "primary reviewer." If the protocol involves hazardous agents, an EH&S representative also reviews the protocol primarily as part of the ancillary review process. If the protocol involves radioactive agents, a RS representative also reviews the protocol primarily as part of the ancillary review process. The IACUC Chair must approve exceptions.

The responsibility of the primary and veterinary reviewers is to work with the principal investigator (PI) to make modifications to the protocol, if necessary, to bring it into compliance with all federal, state and institutional requirements. In all cases, the reviewers' identity is not known to the PI.

IACUC members have access to the full protocol at least one week prior to the meeting via an electronic protocol submission and review system. Members are notified of their full review assignments via email

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and can input and view all IACUC member comments submitted through the electronic system. Members are encouraged to communicate concerns they may have to either the veterinary or primary reviewer prior to the meeting so reviewers have the opportunity to communicate with the PI and be prepared to respond to the concerns. Hard copies are provided to any member upon request.

The IACUC is scheduled to meet once every month. The IACUC Chair calls the meeting to order and confirms a quorum of the membership is present before conducting business. If a quorum cannot be obtained, the meeting will be rescheduled. The IACUC Chair follows an agenda and announces each item of business in order. Members are encouraged to notify the IACUC Project Coordinator of any potential conflicts prior to the meeting. Before discussion of the protocols, the Chair reminds the members that they must recuse themselves from the vote and discussion of any protocol that they either have a conflict with or a perceived conflict. If members need to leave the meeting for any reason, quorum is confirmed by the Chair prior to continuing the meeting. At the IACUC meeting in which the full protocol is being considered, the primary reviewer or their alternate, if applicable, presents the protocol to the committee. If neither is available, the IACUC Chair presents the protocol. Following presentation and discussion of the protocol, the primary reviewer makes a recommendation to either approve, approve pending the receipt and approval of specified protocol revisions, table further consideration of the protocol until the next meeting so that specified issues can be addressed with the PI, or to disapprove the protocol. The Chair then solicits comments from the entire committee including the veterinarian, and ensures that all opinions are heard as part of the deliberation. Once a consensus is apparent, the Chair asks for a motion. Once a motion has been made, it must be seconded by another voting member. The Chair then asks for a vote or abstention on the motion as indicated by a show of hands. For the motion to pass, a majority of the quorum (greater than 50% of voting members or their pre-appointed alternate) present must vote to agree.

Following a discussion of the recommendation, including modifications if indicated, the committee votes to either: approve the protocol as submitted; require modifications to secure approval; table the protocol until the next meeting so that specified issues can be addressed with the PI; or to disapprove the protocol. If the protocol is recommended for designated member review, the review is conducted as indicated in section III.D.6.b. and per the IACUC procedure on the Use of Designated Member Review (DMR) to Approve Protocols Subsequent to Full Committee Review (FCR) which requires a unanimous vote of the quorum of members present at the convened meeting. Any member at any time may request to see the revised protocol and/or request FCR of the protocol.

IACUC action is based on a majority vote of the quorum present. No member may participate in or be present for the IACUC review or approval of a protocol in which that member has a conflicting interest except to provide information requested by the IACUC. The IACUC staff notifies the IACUC Chair of any known conflicts associated with a protocol being reviewed.

b. Designated Member Review

Protocols that do not require full committee review according to the above criteria are automatically eligible for designated member review.

Designated member reviewer assignments are made by the IACUC Chair after being proposed by IACUC staff. At least two members of the IACUC, typically a veterinarian and a scientist, are assigned to review protocols eligible for designated member review. The members are notified of their review assignments via email through the electronic protocol submission and

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review system. No member can participate in the IACUC review of a protocol or activity in which that member has a conflicting interest except to provide information requested by the IACUC. If the protocol involves hazardous agents, an EH&S representative on the IACUC also reviews the protocol primarily as part of the ancillary review process. If the protocol involves radioactive agents, a RS representative also reviews the protocol primarily as part of the ancillary review process. The IACUC Chair must approve exceptions.

Notification of all submissions eligible for DMR review is sent to all IACUC members via the electronic system when the submission enters grace period. During this time, no changes may be made to the submission and reviewers cannot be assigned. IACUC members have access to the full submission via the electronic protocol submission and review system. After five calendar days, if no member calls for FCR of the submission, the software allows reviewers to be assigned for DMR. The review proceeds with comments made by the reviewer, summarized by the IACUC office, and answered by the researcher until either approval is granted or the protocol is brought for FCR.

Designated reviewers have the option to approve a protocol, require modifications to secure approval, or refer the protocol to the full committee for review. They cannot withhold approval of a protocol. Designated reviewers are encouraged to communicate concerns they may have to either the veterinary reviewer or the IACUC Chair.

If necessary, the designated reviewers work together with the PI to make modifications to the protocol to secure approval. All committee members have access to protocol changes and have an opportunity to request full committee review prior to approval by the designated reviewer(s).

If a protocol is assigned to more than one designated reviewer, the reviewers must be unanimous in any decision, they must review identical versions of the protocol and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications. However, a single designated member may refer a protocol to full committee review.

Once all designated reviewers approve the protocol and IACUC staff have verified that all required training has been completed, or the review by EH&S or RS has been completed, the PI is notified via email that the protocol has been approved by the IACUC. If any one of the designated reviewers requests a full committee review, the protocol is reviewed at the next convened meeting of the IACUC. Submissions approved via DMR automatically appear as items of notification on the next meeting's agenda.

In all cases, members determine whether a protocol is more beneficial than harmful by taking into consideration the pain level the animal may experience during experimental procedures and the benefit to society. PIs also are required to describe in the protocol, why the research is important and how society will benefit from the research.

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7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes (amendments) regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Amendments to protocols must be submitted to the IACUC via an electronic protocol submission and review system. Amendments may be subject to either Full, Designated Member or Administrative Review.

Major amendments requiring Full Committee review are those that have the potential to impact substantially and directly on the health and wellbeing of the experimental animal. Such changes include items identified in Section III D.6.a or the addition of or change to protocols that would have originally fit the criteria for Full Committee review as described in Section III D.6.a of this document.

Major amendments subject to Designated Member review are typically delegated to a scientist and veterinary reviewer.

These changes include but are not limited to the following:

- Addition of or changes to animal procedures anticipated to cause more than momentary pain and/or distress to a protocol currently approved with procedures that cause more than momentary pain and/or distress, typically category D;
- Any increase in the number of animals originally justified and approved;
- The addition of animal procedures anticipated to cause more than momentary pain and/or distress to a protocol without procedures that cause more than momentary pain and/or distress, typically category B or C;
- The addition of animal procedures anticipated to cause more than momentary pain and/or distress to animals in a protocol without procedures that cause more than momentary pain and/or distress, typically category B or C;
- Addition of hazardous materials.

Minor amendments subject to Designated Member review are typically delegated to at least one reviewer.

These changes include but are not limited to the following:

- Changes in antibiotics, analgesics or anesthetics;
- Changes in euthanasia method(s) to another euthanasia method approved in the 2013 AVMA Guidelines for the Euthanasia of Animals;
- Changes in animal procedures not anticipated to cause more than momentary pain and/or distress, typically category B or C;
- Changes in non-survival animal procedures anticipated to cause more than momentary pain and/or distress, typically category D;
- Changes in Principal Investigator;
- Addition of non USDA-covered species to a protocol that previously included non-USDA-covered species;

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Designated reviewers have the authority to approve an amendment as written, request modifications to secure approval, or refer the amendment to the full committee for review. They cannot withhold approval of a protocol. The processes used for full committee review and designated member review described in this section are the same as those described in section III.D.6.

Minor amendments subject to Administrative review are typically delegated to a member of the IACUC staff. These changes are limited to the following:

- Additions or deletions of personnel other than the PI;
- Additions or deletions of funding sources;
- Additions or deletions of locations approved by the IACUC.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

   Letters are generated to investigators via an electronic protocol submission and review system informing them of IACUC decisions relative to their protocols. These letters are sent electronically by the IACUC staff. Approval letters for new protocols specify approval for a period of 3 years with an annual continuation after years 1 and 2, for protocols proposing the use of USDA-covered species or those requiring annual review by the funding agency. If protocol approval is withheld, the PI will receive a letter indicating the reasons for withholding approval. The PI will then have 5 business days to respond to the letter in writing. No animal protocol may be activated in the absence of formal written approval by the IACUC. Once a protocol has been approved, the information is automatically transferred to the DCM animal facility management database. This provides proof of IACUC approval for DCM, the authorized purchasers for animals used at NYUGSoM with the exception of zebrafish and frogs. Animals cannot be purchased for protocols not approved by the IACUC.

   The meeting minutes, monthly meeting agenda and all approved protocols are available at all times to the Institutional Official via the electronic protocol submission and review system.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC. A complete review at least once every 3 years is required for all previously approved protocols according to PHS Policy IV.C.1.-5.

   The IACUC procedures for conducting continuing reviews for protocols approved for the use of USDA-covered species or those requiring annual reviews by the funding agency are as follows:

   a. A minimum of six weeks prior to the end of the first and again prior to the end of the second year of a protocol proposing the use of USDA-covered species or required by the funding agency, the PI submits an Annual Review Protocol form on which they indicate if they plan to continue the study; provide a progress report; and report any problems or adverse events that may have occurred during the past year.
   b. The designated review process is typically used for Annual Review Protocols. A minimum of one IACUC member is designated to perform the designated member review. Designated member review assignments are assigned by the IACUC Chair after being proposed by IACUC staff.

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c. From this point, the process is exactly the same as that described in section III, D., 6, b., of this Assurance document.
d. Continuing IACUC oversight for activities proposing the use of non-USDA-covered species is accomplished through post-approval monitoring activities such as laboratory inspections by IACUC Specialists in addition to IACUC semiannual inspections, protocol audits and observation of selected procedures by veterinary or IACUC scientist members.
e. The process for reviewing Three-year Renewal Protocols is identical to the process used for reviewing New Protocols as described in section III. D., 6., a., of this Assurance document with the addition that the PI submits a New Protocol/Three-year Renewal Protocol form a minimum of 6 weeks prior to the end of the three year approved period to ensure approval prior to the 3 year expiration date.

10. Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6.

The IACUC procedures for suspending an ongoing activity are as follows:

A decision to suspend a protocol must be made at a convened meeting of a quorum of the IACUC by a majority vote of the members present. If necessary, the IACUC Chair may call an emergency meeting. If a decision is made to suspend a protocol, the PI is notified in writing, the decision is selected in the electronic protocol submission and review system, which prevents any future purchases of animals for the protocol, and the appropriate authorities are notified. A separate notification is also sent in writing to the PI's designated chair. If necessary, any existing animals related to a suspended protocol are transferred to the direct control of DCM under an IACUC-approved holding protocol. Animals on the holding protocol cannot be manipulated experimentally and federal funds cannot be utilized to maintain the animals. If the IACUC suspends an activity involving animals, the Institutional Official in consultation with the IACUC shall review the reasons for suspension and take appropriate corrective action if necessary. The IO reports the suspension, in writing, with a full explanation to OLAW.

The Sponsored Program Administration (SPA) department verifies IACUC approval of those sections of applications and proposals related to the care and use of animals. As such, SPA is responsible for notifying agencies identified as funding sources for protocols suspended by the IACUC of the suspension.

11. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The institutional entities involved in the Occupational Health and Safety program are: Environmental Health and Safety (EH&S), Occupational Health Services (OHS), Radiation Safety, IACUC and DCM.

Environmental Health and Safety is committed to an enterprise-wide exemplary culture of safety. EH&S develops and manages programs that:

- Protect NYU Langone personnel in all departments and on all levels from health and safety hazards
- Ensure waste is discarded in an environmentally sound manner
- Facilitate compliance with regulatory requirements

Most of the EH&S staff have one or more advanced degrees in relevant disciplines. Some are also credentialed as Certified Industrial Hygienists (CIHs) and/or Certified Safety Professionals (CSPs).

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Occupational Health Services performs Pre-Employment Physical examinations and Annual Health Assessments on all personnel working in research and/or have significant exposure to animals. OHS also provides evaluation and treatment of all occupational injuries and exposures reported by the staff with referrals to specialists as indicated. The clinical staff in OHS are all certified Nurse Practitioners, MD's, Registered Nurses and LPN's who perform N95 fit testing.

The use of hazardous materials, including carcinogens, infectious agents, toxins, radioisotopes, and transplantable tumors must be in conformance with *the Guide* and all other applicable regulations. Hazardous agents associated with animal studies are identified in a section of the IACUC Protocol Form.

Protocols involving radioisotope hazards are assigned to the Department of Radiation Safety for review. The Department of Radiation Safety maintains a database of investigators who have been trained to work with radioisotopes and whose laboratories have received the requisite approvals. The Department of Environmental Health and Safety conducts a review, in similar fashion, for protocols involving other hazardous materials (biological or chemical). Special consideration is always given to precautions necessitated by the route of exposure to the agent and the anticipated metabolism of the agent in the experimental animal. EH&S members are voting members of the IACUC.

Research staff is informed about zoonoses and other potential hazards associated with laboratory animals through the required web-based training modules and the DCM orientation lecture. Animal facility staff are regularly informed and educated about issues related to occupational health in staff meetings and during their annual health assessments.

Each NYULH Department manager/supervisor is responsible for the safety of contractors and visitors in their area and is directed to contact EH&S for guidance as necessary.

Work related hazards are frequently discussed during IACUC inspections or when a potential hazard is noted. Potential and existing hazards are discussed and addressed at weekly Executive and Senior DCM Leadership meetings. Worksite injuries for DCM employees are documented and monitored for trends. DCM and EH&S work swiftly and diligently to identify the root causes of accidents and injuries.

The NYU Langone Health Institutional Biosafety Committee reviews work with recombinant DNA (including transgenic mouse and gene transfer registrations), select agents and toxins, oncogenic biological material, and human and other primate pathogens assigned to BSL3 or higher. Members of EH&S are voting members of the IBC. The IACUC identifies protocols that may require personnel to be provided more extensive information on zoonoses or other potential hazards. Once a protocol has been identified, more in-depth training is provided by the EH&S and/or DCM staff.

Laboratories are inspected annually to monitor compliance with chemical hygiene and disposal requirements. The results of these inspections are communicated to lab staff for correction. Research labs working at biosafety level 2 must also obtain an annual BSL2 certification. To gain BSL2 certification, the lab must be inspected by EH&S, and make any needed corrections based on the inspection. The inspection includes: evaluation of appropriate work practices and containment, signs and labeling, and documentation of Standard Operating Procedures (SOPs).

EH&S has departmental liaisons to support groups such as Facilities, Security and Environmental Services. The EH&S liaisons have an established relationship with the departmental supervisors which

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ensures that issues, including those involving animal research, are addressed promptly. Hazard communication training is completed online and in person training and consultations are provided as necessary and required.

All employees are required to report any job-related injury or illness, including a needlestick, regardless of severity. Employees are trained during orientation and required annual training that they must report an injury or illness to their supervisor. Employees are also required to document all job-related injuries and illnesses by completing an injury report (e.g. Employee Occupational Injury/Illness Report (EOIIR) or Confidential Work Related Injury Investigation Report). Injury report forms are completed when the employees are seen at OHS or at the NYU Langone Perelman Emergency Dept. Employees who receive initial care at a different location must report the injury or illness to OHS as soon as possible afterwards. Employees must also contact HR to file for a workers' compensation claim number to cover medical expenses and/or reduced earnings that may result from the on-the-job injury/illness.

Supervisors are notified of all injury reports and expected to take corrective action where appropriate and required. EH&S provides ongoing monitoring of injury/illness reports. EH&S investigates all major accidents/incidents as well as injury data trends suggesting the presence of systemic hazards. EH&S coordinates the annual posting of the OSHA required 300A form (Summary of Work Related Injuries and Illnesses) and generates an annual report, evaluating occupational injury/illness data.

Medical Evaluation and Preventive Medicine for Personnel

All persons who work with laboratory animals must have a pre-employment physical examination and annual health assessment. No one with significant animal exposure is exempted from the personal medical evaluation. Staff members and students who work with laboratory animals must comply with all NYU Langone policies including those pertaining to pre-employment physical, Annual Health Assessment, and mandatory vaccinations. Persons who work with laboratory animals are not permitted to decline or opt out of any of the aforementioned mandatory requirements with the exception that approved medical and / or religious exemptions for vaccination will be considered. Any non-mandatory vaccinations allow the employee to sign a declination. All employee medical records reside in the Epic EMR or Axion EMR systems in use at NYU Langone Health and are strictly confidential, with access granted to approved practitioners only. HIPPA regulations are followed.

All employees of NYU Langone, including staff who work with lab animals, part-time staff, interns and Non-Traditional Volunteers (NTV) must complete the pre-employment process in OHS. All bloodwork and vaccines are provided free of charge. Employees are evaluated to determine fitness for duty. Employees with conditions that may place them at risk while fulfilling their job duties will not be cleared for work. If an employee is determined to be significantly immunocompromised the OHS clinician will not clear the employee for duty and will refer the employee back to his/her treating physician for a note clearing them to work under their current job description. New employees are medically cleared for the appropriate respirator under the Respiratory Protection Policy and fit tested or PAPR trained at pre-employment and annually thereafter. At the pre-employment physical and in subsequent Annual Health Assessment (AHA) visits, all employees, including any employee who attests to being pregnant or immunocompromised are advised by an OHS clinician to report any concerns regarding health and safety at work to their manager, OHS and EH&S. All employees are advised to contact OHS with any questions or concerns regarding work restrictions and not to report to duty if they may be ill and/or contagious. Employees who may have an infectious illness of public health concern are required to be seen in OHS prior to returning to duty for medical clearance to return to work. During the pre-employment physical and in subsequent AHA visits, all employees, including any employee who attests to being pregnant or immunocompromised, are advised by an OHS clinician to follow proper

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work practice and PPE requirements to avoid exposure or work related hazards. Each Principal Investigator and supervisor is responsible for ensuring their laboratory staff/employees are appropriately trained and equipped to follow job-specific safe work practice and PPE requirements.

All employees are advised to attest on the Annual Health Assessment, that they are aware if they should have any concern regarding their work environment, safety issue, occupational exposure or work injury, they should report those concerns to their Supervisor and/or EH&S and complete an EOIIR which will be reviewed by OHS and the employee contacted by OHS clinician as outlined in the OHS policy "Occupational Injury and Illness." Animal facility staff are further advised to follow the instructions in the section of this policy labeled "Research Specific Occupational Injury/Exposures: DCM, IACUC, OSR" to report concerns regarding a potential exposure or work-related injury.

The attestation is performed by responding to the following question on the AHA form:

19. Are you aware that any concern you have regarding your work environment, a safety issue, occupational exposure, or work injury should be reported to your Supervisor and/or EH & S immediately at time of concern and an incident report (EOIIR) completed by you? YES ___ NO___

In addition, the following information is reviewed in EH&S training for animal facility staff:

- The importance of communicating questions regarding workplace hazards to the supervisor and/or EH&S
- General awareness of the potential for increased individual risk arising from reproductive or health conditions such as decreased immune competence, allergies, or certain medications
- The fact that employees may confidentially consult an OHS clinician to discuss potential risks associated with an occupational exposure and a particular health status.

Each NYU Langone Laboratory Manager/Supervisor is responsible for the safety of their contractors and visitors and expected to advise and inform visitors and other personnel with incidental animal contact of specific health risks and any required precautions. Visitor incidents are documented on Security incident reports and forwarded to Risk Management. Risk Management oversees NYU Langone's processes for investigating and reporting visitor injuries and illnesses. Training for contractors with significant exposures (i.e. contractors working on projects within the vivarium) is conducted by DCM veterinarians and staff.

Initial Health Assessment and Requirements Prior to Employment, Joining Staff or Volunteering
A health assessment is performed before hire, joining the staff, prior to a student rotation, or volunteering to screen individuals for conditions which may either pose a risk to patients or personnel, or interfere with the performance of duties. This assessment is referred to as an "initial health assessment". The policy applies to individuals who:

1. provide direct patient care
2. work in a patient care or clinical support area without direct patient care responsibilities
3. work in research or clinical laboratories
4. volunteer
5. act as a clinical observer
6. will have exposure to research animals

The purpose of the initial health assessment is to ensure employees and staff and students are able to safely perform their assigned jobs and meet requirements to maintain a safe and healthy workplace, and

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is provided without cost to the individual if performed by the Occupational Health Service. This assessment is not intended as a health maintenance physical examination. Faculty and licensed independent providers may visit their personal healthcare providers to satisfy the requirements this assessment. The policy does not cover:

- Medical students
- Construction contractors

The components of the initial health assessment vary by work responsibilities.
Individuals who work in a clinical or research laboratories:

a. Review of medical and occupational history
b. Screening for M. tuberculosis infection for personnel who work in TB labs or work with non-human primates
c. N-95 respirator medical clearance and fit test for individuals identified in the Respiratory Protection Program or personnel who work with animals and request an N-95 respirator to prevent allergy to animal allergens.
d. Review of immunizations and immunity status to ensure compliance with current NYU Langone Hospitals policy.

Annual Health Assessment
Faculty, staff, students and volunteers must complete an annual health assessment (AHA) to ensure they are free of health impairments which pose a potential risk to patients or personnel, or which may interfere with the performance of duties. Employees are required to complete an AHA as a condition of continued employment. The purpose of the AHA is to ensure these individuals are able to safely perform their assigned jobs and meet requirements to maintain a safe and healthy workplace. The AHA requirements are determined by regulatory requirements, NYU Langone policy and/or a risk assessment which includes likelihood of work related exposure or injury. The AHA is not intended as a health maintenance physical examination. Faculty and licensed independent providers may visit their personal healthcare providers to satisfy the requirements of the AHA.

1. AHA will be due yearly in the month of either the individual's initial hire date or their last re-assessment date. As of March 1, 2020, AHA policy will change and an AHA will be required in the employee's month of birth.
2. Individuals will be notified directly via email, or other means, notifying them their AHA is due.
3. Department managers or supervisors will be provided AHA compliance reports.
4. Employees will have the entire "due" month to complete their re-assessment.
5. The components of the AHA vary by work location and job type.
6. The AHA will assess for changes to the individual's health which may impact their ability to perform their job and/or be a risk to patient safety, including dependence on alcohol or drugs.
7. Documentation of health assessments will be maintained in the Occupational Health Service medical record following OSHA standards.
8. Every performance evaluation must include a review by the supervisor of the employee's compliance with this policy.
9. Employees will be given reasonable notice that their assessments are due. If compliance is not reached in thirty days, the employee may be subjected to disciplinary action up to and including termination.

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NYU Langone OHS provides medical services to all employees during regular business hours and to students for initial evaluation and treatment, with referral for further follow up care. When necessary referral to a specific specialist may be recommended. After hours, the Emergency Department is available to all employees. For incidents of occupational exposures the NYU Exposure Hotline is available where an Infectious Disease Specialist, is available to evaluate and treat the employee exposure.

Personal Hygiene

Protection against animal allergen exposure is primarily effected by optimization of engineering controls to remove allergens from workers' immediate environment and the use of a disposable gown or lab coat, gloves, face or hair covers, paper face mask, protective eye wear, and shoe covers. All animal husbandry, cage sanitation, and veterinary technicians are required to change into work uniforms provided and laundered by the institution. All staff members working with laboratory animals wear protective clothing and equipment, such as gloves and masks when handling animals. A disposable gown that is discarded after exposure must be worn when inside animal rooms. Cloth lab coats are not permitted to be worn within the animal rooms. Thorough hand washing and cleaning is necessary after any animal contact. A respirator may be recommended for those at high risk or who have exposures to infectious or toxic agents. Information is obtained from the Department of Environmental Health and Safety who must assist in the selection, fitting, and instruction in the use of a respirator. OSHA requires a medical evaluation prior to using a respirator. The respirators selected must be fit-tested for each individual by Occupational Health Services or by Department of Environmental Health and Safety. Animal care technicians, technicians working in cage wash areas, and all veterinary technicians are required to change into work uniforms (clean scrubs and facility dedicated work shoes) provided by DCM. At a minimum all DCM personnel wear nitrile gloves when handling animals. Hair bonnets, face masks, coveralls, and shoe covers are required when working in the barrier areas. Hearing protection is provided in cage wash areas and eye protection in the form of a face mask is provided in areas that require it. A respirator may be recommended for those at high risk or who have exposures to infectious or toxic agents. Information is obtained from the Department of Environmental Health and Safety who must assist in the selection, fitting, and instruction in the use of a respirator. OSHA requires a medical evaluation prior to using a respirator. The respirators selected must be fit-tested for each individual by Occupational Health Services or by Department of Environmental Health and Safety.

Facilities' Procedures and Monitoring

The DCM Operations Manager, DCM Veterinarians, the DCM Liaison and Staff Development Specialists, Director and Senior Director develop Standard Operating Procedures (SOPs) in conjunction with Environmental Health and Safety for the husbandry of animals assigned to hazardous agent protocols. The Operations Manager and the DCM Liaison and Staff Development Specialist are responsible for training husbandry and cage wash personnel to perform procedures described in the associated SOP(s), and for verifying that the SOP(s) is precisely implemented. DCM coordinates with the Department of Environmental Health and Safety and the Director of High Containment (oversees ABSL-3) to ensure that husbandry and research staff are adequately trained prior to working in ABSL-2 or ABSL-3 spaces respectively, that appropriate personal protective equipment is worn, that staff are N95 fit tested on an annual basis if working in ABSL-3, and that all biocontainment procedures are followed. ABSL-2 and ABSL-3 standard operating procedures are reviewed annually. Investigators are required to disclose any and all hazardous agents they plan to work with during their initial facility tour and prior to receiving facility access. All rodents housed in ABSL-2 and/ or ABSL-3 rooms are maintained in negatively pressurized micro-isolator cages. ABSL-2 rooms are separate rooms and are clearly marked with an appropriate hazard sign and are equipped with a Class II, Type A/B3 Biosafety Cabinet. ABSL-3 housing is an access restricted housing suite that is clearly marked with the

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appropriate hazard signs. Rodent cages within ABSL-2 and ABSL-3 housing or procedure rooms can only be opened within the protection of a Biosafety Cabinet. All such rooms are managed with ABSL standards as established by the Department of Environmental Health and Safety Office. There are no infectious biohazards above the ABSL-3 level.

E. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table in section X on page 30.

F. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

All personnel listed on an IACUC protocol, directly involved with the care and use of research animals are required to complete appropriate portions of a multifaceted training program.

The IACUC reviews the institutional training program during the semi-annual program review. Training requirements are discussed as part of each semiannual program review or sooner as needed. Training completion and personnel approval data is presented to the committee along with a summary of additions or changes made in the previous semiannual period or planned for the next. This informs the discussion of inspection findings, IACUC investigative actions and other post approval monitoring activities that also occur as part of the program review. All members are encouraged to participate in or audit training activities required of researchers. IACUC members are provided with an opportunity to review and comment on updated mandatory training modules that have recently been imported into the institution's Learning Management System (LMS) prior to their implementation. Designated IACUC members periodically attend live training workshops to evaluate their effectiveness, and suggest changes or adaptations when indicated. The credentials and experience level of all research personnel are listed on the IACUC protocol. Experience provided is detailed with respect to species. The IACUC evaluates each individual's experience level at the time of IACUC protocol review, or alternatively at the point at which a personnel amendment is submitted. Training requirements are then assigned based on an individual's previous experience, the species they will be working with, and the type of procedures detailed on the IACUC protocol.

All required online training modules contain quiz questions to help assess user competency with respect to training module content and individuals are provided with a minimum quiz score they must obtain. With respect to any required hands-on trainings, the trainer is responsible for verifying that an individual is proficient before signing them off as having completed a particular training requirement.

The IACUC utilizes the LMS to provide and/or record completion of the IACUC's regulatory training lecture and training for $C0^2$ euthanasia and survival surgery procedures (in non-regulated species.) In addition, the IACUC requires completion of regulatory, species-specific and procedure-specific modules via the CITI online training program. These completion records are associated with the individual's unique institutional identifier (or Kerberos ID) and are electronically transferred to the animal protocol software directly from the LMS and from CITI. The DCM In Vivo Research Orientation is currently a stand-alone online module. The completion records for the DCM orientation, hands-on rodent biomethodology wet-lab, and any additional training provided is maintained in a cloud (shared) spreadsheet until manually entered into the animal protocol software. The training record for an individual is visible at all times via

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the protocol software to all personnel with access to that protocol, all IACUC members and staff, and additional animal care and use personnel identified as Training Coordinators.

The DCM Liaison and Staff Development Specialist maintains records of research staff and DCM employee training on an Excel SharePoint file that can be readily accessed and reviewed by IACUC staff. The centralized SharePoint file includes records of IACUC member training.

Research Staff Training

There are four components to the training program for research staff: Orientation lecture, web-based components, a tour of the facility, and a techniques component. All research staff must complete the IACUC in-person orientation lecture, DCM online orientation, web based components and facility tour (for those requesting facility access). The techniques component is voluntary for personnel with previous experience, and limited to staff performing the animal procedures.

The IACUC orientation lecture is conducted by the IACUC Assistant Director or the IACUC Specialists (or other designated trainers) during which the following subjects are presented: humane methods of animal maintenance and experimentation; occupational health and safety; laws and regulations governing the care and use of laboratory animals; IACUC protocol review process; the importance of adhering to the approved protocol; when and why to request an amendment to an approved protocol; Russell and Burch's 3 R's including methods that minimize the number of animals required to obtain valid results; minimize distress and IACUC policies and guidelines. The DCM online orientation includes DCM policies and guidelines; procedures for animal ordering and importation; and how to request DCM services.

The web-based training currently uses courses provided by the Collaborative Institutional Training Initiative (CITI) or those in-house developed courses in the institution's LMS.

Researchers must complete the following CITI courses:
Working with the IACUC course, Reducing Pain and Distress in Laboratory Mice and Rats, and all applicable species-specific modules.

Additional CITI modules are available to be completed by all personnel on a voluntary basis.

If applicable, researchers must complete the Aseptic Technique for Survival Surgical Procedures and Rodent CO^2 euthanasia courses in the institution's LMS.

Individuals with less than one-year experience with the species and techniques assigned as listed on an IACUC protocol must complete the DCM Hands-On Mouse or Rat Bio-methodology Workshop if applicable.

After personnel are approved on a protocol, they must complete the tour of each animal facility in which they will be working. The tour includes an explanation of the gowning procedures required to enter the facility, operational issues such as where to find clean cages and bottles, and where to put soiled cages, use of the microisolation caging system and barrier technique when applicable, euthanasia of rodent species via CO^2, facility security, etc. Access is granted after successful completion of the tour.

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Librarians at NYUGSoM Ehrman Medical Library are available to provide services to research staff in conducting comprehensive literature searches on appropriate methods of animal care and use, on alternatives to the use of live animals in research and prevention of unnecessary duplication of research involving animals.

DCM/CMD Animal Technician Staff Training

In-house training courses are given by the DCM Liaison and Staff Development Specialist, DCM Operations Management staff, Animal Care Supervisors, and DCM Veterinarians or Veterinary Residents. Training courses are given during regular work schedules and include training on Standard Operating Procedures (SOPs), zoonotic diseases, blood borne pathogens, laboratory animal allergens, identifying and reporting animal health and welfare cases, biological and chemical hazard training, ergonomic training and training on the DCM Disaster Preparedness Plan. In addition, Environmental Health and Safety provides annual risk-based training targeted to all DCM staff, and the IACUC Assistant Director or IACUC Specialist provides regulatory trainings. Additional training opportunities are provided, such as seminars presented by investigators or vendors on topics that relate to research and the in vivo work environment. Study materials for AALAS Certification at the ALAT, LAT and LATG levels is provided on an as-needed basis, and all technicians are encouraged to pursue a certification path within one year of hire. New DCM animal technicians are required to attend the IACUC Orientation lecture described in the Research Staff Training section of this Assurance, and are also required to attend the Mouse Hands On Training Workshop and the Rat Hands On Training Workshop. Both workshops teach staff how to properly and safely handle mice and rats, safety considerations when working around isoflurane gas anesthesia, as well as how to humanely euthanize rodents using CO^2 and how to confirm death. Any technician working with a USDA-Covered species, such as a rabbit or pig, is provided with a separate hands-on training work shop that covers the safe handling of the respective species and reviews species-specific signs of illness, pain and/or distress.

IACUC Member Training

When first appointed, IACUC members are provided orientation by the IACUC Assistant Director and training with the IACUC Project Coordinator. The orientation by the Assistant Director includes topics discussed in the IACUC Orientation lecture described in the Research Staff training section of this Assurance document. During the orientation and training sessions, new members receive a packet containing various background materials and resources, including the Animal Welfare Act and regulations, the PHS Policy, *the Guide*, the AVMA Guidelines on Euthanasia and other materials. They also receive a copy of the latest Assurance upon request. In addition, NYUGSoM IACUC policies and procedures such as processes for protocol review and facility inspections are discussed with new members. New members also are required to complete the Essentials for IACUC Members course. All IACUC members are encouraged to attend local and national IACUC conferences. The institution provides access to appropriate resources such as online courses, webinars and periodicals and if necessary, specific training to assist IACUC members in understanding their roles and responsibilities and evaluating issues brought before the committee. Finally, IACUC members raise topics of interest for training and discussion at regularly convened meetings of the Committee.

Frequency and Documentation of Training

Research staff receive training on an as-needed basis after initial completion of the Orientation lecture, IACUC or DCM required web-based training, and tour of the applicable animal

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facilit(ics). An electronic newsletter is sent to all research staff as a means of keeping them updated on animal research issues.

Training for DCM animal care and veterinary technicians consists of an employee onboarding training program and a refresher training program. The new employee onboarding program is designed as a 3-month training program and covers a multitude of topics including lab animal allergies, zoonoses, ergonomics, handling workplace injuries, the disaster plan, rodent CO^2 euthanasia, reducing pain and distress in laboratory mice and rats, how to identify and separate overcrowded cages, and species handling skills. New employees must also attend the IACUC Orientation and must participate in a shadowing program with designated Senior Technicians.

Refresher trainings are held to ensure that employees comprehend the current procedures as written in SOPs, are aware of important policies related to animal welfare, and are working safely in the facility. Annual refresher topics include Chemical and Acid Safety Training, Rodent CO^2 Euthanasia Training, ABSL-2 Training, and an annual review of Aseptic Cage Change Technique. In addition, staff receive annual training on the Disaster Plan, and a member of Environmental Health and Safety provides an annual training on Blood Borne Pathogens.

The DCM Liaison and Staff Development Specialist maintains records of DCM employee training on an Excel SharePoint file that can be readily reviewed and accessed by IACUC staff. The IACUC office maintains records of IACUC member training.

IV. Institutional Program Evaluation and Accreditation

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

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

V. Recordkeeping Requirements

A. This Institution will maintain for at least 3 years:
   1. A copy of this Assurance and any modifications made to it, as approved by the PHS
   2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
   3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
   4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Jeremy Paul, PhD.
   5. Records of accrediting body determinations

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B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.

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

VI. Reporting Requirements

A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
   1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
   2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
   3. Any change in the IACUC membership
   4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Jeremy Paul.
   5. Any minority views filed by members of the IACUC

B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
   1. Any serious or continuing noncompliance with the PHS Policy
   2. Any serious deviations from the provisions of *the Guide*
   3. Any suspension of an activity by the IACUC

C. Reports filed under VI.A. and VI.B. above will include any minority views filed by members of the IACUC.

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VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Jeremy Paul, PhD	
Title: Assistant Dean, Basic Science Research Operations	
Name of Institution: NYU Langone Health	
Address: Medical Science Building 550 First Avenue, (b) (4) New York, NY 10016	
Phone: (b) (6)	**Fax**: n/a
E-mail: Jeremy.paul@nyulangone.org	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: (b) (6)	**Date**: 2/3/20

B. PHS Approving Official *(to be completed by OLAW)*

Name/Title:
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500
Bethesda, MD USA 20892-7982
Phone: +1 (301) 496-7163
Fax: +1 (301) 451-5672

(b) (6) Digitally signed by Nicole L. Lukovsky-akhsanov -S
Date: 2020.03.09 11:36:26 -04'00'

Signature:	Date:
Assurance Number: D16-00274 (A3435)	
Effective Date: 3/9/2020	Expiration Date: 3/31/2024

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VIII. Membership of the IACUC

Date: 01/21/2020	
Name of Institution: NYU Grossman School of Medicine - an administrative unit of New York University	
IACUC Chairperson	
Name*: Ann Marie Schmidt	
Title*: Dr. Iven Young Professor of Endocrinology, Professor of Medicine, Biochemistry and Molecular Pharmacology and Pathology	Degree/Credentials*: M.D.
Address*: Science Building 435 East 30th Street [redacted] (b) (4) New York, New York 10016	
E-mail*: Annmarie.schmidt@nyulangone.org	Fax*: [redacted] (b) (6)
Phone*: [redacted] (b) (6)	

IACUC Roster

Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
Ann Marie Schmidt	M.D.	Chairman (Professor of Medicine, Biochemistry and Molecular Pharmacology and Pathology)	Scientist
[redacted] (b) (6)			Scientist
			Scientist
			Scientist

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Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
[redacted]	[redacted]	[redacted] (b) (6)	Scientist
[redacted]	[redacted]	[redacted]	Scientist
[redacted]	[redacted]	[redacted]	Scientist
[redacted]	[redacted]	[redacted]	Scientist
[redacted]	[redacted]	[redacted]	Scientist
[redacted]	[redacted]	[redacted]	Scientist
[redacted]	[redacted]	[redacted]	Scientist
[redacted]	[redacted]	[redacted]	Scientist
[redacted]	[redacted]	[redacted]	

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Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
[redacted]	[redacted]	[redacted] (b) (6)	
Jennifer Pullium	M.V.B., D.A.C.L.A.M.	Member (Senior Director, DCM)	Veterinarian
[redacted]	[redacted]	[redacted] (b) (6)	Veterinarian
			Veterinarian
			Veterinarian
			Veterinarian
			Veterinarian

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Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
[redacted] (b) (6)			
			Nonscientist
			Nonscientist
			Nonaffiliated
			Nonaffiliated

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** PHS Policy Membership Requirements:

Veterinarian veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

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IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

(b) (6)

[redacted]

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X. Facility and Species Inventory

Date: 10/18/2019
Name of Institution: NYU Grossman School of Medicine
Assurance Number: D16-00274 (A3435-01)

Laboratory, Unit, or Building*	Approx. sq.ft./m (acreage) animal housing	Approx. sq.ft./m (acreage) support/ procedure space	Species Housed [*use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog*]	Approximate Average Daily Inventory
(b) (4)	6,623	3,390	Mice, Rats	7261 mouse cage 20 rat cage
	7,053	4,209	Mice, Rabbits, Pigs	6246 mouse cage, 18 rabbit 6 swine
	2,693	1,626	Mice, Rats	1,272 mouse cage 42 Rat cage
	12,800	5,200	Mice	7800 mouse cages
	2,580	1,800	Mice and Rats	1200 Mouse 360 Rat Cages
	559.40	N/A	Mice and Rats	1341 mouse cage 5 rat cages
	1,166	926	Mice and Rats	2692 mice
	126	N/A	Zebra Fish	25000 fish
	51	N/A	Mice	20 mouse cages
	107	62	Zebra Fish	200 fish
	90	125	ABSL3 Mouse cage	35 mouse cage
	685	NA	Gnotobiotic Mouse Cage	100 mouse cage

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(b) (4)	69	N/A	Mice	137 mouse cages
	400	N/A	Zebra Fish	20000 fish
	457	N/A	Gnotobiotic Mouse Cage	75 mouse cages
	400	N/A	Zebra Finch	TBD- Used as scheduled
	45	62	Zebra Finch	200 birds
	90	62	Frogs	79 frogs
	47	51.1	Rats	50 rat cages
	113	62	Mice/ABSL2	206 mouse cages

Date: 12/4/2019

Name of Institution: NYU Winthrop Hospital

Assurance Number: Formerly D16-00274 (A3697-01)

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed	Approximate Average Daily Inventory
(b) (4)	6,200	Mice, Rats	800 mouse cages/0 rat cages

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

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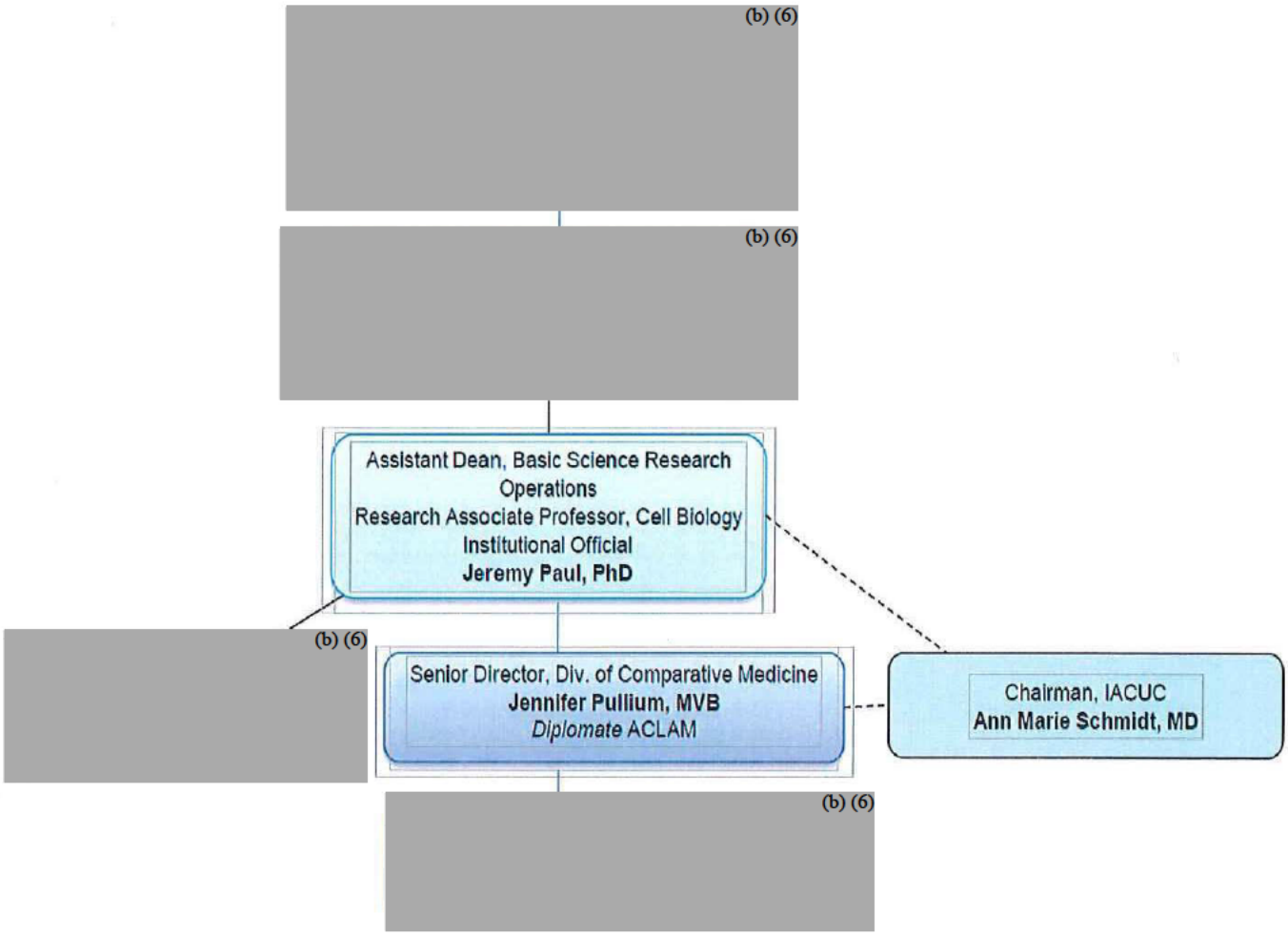
XI. Lines of Authority for the Animal Care and Use Program



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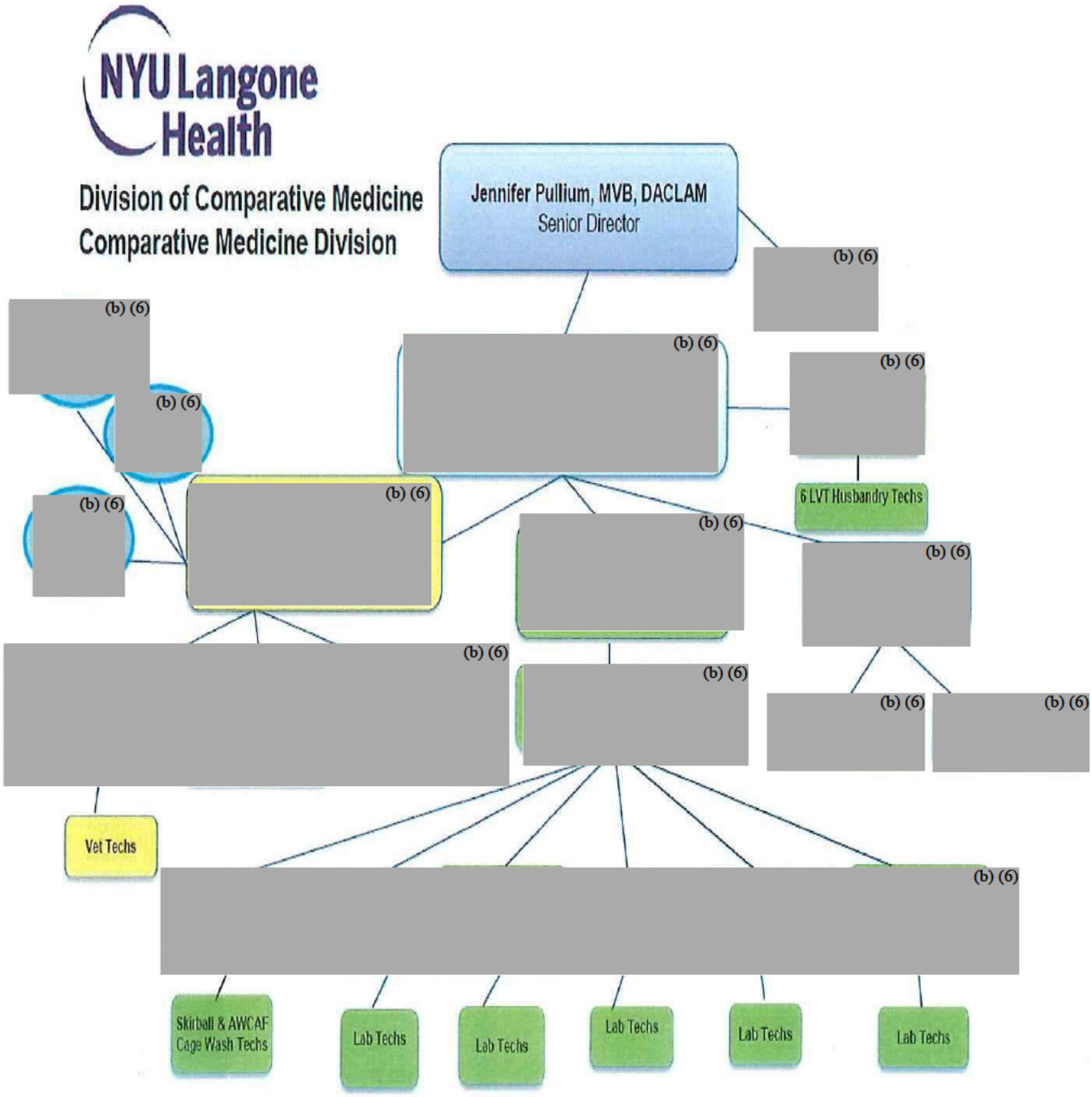
XII. Division of Comparative Medicine



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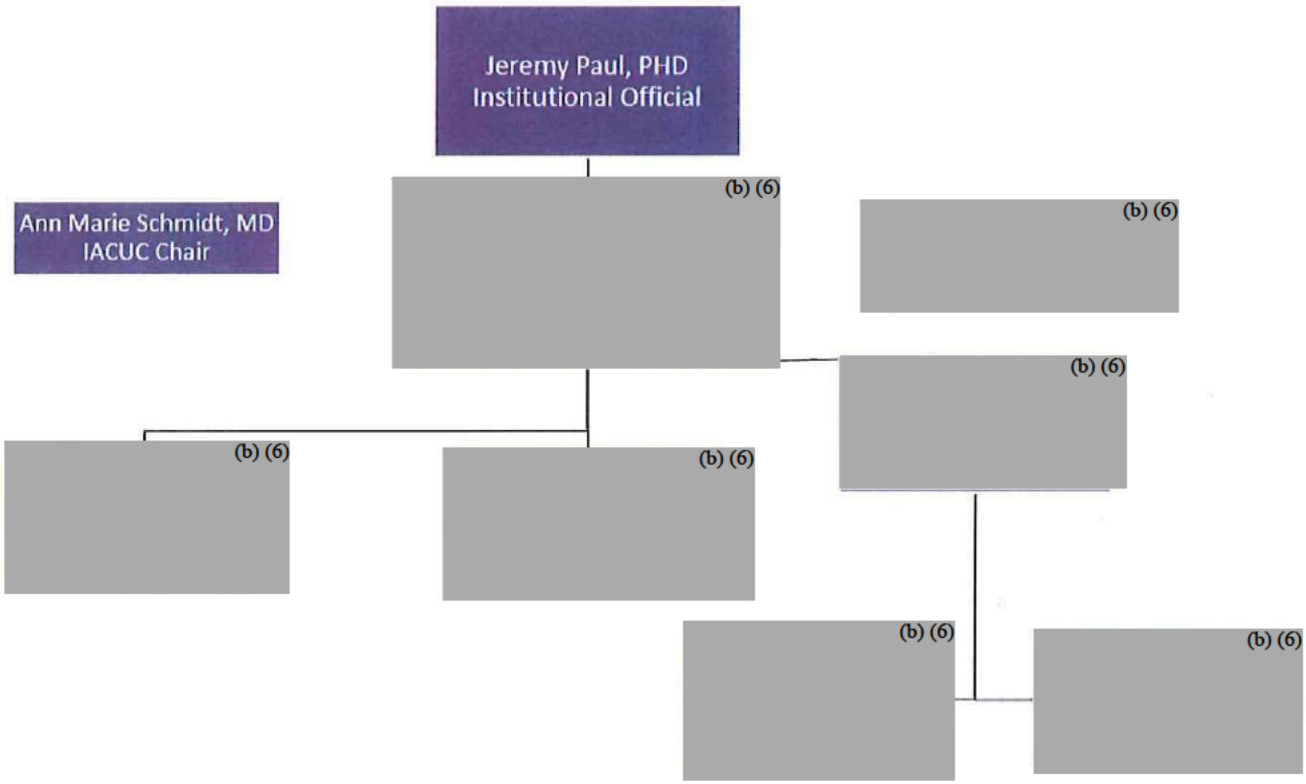
XIII. Division of IACUC and IBC Administration Organizational Chart



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