DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Division of Assurances
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Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

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Division of Assurances
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March 16, 2009

Reference: Renewal Assurance **#A3756-01**

Eric W. Young, M.D.
Acting Director (00)
VA Ann Arbor Healthcare System
2215 Fuller Road
Ann Arbor, Michigan 48105

Dear Dr. Young:

I am pleased to inform you that The Office of Laboratory Animal Welfare (OLAW) reviewed and approved the renewal of your institution's Animal Welfare Assurance (Assurance) that was submitted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), as revised August 2002.

Your Assurance renewal, number **A3756-01**, became effective on **March 16, 2009** and expires on **March 31, 2013**. This Assurance supersedes all previously issued Assurances. Please include the Assurance number in all correspondence to OLAW. A copy of the Assurance signature page is enclosed.

The Assurance is a key document in defining the relationship of your Institution to the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance, I would especially call your attention to the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that a Report to OLAW is required at least once every 12 months. The reporting period, unless requested otherwise in writing, is the calendar year. Reports, for the previous calendar year, are due **January 31**.

If I may be of further assistance, please do not hesitate to contact me.

Thank you for your attention in these matters.

Sincerely,

Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare, NIH

Enclosure

cc:
Dr. Michael Olszewski

VA Ann Arbor Healthcare System
Animal Welfare Assurance #A3756-01
ANIMAL WELFARE ASSURANCE
in accordance with the PHS Policy for
Humane Care and Use of Laboratory Animals

I, Eric W. Young, M.D. as named Institutional Official for animal care and use at the VA Ann Arbor Healthcare System, hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

I. APPLICABILITY OF ASSURANCE

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

"Institution" includes the following branches and major components of the VA Ann Arbor Healthcare System: All components [departments, units, services, etc.] of the medical center that are physically located at 2215 Fuller Road, Ann Arbor, Michigan. There are no satellite facilities and/or other covered components.

II. INSTITUTIONAL COMMITTMENT

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

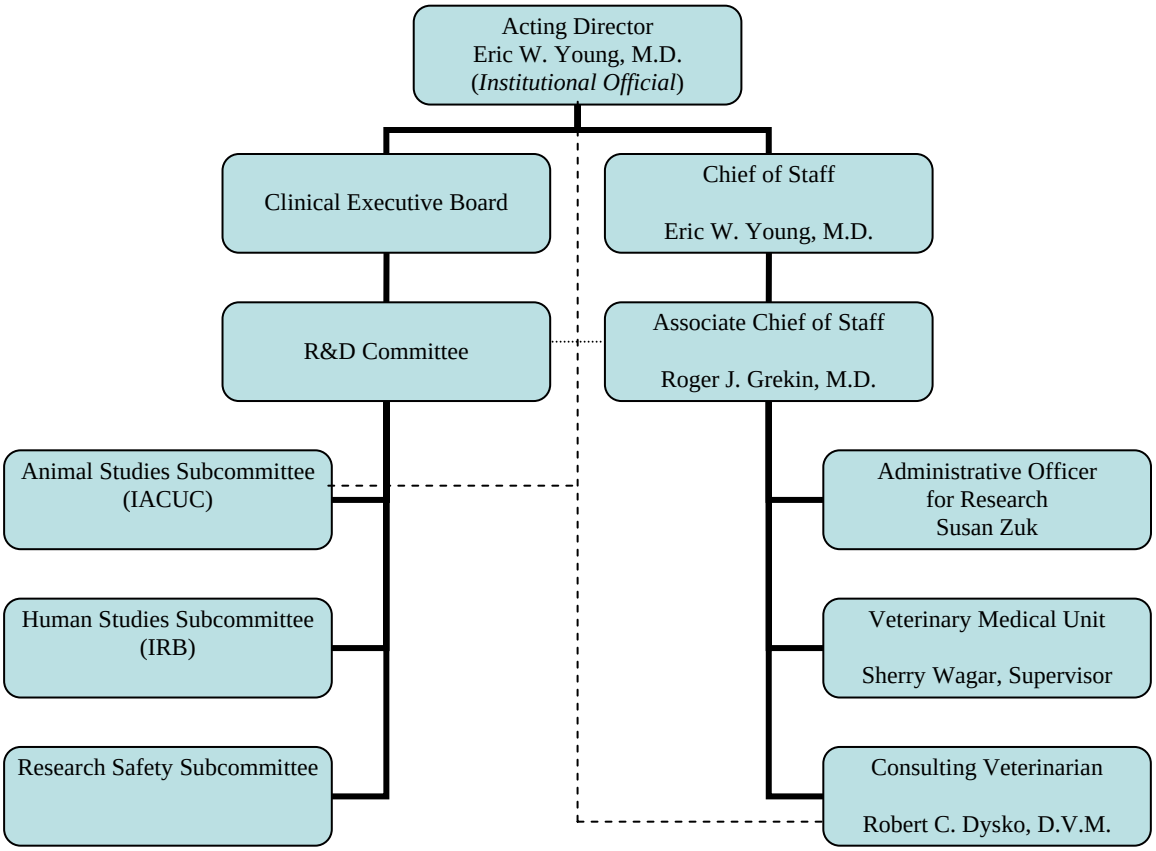
B. This institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."

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 as well as all other applicable laws and regulations pertaining to animal care and use.

D. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide).

III. INSTITUTIONAL PROGRAM FOR ANIMAL CARE AND USE

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



Notes:

1. As indicated above, there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.
2. Correspondence [e.g., meeting minutes, recommendations, reports, etc.] from the IACUC to the IO may be routed through administrative channels for informational purposes. However, such correspondence may not be influenced, changed, or delayed in any manner whatsoever.

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

Veterinarian: Robert Dysko

Qualifications:

Degrees: D.V.M., Iowa State University, 1983; Diplomate, American College of Laboratory Animal Medicine, 1987.

Experience: Dr. Dysko has 24 years of experience in laboratory animal medicine. He currently serves as Associate Professor of Laboratory Animal Medicine and Associate Chair, Unit for Laboratory Animal Medicine (ULAM), University of Michigan.

Authority: Dr. Robert Dysko has direct program authority and responsibility for the Institution's animal care and use program including the authority to implement the PHS Policy and the recommendations of the Guide..

Percent of Time Contributed by the Veterinarian: Dr. Dysko is present at the Institution an average of approximately 3 hours per month. 100 percent of this time is contributed to the animal care and use program. In addition Dr. Dysko contributes on average approximately 10 hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

Provisions for Backup Veterinary Care: The VA Ann Arbor Healthcare System contracts with the University of Michigan Unit for Laboratory Animal Medicine (ULAM). Weekday backup for Dr. Robert Dysko consists of the veterinary resident assigned to the VA facility. If the resident is unavailable, then back-up support is to be offered by the Director of ULAM, Dr. Howard Rush. In addition, weekend, holiday and evening schedules are established to ensure that a veterinarian is always available for emergencies. There are six veterinary residents and seven faculty veterinarians who rotate on the emergency call schedule for the VA facility. Veterinary care can be obtained 24 hours a day, 365 days a year, by contacting the University of Michigan Unit for Laboratory Animal Medicine.

C. The Institutional Animal Care and Use Committee (IACUC) at this Institution is properly appointed in accordance with the 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 five members, and its membership meets the compositional 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, profession, titles or specialties, and institutional affiliations (**Attachment A**).

D. The IACUC will:

1. Review at least once every six months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows: The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare), and the VHA Handbook 1200.7 – Use of Animals in Research, as a basis for the review. To facilitate the evaluation, the Committee will use a standard VA checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation will include, but not necessarily be limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); and e) Occupational Health and Safety. In addition, the evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded from participating in any portion of the reviews.

2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows: At least once every six months the IACUC will visit all of the institute's facilities where animals are housed or used, i.e.,

holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals is also inspected. The Committee uses the Guide and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) and the VHA Handbook 1200.7 – Use of Animals in Research, as a basis for the review. To facilitate the evaluation, the Committee will use a standard VA checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel. No member will be involuntarily excluded for participating in any portion of the inspections. At least two members of the IACUC conduct the inspection as delineated above.

The inspection is conducted by at least two Subcommittee members. Generally, the Veterinary Medical Consultant, the Supervisor of the Veterinary Medical Unit, Administrative Officer for Research, the Animal Studies Coordinator, and any other available Subcommittee member are in attendance. The team has available the report from the last inspection to document that corrections from the previous inspection have been completed. After completing the facility inspection, the team meets to discuss deficiencies and necessary corrective action(s). No member is involuntarily excluded from participating in any portion of the inspection.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy at IV.B.3. and submit the reports to the VA Central Office through the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows: Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using a standard VA format that is based the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website. The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy, identify specifically any departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Since the institution is accredited by AAALAC International the report will identify those facilities as such. Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will reflect such. The completed reports will be submitted to the R&D Committee and the Institutional Official in a timely manner, but generally within 30-60 days. After the report is forwarded to the Research and Development Committee and the Institutional Official for review and approval, a copy is submitted to VA Central Office.

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

Information is posted throughout the Veterinary Medical Unit providing instructions for reporting concerns involving the care and use of animals at this institution. Concerns raised will be discussed at the regularly scheduled meetings. Special meetings may be convened if matters of sufficient seriousness arise. Individuals may also contact the Animal Hotline at the University of Michigan to report concerns. The University refers concerns regarding VA-housed animals to the veterinarian assigned to the VA and the supervisor of the Veterinary Medical Unit (or if appropriate, the VA Animal Studies Coordinator or Chair of the Subcommittee on Animal Studies). These concerns will be reviewed by the Subcommittee on Animal Studies. As warranted, non-compliance would be reported by the Institutional Official (Medical Center Director) to VA Central Office (VACO), Office of Research Oversight (ORO), AAALAC, and OLAW. All employees are protected by the Department of Veterans Affairs Whistleblower Protection Policy as outlined in the Employee Handbook.

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:

Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee. The Committee's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter. Such documents are reviewed and approved by the Committee and then submitted through the R&D Committee to the IO.

Notes:

1. As noted in Part III.A. above, once IACUC meeting minutes and recommendations are approved by the IACUC, they must be forwarded without revision, alteration, or delay to the IO.
2. As delineated in Part III.A. above, there exists direct and open lines of communication between the IACUC and the IO. If deemed to be warranted, the IACUC may submit recommendations directly to the IO.

6. In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals. The IACUC procedures for protocol review are as follows:

Prior to the review, each IACUC member receives a copy of the full protocol that will be reviewed at the upcoming monthly IACUC meeting. One committee member is designated to lead the discussion for a Full Committee Review (FCR). If minor modifications are required after initial FCR, the protocol may subsequently go to Designated Member Review (DMR). At least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to approve, require modifications in (to secure approval) or request full committee review of those protocols. If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. If FCR is requested, approval of those protocols may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present.

Generally, the FCR method will be used. However, should a situation warrant it, the institution or IACUC may want to use the designated-member review (DMR) method. In such instances the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR; records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after 3 business days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.

Approval of required modifications. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:

1. FCR or DMR following the procedures delineated above.
2. Alternatively, DMR may be used if such is approved by all members present at the properly convened meeting at which the required modifications are developed and delineated AND if the entire current Committee has previously approved and documented a policy of using DMR for required modifications. Provided, however, that if any member calls for FCR of the modifications such modifications can only be reviewed and approved by FCR.
3. Minor modifications of an administrative nature, i.e., correcting typographical or grammatical errors, or obtaining required signatures, etc. may be confirmed by IACUC administrative/support personnel.

No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Note: Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. Further, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.

b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.

d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.

f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

7. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows: Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph III.D.6. above.

Examples of changes considered to be significant include, but are not limited to:

a. Change in principal investigator
b. Change in study objective/goals
c. A large increase in the number of animals approved by the Subcommittee (>10%)
d. Any procedure that has the potential to increase pain/distress
e. New or additional procedures, especially those that involve more than momentary restraint, or other surgical or invasive procedures not listed in the approved protocol
f. Significant food/water restrictions (not routine fasting)
g. Increase in bleeding volumes or time points
h. Change in frequency of observations for morbidity (decrease)
i. Change in dose volume of experimental materials (increase)
j. Change in dose route (i.e., changing from IP to IV infusion)
k. Change in dose frequency (increase)
l. Change in experimental vehicle or adjuvants
m. Change in animal housing or husbandry
n. Change in experimental end point (longer duration of study)
o. Addition of hazardous agent (requires review & approval by Subcommittee on Research Safety)
p. Change in method of euthanasia
q. Extension of the study
r. Change in method of anesthesia, sedation or analgesia

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 committee 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 as follows: A written summary of the committee deliberations and decisions, signed by the chair, will be forwarded to each investigator. If a proposal is reviewed outside a scheduled meeting, the primary reviewer will prepare a summary of committee comments

and required modifications. A memorandum is prepared by the Animal Studies Coordinator, signed by chair, and forwarded to the investigator. The IACUC minutes are forwarded to the R&D Committee for review and approval. The R&D Committee will document its review of the Subcommittee minutes in the R&D Committee's minutes and forward them (with Subcommittee minutes attached) to the Chief of Staff and Institutional Official for final approval.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy at IV.C. 1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows: All ongoing activities are monitored continuously by the animal care and use staff.

The Research Administrative Office maintains a computer database of approval dates. Approximately three months before the one-year deadline, investigators are sent a notice reminding them that they are due for either continuing/annual review or three-year renewal. The investigators are required to return a Request for Continuing Review Form. The forms and the associated protocols are reviewed by a member or members of the IACUC at least annually. Annual protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.

Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review. If activities require continuation beyond the expiration date, a new protocol must be submitted, reviewed, and approved <u>prior</u> to the expiration date as described in Paragraph III.D.6. above

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

The Subcommittee may suspend an activity that it previously approved if the Subcommittee determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the *Guide*, the PHS Policy, the VA's Assurance, or VA policy. The Subcommittee may suspend an activity only after review of the matter at a convened meeting of a quorum of the Subcommittee and with the vote for suspension by a majority of the quorum present. The R&D Committee, Chief of Staff, or Director cannot overrule a decision by the Subcommittee on Animal Studies to suspend an activity. If the Subcommittee suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Assurance, the Institutional Official (Director) in consultation with the Subcommittee shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to VACO, ORO, AAALAC, and OLAW.

E. The Occupational Health and Safety Program for personnel working in laboratory animal facilities or have frequent contact with animals is as follows: The Employee Health Service administers the VA health program for the VMU and VA personnel. The health program for personnel who work in the animal facilities or have frequent contact with animals is as follows:

1. <u>Administration and Records</u> – The program is administered and supervised by the

Employee Health Service (EHS) and covers all personnel involved in animal care and/or use, and anyone with the need to enter areas where animals are housed or used. The EHS cooperates with the various departments and units in scheduling examinations and in treating employees covered by the program. The EHS has developed a pre-employment health questionnaire and physical screening form. This form is completed annually by all VA Employees with risks associated with the use of animals, including Veterinary Medical Unit staff, investigators, laboratory technicians, and students, and also includes engineering and maintenance personnel, custodial staff, and consultants. Implementation of this program will not alter the present handling of Workmen's Compensation injuries and related medical problems through the VA Ann Arbor Healthcare System.

2. Pre-employment and Initial Procedures – Specific procedures required for the Occupational Safety and Health Program for the animal facility are dependent upon the degree and type of exposure to laboratory animals as well as the nature of the work being done. The following table summarizes suggested procedures for four risk categories. Additional risk categories may be added by the Medical Center:

Risk Category	**Definition**	**Pre-Employment Physical**	**Annual Question-naire**	**TB Skin Test or Chest Radio-graph**	**Rabies Vaccine or Sero-logy**	**Tetanus Toxoid**	**Pre-Employment and Annual Serum Banking**	**Toxo-plasma Serology**	**Rubeola Vaccine**	**Q Fever Vaccine**
1	Exposure to rodents or rabbits	++	++	o	o	++	o	o	o	o
2	Exposure to Carnivores (dog, cat, ferret)	++	++	o	+++	++	o	F + M o	o	o
3	Exposure to ruminants	++	++	o	+	++	o	o	o	+
4	Exposure to Primates	++	+++	+++	+	++	+	o	+	o

Key: **o:** Not ordinarily required.
+: May be advisable in some circumstances.
++: Usual practice.
+++: Essential component of an effective program.

M: Male
F: Female

3. Most Common Hazards and Risks Associated with the Use of Animals in Research – The hazards associated with the use of animals in research can be divided into three categories:

a. Physical Hazards - Examples include animal bites and scratches, sharps injuries, injuries associated with moving cages or equipment, and adverse consequences from excessive noise or accidental exposure to workplace . The key to preventing these injuries is proper training and meticulous attention to proper work practices.

b. Allergies - Allergic reactions are among the most common conditions that adversely affect the health of workers exposed to laboratory animals. Nasal symptoms, itchy eyes, and skin rashes are the most frequent manifestations, but in serious cases, asthma or

anaphylaxis can occur. Allergens include urine, dander, and saliva, especially from rodents. Controlling exposure to allergens is the most effective strategy for prevention.

c. Zoonotic Diseases - Zoonotic diseases are those that can be transmitted from animals (or animal tissues) to humans. Although there are a substantial number of animal pathogens that can cause disease in humans, zoonotic diseases are not common in modern animal facilities, largely because of successful efforts at prevention and detection. Unfortunately some infections of animals may produce serious disease in humans *even when the animals themselves show few signs of illness*. Therefore, you must be aware of possible consequences when working with each species of animal and take precautions to minimize the risk of infection.

4. Prevention - Common sense steps that can be taken to lessen the risk of contracting a zoonotic disease are as follows:.

a. Do not eat, drink, or apply cosmetics or contact lenses around animals.
b. Wear gloves when handling animals or their tissues.
c. To reduce the risk of needle stick injuries, consider sedating or anesthetizing animals if hazardous materials will be used, or if manual restraint is problematic.
d. Work in pairs whenever possible.
e. Do not recap used needles! Instead, discard them promptly in a biohazard "sharps" container.
f. When performing procedures such as bedding changes, blood or urine collections, or necropsies, work in biological safety cabinets or with specialized personal protective equipment.
g. Consult your supervisor, the Safety Officer, or Employee Health if you need additional training at any time.

5. Exposure Incidents – Employees who experience on-the-job injuries, bites, scratches or other exposure to possibly infectious animal secretions, will be seen by Employee Health (or ER when Employee Health is not available). The employee will be evaluated for potential pathogens and will be given first aid as necessary. Employees will be followed in Employee Health for any signs of infection or systemic disease.

6. Laboratory Allergies – Employees who develop allergies as a result of exposure to laboratory animals will be evaluated by Allergy Clinic for testing and treatment.

7. Training – Training on animal handling and care and zoonosis is provided by on-the-job training and attendance at the educational laboratory animal programs offered by the University of Michigan Unit for Laboratory Animal Medicine. It is also required that each person with animal contact utilize the website www.citiprogram.org and take the mandatory courses for animal studies training. If a person becomes pregnant, ill, or immunocompromised at any time, a consultation with Employee Health and their direct Supervisor is advised. In general, working with animals, working with hazardous agents, and/or toxic chemicals in particular is discouraged during pregnancy.

8. Personal Protective Equipment – Personal protective equipment (PPE) is provided for all animal caretakers. PPE provided includes caps, masks, gowns, gloves, eye wear, face shields, rubber boots, steel toed shoes, and ear protection. PPE is assigned to all appropriate areas.

F. The total gross number of square feet in each animal facility, the species housed therein and the average daily inventory, by species in each facility is provided below:

Laboratory, Unit, or Building*	Gross Square Feet (including service areas)	Species Housed in Unit (use common names)	Approx. Average Daily Inventory
Bldg 31, Level B	13,363	Mice	2224
		Rats	198
		Dogs	<1

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

IACUC Training - Each IACUC member will be provided with a copy of the following: 1) The PHS Policy for the Humane Care and Use of Laboratory Animals; 2) The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals; 3) The ARENA/OLAW IACUC Guidebook; and 4) A copy of this Assurance. x

All members of the IACUC will complete the Essentials for IACUC Members Curriculum located at the Collaborative Institutional Training Initiative website, www.citiprogram.org on an annual basis.

Note: Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting, MISMR meeting, or similar course is encouraged as an IACUC training session.

Animal Care and Use Personnel – The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: All personnel performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review. Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol. All persons involved in animal care and use will be required to attend an orientation session given by the Veterinary Medical Unit Supervisor, or other qualified individual(s), which covers general procedures for the Veterinary Medical Unit.

On-line training will be used in concurrence with in-house training. All personnel utilizing animals will complete the Working with the VA IACUC Curriculum, the species specific course, and the Post Procedure Care of Rodents Currciculum (if applicable) located at the Collaborative Institutional Training Initiative website, www.citiprogram.org. Online training modules include the laws and regulations covering laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's. The training includes information on research or testing methods that minimize the numbers of animals required to obtain valid results and limit

animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c). Approval and completion of on-line training will be documented.

Training in experimental methods, i.e., specific animal manipulations and techniques, will be conducted based on the types of research being conducted at the institution. Supplemental training is also provided by the University of Michigan, Unit for Laboaratory Animal Medicine regarding animal husbandry, animal handling, and species-related techniques workshops.

Note: For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu of some Institutional required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

IV. INSTITUTIONAL PROGRAM EVALUATION AND ACCREDITATION

All of this institution's programs and facilities for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with 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 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 and VA Central Office. Semiannual reports of IACUC evaluations will be maintained by the this Institution and made available to the OLAW upon request.

This Institution is Category One (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. 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 the Institutional Official, Director, VA Ann Arbor Healthcare System.

5. Records of accrediting body determinations.

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

C. All records shall be accessible for inspection and copying by authorized Office of Laboratory Animal Welfare (OLAW) or other PHS representatives at reasonable times and in a reasonable manner.

VI. REPORTING REQUIREMENTS

A. This Institution's reporting period is from January 1 – December 31. The IACUC, through the Institutional Official, will submit an annual report to OLAW on January 31 of each year. The report will include:

1. Any change in the accreditation status of the institution (e.g., if the institution's AAALAC accreditation is revoked), any change in the description of the Institution's program for animal care and use as described in this Assurance, or any change in the IACUC membership. If there are no changes to report, this Institution will provide 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 and submitted the evaluations to the Institutional Official, Director, VA Ann Arbor Healthcare System.

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 within the PHS policy.

2. Any serious deviations from the provisions of the Guide.

3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A.2 and VI.B. above shall include any minority views filed by members of the Animal Care and Use Committee.

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Eric W. Young, M.D.

Title: Acting Director (00)

Name of Institution: VA Ann Arbor Healthcare System

Address: 2215 Fuller Road
Ann Arbor, MI 48105

Phone: 734-845-5458

Fax: 734-845-3245

E-mail: eyoung@umich.edu

Signature:

Date:

B. PHS Approving Official

Name:

Title:

Address:

Phone:

Fax:

E-Mail:

Signature:

Date:

C. Effective Date of Assurance

D. Expiration Date of Assurance

VII. INSTITUTIONAL ENDORSEMENT AND PHS APPROVAL

A. Authorized Institutional Official

Name: Eric W. Young, M.D.

Title: Acting Director (00)

Name of Institution: VA Ann Arbor Healthcare System

Address: 2215 Fuller Road
Ann Arbor, MI 48105

Phone: 734-845-5458

Fax: 734-845-3245

E-mail: eyoung@umich.edu

Signature: Eric W. Young

Date: 3/9/09

B. PHS Approving Official

Eileen M. Morgan
Director, Division of Assurances, OLAW
National Institutes of Health
RKL1, Suite 360-MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Signature: Eileen M. Morgan

Date: 3/17/09

C. Effective Date of Assurance 3/16/09

D. Expiration Date of Assurance 3/31/13

A3756-01

Attachment A

MEMBERSHIP OF THE INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE DATE: March 5, 2009

NAME OF INSTITUTION: VA Ann Arbor Healthcare Ssytem
ASSURANCE NUMBER: A3756-01

Chairperson Name, Title, and Degree/Credentials	Business Address, Phone, Fax, and Email of Chairperson
Name*: Michael Olszewski	Address*: VA Ann Arbor Healthcare System - Research (11R) 2215 Fuller Road Ann Arbor, MI 48105
Title*: Research Biologist	

Degree/credentials*: D.V.M., Ph.D.	Phone*: 734-845-3439	Fax*: 734-845-3241	Email*: olszewsm@umich.edu

Name of Member/Code**	Degree/Credentials	Position Title	PHS Policy Requirements***
Michael Olszewski	D.V.M., Ph.D.	Research Biologist	Scientist
Tommy Burdette	x	Chaplain	Non-affiliated & Nonscientist
Robert Dysko	D.V.M., M.S., DACLAM	LAM Veterinarian	Veterinarian
Karen Hall	M.D.	Staff Physician/Geriatrics	Member
Thomas Marrow	Ph.D.	Neurophysiolgist	Scientist
Munmun Chartpadhyay	Ph.D.	Researcher, Neurology	Scientist
Sherry Wagnor	A.A., L.V.T., R.L.A.T.G.	Supervisor, Vet Med Unit	Member
Roger Grekin*	M.D.	Associate Chief of Staff for Research & Development	Nonvoting
Susan Zuk*	M.S.	Administrative Officer	Nonvoting
Catherine Kaczmarek*	B.S.	Program Support Assistant	Nonvoting
Scott Sample*	M.S.	Research Compliance Officer	Nonvoting

*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.
***PHS Policy Requirements - identify which IACUC members meet the four criteria below:

- Veterinarian (V) - a veterinarian with direct or delegated program responsibility.
- Scientist (S) - a practicing scientist experienced in research involving animals.
- Nonscientist (NS) - a member whose primary concerns are in non-scientific areas (e.g. ethicist, lawyer, member of the clergy).
- Nonaffiliated (NA) - 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 the interests of the general community in the proper care and use of animals and should not be a laboratory animal user. A consulting attending veterinarian may not be considered nonaffiliated.

Notes:

1. All members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Ad hoc or nonvoting members may be listed and identified as such, but are not considered members for the purpose of the PHS Policy, and do not contribute to a quorum.
2. If Alternate members are listed, identify for whom (by name or code number, not specialty) they will serve as Alternates.

OTHER KEY CONTACTS (OPTIONAL)

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

Name: Susan Zuk
Title: Administrative Officer, Research Service
Phone: (734) 845-3967
Fax: (734) 84503241
E-mail: susan.zuk@va.gov

Name: Catherine Kaczmarek
Title: IACUC Coordinator
Phone: (734) 845-3439
Fax: (734) 845-3241
E-mail: catherine.kaczmarek@va.gov