ROBLEY REX VA MEDICAL CENTER, LOUISVILLE, KENTUCKY
ASSURANCE NUMBER A4531-01

I, Stephen D. Black, FACHE, MedicalCenter Director, as named Institutional Official for animal care and use at Robley Rex VA Medical Center, 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

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

"Institution" includes the following branches and major components of the Robley Rex VA Medical Center Louisville, Kentucky. All components of the VA animal care and use program are located at (b)(6) Louisville KY 40206 should be included within this assurance. Research animal housing and procedure rooms are in (b)(6) (b)(6) and the location of some laboratories where animals are used is in the (b)(6) offices, including those for the VA IACUC, are on the (b)(6) floor of the (b)(6) Building. There are no satellite or affiliate facilities covered as part of this "institution".

II. INSTITUTIONAL POLICY

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

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

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

D. This institution maintains an established program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide, 2011).

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

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III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are clear. The Medical Center Director (MCD) of the Robley Rex VA Medical Center, Stephen D. Black, FACHE, serves as the Institutional Official (10). The Attending Veterinarian or Veterinary Medical Officer (VM), (b)(6), reports directly to (b)(6), M.D., (b)(6) in all matters pertaining to animal welfare and compliance, and may contact the 10 directly and the Chief, Veterinary Medical Officer (CVMO) when needed. The Louisville VA delegates program authority through the 10 to the ACOS RD&RE, VA R&D and subsequently, to the VMO directly to implement animal care and use policy, provide veterinary care for the research animals and supervise VMU operation. (b)(6) is also a member of the VA IACUC, which supports the veterinarian in implementation of PHS Policy, the recommendations of the Guide, and the VA Handbook 12.007. (b)(6) and (b)(6) VA IACUC Chairperson, may also report directly to the 10 with issues concerning the VA animal care and use program. (b)(6) and (b)(6) meet semi-annually with the Medical Center Director to discuss the animal care and use program and facilities report. Additionally (b)(6) may directly contact the CVMO, Department of Veterans Affairs, and is required to report any significant program deficiencies. (b)(6) oversees the operation of all VA Animal Care and Use Programs.

Within the Office for VA R&D, the ACOS R&D supervises the (b)(6) who oversees the VA IACUC Coordinator and managerial and administrative support for the IACUC.

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

(b)(6) has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

(b)(6) D.V.M., M.S., (b)(6)

(b)(6)

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(b)(6)

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in the PHS Policy at IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, position titles, specialties and institutional affiliations. It should be noted that both the non-affiliated and non-scientist members are not laboratory animal users and have no science or medical background, and therefore meet recommendations of the Guide as representatives of general community interest.

D. The IACUC will:

1. Review at least once every six months the institution's program for humane care and use of animals, using the Guide as a basis for evaluation. All members of the IACUC participate in the program review and semi-annual inspections. The IACUC conducts the semi-annual program evaluations during a regularly scheduled meeting, for which a quorum is required. The IACUC members use a standard checklist provided by the Office of the CVMO for use. Although it is specific for VA programs, it meets all OLAW, VA, and other regulatory agency guidelines. The checklist for program components for institutional policies and responsibilities includes the following areas: 1) IACUC membership and functions, 2) IACUC records and reporting requirements, 3) veterinary care, 4) personnel qualifications and training, and 5) occupational health and safety of animal research personnel 6) any "minority views" (if they exist).

2. Inspect at least once every six months all of the institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC inspects all of the

VA animal facilities and laboratories as a regularly scheduled meeting, for which a quorum is required. All members of the IACUC participate in the semi-annual inspections. Members inspects all animal housing and support areas, as well as investigator laboratories where animals are used. An agency-wide checklist is used for comments by the members to note any issues of concern, especially regarding animal colony location, facility construction, room and cage maintenance, animal health, environmental enrichment, provision of food, water, and bedding, waste disposal, pest control, and animal identification and records.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the 10. The IACUC process for developing reports and submitting them to the 10 is as follows. Suggestions for improvement or deficiencies noted by the IACUC members on the VA VMU semi-annual inspection checklist, which is uniform for all VA Medical Center Animal Care and Use Programs and conforms to VHA Handbook 12.007 and VA ORO (Office for Research Oversight) specifications. Categories of deficiencies noted are minor or significant issues. The location, full description of the deficiency, and the proposed correction date are comments listed on a standardized form that accompanies the checklist. The comments are in a table format compiled by the IACUC Coordinator and the final copy approved and signed by a quorum of the members at the next regularly scheduled IACUC meeting. The VMO, IACUC Chairman, and the ACOS present the semi-annual report to the 10 in a scheduled meeting, and follow-up meetings scheduled as necessary to meet correction deadlines. The deficiencies and correction dates carry forward as an agenda item for the VA IACUC each month to ensure that correction of issues occurs in a timely manner, and appear in the IACUC minutes and the subsequent semi-annual report. The VA R&D Committee also reviews and approves the semi-annual inspection report.
Additionally, approved departures, with the reasons for each, the PHS Policy, or the Animal Welfare Act Regulations (AWAR), also referred to as an exemption, and are approved by the IACUC prior to implementing. They are also reviewed at least annually or more often if required by the AWAR. Each departure will be stated and reported in the semi-annual report to the 10 for each six-month reporting period during which the IACUC approved departure is in place.

4. Review concerns involving the care and use of animals at the institution. A description of the IACUC procedures for reviewing concerns is in an IACUC policy entitled, "Policy for Responding to Reported Deficiencies in Animal Care and Treatment." Individuals may report an animal welfare concern to the IACUC Chairperson, any member of the IACUC, the Attending Veterinarian, the 10, or the CVMO directly if the individual thinks the response by local contacts is inadequate. They may also place a written concern in a drop box in the VA Research Service hallway. Identity of the "whistle blower" is confidential, and they can be no retribution or reprisal because of reporting a concern. An IACUC subcommittee investigates the concern and reports their findings and proposed corrective action at a convened IACUC meeting. If the corrective action includes suspension of a project and reporting the incident to regulatory and funding agencies, a letter drafted by the IACUC Chairperson then reviewed

and approved by the IACUC and the 10 before notification of the PI. The IACUC then reports that action with a full explanation to OLAW, the CVMO, and the VA Office for Research Oversight (ORO), and USDA if applicable.

5. Make written recommendations to the 10 regarding any aspect of the institution's animal program, facilities, or personnel training occurs routinely followingeach semi- annual inspection. As described above, the VHA Handbook 12.007 requires that the ACOS R&D, IACUC Chairperson, and the VMO meet with the 10 to discuss the findings of the IACUC after each review of the animal care and use procedures and policies, as well as the physical facilities. Personnel training, the Occupational Safety and Health (OSH) program, veterinary care, and maintenance and condition of the animal facilities and laboratories are included in the formal semi-annual report. The purpose of the meeting with the 10 is specifically to inform him of any program deficiencies, their significance, and the suggested corrective action, especially those that require Medical Center Services or funds for correction. The Office of the CVMO must receive the semi-annual report within 90 days of the review date.

6. Review and approve, require modifications in (to secure approval), or withhold approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC must review and approve, require modifications in (to secure approval), or withhold approval of all research proposals involving all animal species and animal tissues or primary cell lines obtained from live animals. All research projects involving animals must be approved by a quorum of voting members of the IACUC at a convened meeting, followed by approval by the VA R&DC prior to initiation of the project. All research proposals using animals must document in the text that (b)(6) consults during the planning stages, prior to IACUC review. The date of continuing review is the date of IACUC approval. For new proposals, completed and reviewed forms including a "Request to Review" form, a Research Narrative, Subcommittee for Research Safety (SRS) Form, and an Animal Component of Research Protocol (ACORP) are submitted to the VA Research Office at least two weeks prior to the IACUC meeting. Three-year renewals are de nova or new proposals. Annual review of protocols and modification of existing protocols require completion of the respective forms (Request for Continued Approval of Animal Use and Request to Modify Animal Use), which are submitted to the IACUC for review and approval annually and when any changes are made in the ACORP. Distribution by email of packets containing an agenda with all business items listed, new protocols, continuing reviews, and modifications to the IACUC members occurs no later than seven business days prior to the IACUC meeting. All ACUC members must receive copies of all protocol forms. With no exceptions, VA Merit Review submissions and all VA sponsored research must use the VA ACORP, which meet all Federal regulations and guidelines for IACUC review. Each initial protocol review receives a full committed review by all members of the IACUC, except in those rare instances when a designated member review (DMR) system is used.

The DMR may also be used to review requested modifications to secure approval. If DMR is the decision of the committee, its use must be in accordance to the following stipulations:

A. ALL members must agree to review by this process. If some members are not present at the meeting to approve the use of DMR, then ALL members must receive notification via email or conference call to approve the use of DMR for each ACORP proposal renewal; request for continuing review of proposal; or request for proposal modification, identified during the committee meeting or by the committee Chair.

B. In those instances when a Designated Member Review (DMR) system is used for initial protocol review by the IACUC, ALL members must receive notification via email or conference call to approve the use of DMR (i.e. have the opportunity to call for FCR) for each ACORP identified during the committee meeting or by the committee Chair. If no one calls for FCR, the IACUC Chairperson may appoint one or more appropriately qualified IACUC members to serve as the designated reviewer(s). If a protocol is assigned more than one designated reviewer, the reviewers must be unanimous in any decision. They must all review identical versions of the protocol and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications.

   The outcomes by DMR when used for initial protocol review are limited to:

   1) Approval;
   2) Request modification to secure approval;
   3) Return the protocol to the committee for review.

   Additionally, any member of the committee may, at any time, request to see the revised protocol and/or request FCR of the protocol (PHS Policy IV.C.2).

C. Consistent parliamentary procedures are used to conduct business. This system allows for discussion of each item, motions, seconds to motions, and official votes tallied by yeas, nays, and abstentions. In addition, if any voting member has a conflict of interest of any type with any agenda item or proposal requiring approval, the member must recuse himself or herself from the meeting. They may not rejoin the committee until the action on the item is completed and then they may reenter the meeting. If a quorum of voting members is lost after recusal, all protocols/modification of protocols/continuing protocol reviews requiring a vote for approval are tabled until the next meeting. Other agenda/business items requiring a vote are also postponed if a quorum is not retained.

For any business item, any member may request that a minority opinion be submitted for placement in the minutes. The committee may review the minority opinion as part of the review of the minutes at the next meeting, but may not vote to remove or revise the minority opinion. Minority opinions addressing individual protocols must be included in the ACORP or other form used for review.

7. Review and approve, require modification(s) to secure approval, or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing new proposals or modifications include a review by the full committee of all agenda items and discussion at a convened meeting. When a quorum is present, the following actions may be recommended in a motion to the IACUC Chairperson:

A. Proposal Approval- all reviewers agree to accept a proposal as submitted;
B. Require Modification(s) to secure approval- reviewers agree that minor changes are required in the protocol, and the proposal may be approved by the designated review system described in Part III, D. 6. or reviewed by the full committee at the next scheduled meeting. All ACUC members are notified of this decision, and are given the opportunity to review the proposal and/or call for a full committee review prior to approval by the designated reviewers;
C. Tabled - reviewers agree that issues of serious concern exist, the committee may request that the PI make significant changes to the proposal before resubmission to the IACUC;
D. Proposal Disapproval- reviewers agree that a proposed study is unacceptable and fails to meet regulatory or local standards and the proposal is withdrawn.
E. For Full Committee Review (FCR) or Designated Member Review (DMR) guidelines and procedures, refer to RASS Policy & Procedure #37, dated February 13, 2018 "VA RASS Review and Approval Policy" (the policy is provided as an attachment).
F. Procedures for review and approval of proposed significant changes follow the same guidelines as outlined in Section 111.D.6.

8. Notify investigators and the institution in writing of its decision to approve or withhold approval for those activities related to the care and use of animals, or for modifications required to secure IACUC approval as set forth in the PHS Policy at IV.C.4. The IACUC procedures to notify investigators and the institution of its decisions regarding protocol review are by a letter and an email from the IACUC Chairperson or Research Office. The investigator is permitted to respond directly to the committee's comments to the Chairperson through the VA Research Office. Tabled or Withdrawn proposal may be resubmitted to the IACUC for review and discussion at a convened meeting. IACUC approval is granted for a period of three years, with an annual review conducted on the anniversary date of IACUC approval. A new proposal must be submitted after three years if the research is to be continued.

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

VA Research Office prompts investigators annually to complete a "Request for Continued Approval of Animal Use", which asks for basic current information, such as IACUC approval number, IACUC approval date, title of project, and species used. The investigator notes on the form if any changes have occurred. The forms are then reviewed by the IACUC and approved by a quorum of committee members at a convened meeting, or if the changes or deemed significant, a modification of the proposal by the investigator is requested. On the third anniversary of the original IACUC approval date, a new ACORP is requested. If the research is to be continued, the specific objectives accomplished and the number of animals used to date from the original proposal must be accounted for in the body of the ACORP. The IACUC may review and approve the proposal if the continuation is reasonable, or may determine that a de novo proposal is required. Annual review forms and three year renewals must be submitted and reviewed within 90 days post the original IACUC approval date or the study may be suspended by the IACUC.
Review of all items requiring full committee review and/or DMR follow the procedures as stated in III.D6.

The IACUC conducts on-going post-approval monitoring (PAM) activities in the following ways:

A. Review at least every six months of entire research project/folder by the IACUC members (can only be performed by members without a conflict of interest).
B. For research projects performed at the Robley Rex VAMC, a full-time husbandry technician oversees all animal receiving and procedures. Copies of active protocols are kept within the facility so that research activity is reviewed for compliance.
C. Animal orders placed by the VA must be compared to the approved protocol to ensure species and allowance for animals is correct.
D. For research that is VA funded but performed at the affiliate institution, laboratories are inspected periodically (at least three to four times annually) to ensure compliance with both affiliate and VA protocols. Additionally, affiliate protocols must be approved for the same species and numbers of animals and accordance is checked at time of animal order and daily by husbandry staff.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6. A quorum of IACUC members at a convened meeting is required to discuss and clearly determine the reason(s) for a suspension, and the corrective action(s) required to reactivate the project. The IACUC, in consultation with the 10, reviews the reasons for suspension of a project, notifies the PI, and takes appropriate action. The IACUC then reports that action with a full explanation to OLAW, the CVMO, and ORO. The investigator is notified of the committee's actions after review by the 10 and notification of the appropriate agencies.

E. The occupational health and safety program for personnel who work in laboratory animal facilities or have frequent contact with animals is well established. The VA has a multidisciplinary approach to evaluate dangers associated with working with animals and hazardous agents. Identification of hazardous agents listed in animal research is required in the ACORP.

A special appendix specifies the type of hazard, and review by appropriate safety subcommittees is documented by signatures of the Chairperson(s) and the Attending Veterinarian. The specific hazards, handling precautions and procedures, and training are the primary responsibility of the VA Subcommittee for Research Safety (SRS). The Subcommittee for Radiation Safety may also be involved. All protocols require completion of a Research Protocol Safety Survey (RPSS) form and an application to use radioisotopes, if applicable. The SRS form includes a description of the hazardous agent(s), special handling procedures, a chemical inventory, and laboratory certification. Training is performed by the designated representative of the SRS that specializes in that area of risk, such as recombinant DNA or radiation.
Predisposing risk factors, such as health status, are taken into consideration when training individuals and reviewing SRS forms. The SRS committee may require that laboratories post warnings for staff that may be pregnant, ill, or immunodeficient. Semi- annual inspections are performed by the SRS to review safety practices and protocols, and all research laboratories, including the animal facility. A checklist is used to generate a formal report noting deficiencies, corrective action, and suggested timetable for correction. These items remain as business items on the Agenda for each SRS meeting until the item has been resolved.

All VA employees, without compensation (WOC) personnel, VA research and education corporation employees, and students with significant animal contact must participate in the Louisville VA Occupational Health and Safety Program. This is consistent with guidelines provided in the VHA Handbook 1200.7 and Appendix C. Employees whose duties require significant contact with dogs, cats, bats, or wild carnivores are provided the opportunity of receiving pre-exposure rabies immunization in accordance with current CDC recommendations. There are no non-human primates to be considered.
The Robley Rex VA Medical Center procures and administers the vaccine at no cost to the employees requesting immunization. Transportation of animals through or into areas used by patients or visitors is avoided whenever possible. All animals transported through patient care areas must be covered and caged such that patients and other non-research staff are not readily aware of their presence.

Laboratory coats, scrubs or gowns, and shoe covers must be worn when entering procedure or animal rooms. Gloves must also be worn if animals are handled. The use of N-95 respirators is also recommended to reduce the risk of exposure to allergenic exposure to animals, and fit testing for respirators is provided. Additional appropriate protective clothing, such as face shields, eye protection, disposable gowns or scrubs are supplied and designated experts and/or the Attending Veterinarian and Husbandry Supervisor provide agent specific training for all affected personnel. Appropriate room signage is used for biohazards and would include specific instructions for individuals that are pregnant, ill, or immunodeficient. The Robley Rex VA Medical Center provides clean uniforms and laundry service for the personnel engaged in the care and use of laboratory animals. There is no smoking allowed, and no eating or drinking allowed in research areas or animal care areas.

A pre-employment physical is conducted to ensure that prospective employees are capable of physical demands of the position, and that pre-existing medical conditions do not place the employee or others at risk. Tetanus and Hepatitis B vaccines are optional. Training for individuals explaining risks associated with working with animals in research is provided during the pre-employment physical and then annually, by distributing a brochure entitled "Occupational Hazards Associated with the Care and Use of Laboratory Animals". Individuals identified at special risk, including employees that may be pregnant, ill, or immunocompromised are provided further training by the Occupational Health physician's assistant that reviews all personal health questionnaires. These records are maintained in this office and as such, are HIPPA protected medical records. This training is provided by individual discussions or one-on-one training as needed and may be confidential, thus only the requirement for additional training would be identified to personnel identified on a need to know Completion of a "Periodic Animal Contact Health Survey" or a signed waiver* is required by all personnel working with research animals and is updated annually and specifically addresses risk assessment. The Survey is written by the University of Louisville (b)(6) physician, (b)(6) M.D. and the Robley Rex VA Employee Health Services (b)(6) (b)(6) who both specialize in OSH for their respective employers. The VA nurse practitioner reviews the VA submissions and provides written recommendations regarding the susceptibility or risk of the individual with respect to the employee's occupational health history. The Survey and any related correspondence is confidential, and enrollment is tracked by Employee Health Services. Injuries or accidents, animal bites, animal scratches and cuts sustained in the animal facility or research laboratory must be reported promptly to the employee's immediate Supervisor. The injured or ill individual must then report to Employee Health Services for treatment by the nurse practitioner, and VA Form 2162, Report of Accident, needs to be completed by the Supervisor and submitted to Employee Health Services and the Director's Office. If an injury or accident occurs after hours, the individual is seen by the VA Emergency Room physicians for treatment and the incident and appropriate paperwork are reported the following business day by the Supervisor.

*The signed waiver indicates the employees declination for further participation in the OSHP. Additionally, those personnel who sign a waiver have the option to re-enter the program by contacting the Occupational Health Office.

G. The total gross number of square feet in each animal facility (including satellite facilities), the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached table.

H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is required annually per VHA Handbook 12.007. The IACUC ensures that all personnel on an animal research protocol have been properly trained before IACUC approval is given, incorporating the web-based training program provided by the VA through the web site www.citiprogram.org.

The training program includes professional, management, and supervisory personnel and animal care investigators, instructors, technicians, trainees, and students that use animals in research. The web based courses include humane practices of animal care and use, research methods that minimize animal numbers, pain, and distress, and species specific training. It also includes essential information regarding the IACUC, and the use of hazardous agents and access to OSH notices. The Louisville VA Medical Center requires all IACUC members to complete the course "IACUC Essentials". Investigators and research staff must complete "Working with the IACUC'\ and the species specific module that applies to their research. Participation and certificates of completion are tracked by the Office of Research Service. A list of training modules available is provided at the www.citiprogram.org web site. Furthermore, all current committee members, including those who are not required to take "Working with the IACUC" received training at a convened IACUC meeting on Planning Research and Completing the Protocol Form to ensure they were properly trained. In the future, this module will be incorporated into the required CITI training. Additional training is provided upon request by the Attending Veterinarian.

IV. INSTITUTIONAL STATUS

As specified in the PHS Policy at IV.A.2, as Category 1, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC). All of this institution's programs and facilities (including satellite facilities) for activities involving animals have also been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months, in accord with IV.B.1.and 2.of the PHS Policy, and reports prepared in accord with IV.B.3.of the PHS Policy.

All IACUC semiannual reports will include a description of the nature and extent of this institution's adherence to the Guide. Any departures from the Guide are identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. The definition of a significant deficiency is as a situation that is or may be a significant threat to animal health or safety. The IACUC, through the 10, promptly reports within 15 days to the CVMO (ORO), ORO, OLAW, AAALAC, and /or USDA, if applicable, any serious or continuing noncompliance with the Guide, PHS policy, ORO guidelines, or the VMU Handbook 12.007. In the case where significant deficiencies may pose a threat to animal health or safety, the deficiency is rectified immediately or the animals are removed to safety.

Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. In each instance, "correct by" dates are 15 days or less unless it is a serious physical deficiency that will require major renovation and/or funding, in which case, an explanation will be provided. The specific date is listed on our semiannual report form next to the item cited under "Corrective Action". This item is then listed as an agenda item for each subsequent IACUC meeting until resolved.

Additionally, semiannual reports are reviewed and approved by the parent VA Research and Development Committee. Semiannual reports of the IACUC evaluations must be submitted to the Medical Center Director and 10, Stephen D. Black, Robley Rex VA Medical Center,

Louisville, Kentucky by the Attending Veterinarian, the ACOS Research & Development, and the Chairman of the IACUC during a regularly scheduled meeting within 60 days of inspection to ensure timely correction.
Semiannual reports of IACUC evaluations will be maintained by this institution and made available to the Office of Laboratory Animal Welfare (OLAW) upon request.

V. RECORD KEEPING REQUIREMENTS

A. This institution will maintain for at least three years:
1. A copy of this Assurance and any modifications thereto, as approved by PHS.
2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to Stephen D. Black, Medical Center Director, Robley Rex VA Medical Center, Louisville, KY, and the CVMO within 60 days of completion.
5. Records of accrediting body determinations.

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

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

VI. REPORTING REQUIREMENTS

A. At least once every 12 months, the IACUC, through the Institutional Official, will report in writing to OLAW:
1. Any change in the status of the institution in the accreditation status by AAALAC, any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in IACUC membership. If there are no changes to report, this institution will provide OLAW with written notification that there are no changes.
2. Notification of the dates that the IACUC conducted its semiannual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to Stephen D. Black, Medical Center Director, Robley Rex VA Medical Center Director, Louisville, Kentucky.

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

1. Any serious or continuing 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 shall include any minority views filed by members of the IACUC

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Stephen D. Black, FACHE	
Title: Medical Center Director	
Name of Institution: Robley Rex Medical Center	
Address: *(street, city, state, country, postal code)* 800 Zorn Avenue Louisville, KY 40206	
Phone: (b)(6)	Fax: (b)(6)
E-mail: (b)(6) @va.gov	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: (b)(6)	Date: 7/8/19

B. PHS Approving Official *(to be completed by OLAW)*	
(b)(6) Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500 - MSC 6910 Bethesda, Maryland 20892 Email: (b)(6) @od.nih.gov Phone: (b)(6) Fax: (b)(6)	(b)(6)
Signature:	Date: July 11, 2019
Assurance Number: D16-00777 (A4531-01)	
Effective Date: July 11, 2019	Expiration Date: February 28, 2023

MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE Date: 12/01/18

NAME OF INSTITUTION: Robley Rex VA Medical Center, Louisville, KY
ASSURANCE NUMBER: A4531-01

Chairperson Name, Title, and Degree/Credentials	Business Address, Phone, Fax, and Email of Chairperson
Name: (b)(6)	Address: Robley Rex VA Medical Center (b)(6) (b)(6) Louisville, KY 40406
Title: Research Associate, Robley Rex VA Medical Center and University of Louisville	
Degree/credentials: Ph.D., VA Principal Investigator	Phone: (b)(6) Fax: (b)(6) Email: (b)(6) @louisville.edu

Name of Member/Code*	Degree/Credentials	Position Title	PHS Policy Membership Requirements**
(b)(6)	PhD	Chairperson	Scientist
	DVM, MS, dip ACLAM	VA Veterinary Medical Officer	Veterinarian
	MA	Retired Teacher	Non-affiliated member, Non-scientist
	BA, MA	VA Chaplain	Non-scientist
		Administrative Officer for VA R&D	Ex-officio, without vote
	DVM, PhD	VA Principal Investigator	Scientist
	PhD	VA Principal Investigator	Scientist
	PhD	VA Principal Investigator	Scientist
	PhD	Committee Member	Scientist
	MD, FASN, FACP	Associate Chief of Staff for Research and Development	Ex-officio, without vote

(b)(6)		VA IACUC Coordinator	Staff, without vote

*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.

**PHS Policy Membership Requirements:

Veterinarian – a veterinarian with direct or delegated program responsibility.

Scientist – a practicing scientist experienced in research involving animals.

Nonscientist - a member whose primary concerns are in a non-scientific areas (e.g. ethicist, lawyer, member of the clergy).

Non-affiliated member - a member who is not affiliated with the institution in any way other than as a member of the IACUC, and who is not a member of the immediate family of a person who is affiliated. 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 attending veterinarian may not be considered non-affiliated.

NOTE: Nonvoting members must be so identified

FACILITY AND SPECIES INVENTORY

Date: 12/20/18

NAME OF INSTITUTION: Robley Rex VA Medical Center, Louisville, KY
ASSURANCE NUMBER: A4531-01

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed in Unit (use complete common names)	Approx. Average Daily Inventory
Veterinary Medical Unit (VMU), Building (b)(6) Robley Rex VAMC	4,396	Rat	22
		Mouse	334
Building (b)(6) Animal Research Laboratories, Robley Rex VAMC	840	Rat	20

*Institutions may identify animal areas in any manner, e.g., initials, ID number, etc. However, the name and location must be provided to OLAW upon request.

RESEARCH & DEVELOPMENT
ROBLEY REX VA MEDICAL CENTER
LOUISVILLE, KENTUCKY

RASS POLICY & PROCEDURE #37
February 13, 2018

VA RASS Review and Approval Policy

1. PURPOSE:

To define the approval processes, as in Full Committee Review (FCR) or Designated Member Review (DMR). Further, to define significant changes that require FCR or DMR and changes that can be handled administratively.

2. POLICY:

All ACORP proposals, triennial de novo ACORP proposal reviews, requests for continuing review of ACORPs (annually), and Requests to Modify existing ACORP proposals, will be reviewed and approved by the RASS by FCR or DMR. Significant changes must be reviewed by this process as well and are defined. Changes that may be handled administratively are also defined.

3. DEFINITIONS:

a. Significant changes described in 1) to 7) below, must be approved by Full Committee Review (FCR) or Designated Member Review (DMR) as described in the PHS Policy IV.C.2.

1) from non-survival to survival surgery;
2) resulting in greater pain, distress, or degree of invasiveness;
3) in housing and or use of animals in a location that is not part of the animal program overseen by the RASS;
4) in species;
5) in study objectives;
6) in Principal Investigator (PI); or
7) that impact personnel safety.

b. Changes that may be handled administratively without IACUC-approved policies, consultations, or notifications include:

1) correction of typographical errors;
1) correction of grammar;
2) contact information updates.

The USDA Animal and Plant Health Inspection Service has reviewed and concurs with this guidance.

4. RESPONSIBILITIES:

The RASS and all members must apply by the above procedures when conducting business to review and approve ACORP proposals, triennial and annual reviews, and requests to modify existing ACORP proposals.

5. PROCEDURES:

a. All ACORP proposals, triennial de novo ACORP proposal reviews, requests for continuing review of ACORPs (annually), and Requests to Modify existing ACORP proposals, will be reviewed and approved by the RASS by FCR when a quorum is present or by DMR. When substantive information is lacking from a protocol, the RASS may take the following actions:

1) If all members of the RASS are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR, or returned for FCR at a convened meeting.

2) If all members of the RASS are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:

(a) All RASS members must agree in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval.

(b) However, any member of the RASS may, at any time, request to see the revised protocol and/or request FCR of the protocol (PHS Policy IV.C.2).

b. This document, signed by all RASS members, below, attests to agreement with the use of DMR as described in this policy, and as described in our PHS Assurance document.

6. REFERENCES: Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy)1, 1986; United States Department of Agriculture's (USDA) Animal Welfare Act2, 1989.

7. Revisions: 4/18/2016, 9/27/2017