MEDICAL COLLEGE OF WISCONSIN

A3102-01

Animal Welfare Assurance for Domestic Institutions

I, David D. Gutterman, MD, as named Institutional Official for animal care and use at the Medical College of Wisconsin, 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. This Assurance covers only those facilities and components listed below.

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

This Assurance covers all branches and major components of the Medical College of Wisconsin.

B. The following are other institution(s), or branches and components of another institution:

This Assurance also covers the following affiliated organizations: Froedtert Hospital, Children's Hospital of Wisconsin, and the BloodCenter of Wisconsin's Blood Research Institute.

Investigators from these other institutions house animals primarily in the centralized animal facility of the Medical College of Wisconsin, although they may occasionally transport animals to labs located in these institutions in order to conduct procedures. As such, these institutions have agreed to accept the oversight of the Medical College of Wisconsin IO and IACUC for their animal use and comply with *PHS Policy*, the provisions of the *Guide for the Care and Use of Laboratory Animals* and the *Animal Welfare Act and Regulations*, as evidenced by letters from each institution.

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 *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) **Chief Executive Officer:** The President and CEO of the institution is John R. Raymond, Sr., MD.

2) **Institutional Official:** The Senior Associate Dean for Research, David D. Gutterman, MD, has been delegated in writing as the Institutional Official, with the authority to commit on behalf of the institution that applicable regulatory standards will be met. Dr. Gutterman reports directly to the Dean and Executive Vice President of the Medical College, who in turn reports directly to President Raymond.

3) **Institutional Animal Care and Use Committee:** The IACUC reports directly to Dr. Gutterman. In addition, the IACUC Office (support staff) is a unit within the Office of Research that reports to Dr. Gutterman and the Senior Department Administrator for the Office of Research.

4) **Attending Veterinarian and Animal Facility Management:** Joseph D. Thulin, DVM, MS, DACLAM, serves as both the Attending Veterinarian and the Director of the Biomedical Resource Center (BRC), which is the institution's organizational component charged with providing animal care and animal facility management. Dr. Thulin reports directly to Dr. Gutterman and the Senior Department Administrator for the Office of Research.

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

1) **Name: Joseph D. Thulin**

Qualifications:
- Degrees: DVM, MS, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Thulin received his DVM in 1988 and MS in Veterinary Pathobiology in 1990, both from the University of Illinois at Urbana-Champaign where he also completed a residency in Laboratory Animal Medicine. Dr. Thulin was certified by ACLAM in 1992. He has worked continuously in laboratory animal practice and management since 1988. He served on the AAALAC Council on Accreditation for 9 years and continues to conduct and participate in site visits as a Council Member Emeritus.

Authority: Dr. Thulin has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:
Dr. Thulin is a full time employee and devotes approximately 95% of his time to the support of the program.

2) **Name: Kenneth P. Allen**

Qualifications:
- Degrees: DVM, DACLAM
- Training or experience in laboratory animal medicine or in the use of the species at the institution:

  Dr. Allen received his DVM in 1999 from the Iowa State University. Following 2 years of private practice, he entered a residency in laboratory animal medicine at the University of Tennessee Health Science Center, which he completed in 2005. Following his residency, Dr. Allen joined the BRC as a Clinical Veterinarian. He attained board certification from ACLAM in 2007.

Responsibilities:
Dr. Allen holds the position of Staff Veterinarian in the BRC and reports directly to Dr. Thulin. His responsibilities include providing clinical and surgical veterinary services, supervising BRC technical and supervisory personnel, reviewing Animal Use Applications, and consulting with investigative staff.

Time contributed to program:
Dr. Allen is a full time employee and devotes approximately 90% of his time to the support of the program.

3) **Name: Eric S. Jensen**

Qualifications:
- Degrees: DVM
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
  Dr. Jensen received his DVM from the University of Wisconsin in 1994. Following 4 years of private small animal practice, he worked as a Clinical Veterinarian at Battelle Memorial Institute, Pharmaceutical Products and Development Division, in 1998 as a Clinical Veterinarian. In this position he provided clinical and surgical care to a wide variety of laboratory species and supervised technical personnel. Since 2002, he has been employed in the BRC.

Responsibilities:
Dr. Jensen holds the position of Staff Veterinarian in the BRC and reports directly to Dr. Thulin. His responsibilities include providing clinical and surgical veterinary services, supervising BRC technical and supervisory personnel, reviewing Animal Use Applications, and consulting with investigative staff.

Time contributed to program:
Dr. Jensen is a full time employee and devotes approximately 90% of his time to the support of the program.

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 is a list of the chairperson and members of the IACUC and their names, 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 *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

The Medical College of Wisconsin Animal Care and Use Program is evaluated twice per year during a convened meeting of a quorum of the IACUC, using the *Animal Welfare Regulations, PHS Policy,* the *Guide for the Care and Use of Laboratory Animals,* and our *Animal Welfare Assurance* as a basis for the evaluation. Information for this evaluation is gathered via a series of interviews with key program representatives conducted by IACUC subcommittees. All IACUC members are invited to participate in the semi-annual program review, with each subcommittee typically consisting of at least two IACUC members. A Program Review Checklist based on the Semiannual Program Review Checklist provided by OLAW is used as a guide during these interviews to ensure that the animal care and use program is evaluated thoroughly; aspects included in the evaluation are Occupational Health and Safety, our Veterinary Care Program, and our Training Program. All areas evaluated are rated as being Acceptable or having Minor or Significant Deficiencies; if deficiencies are noted, then a reasonable, specific action plan and time table for correction is determined.

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* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

Core animal facilities and other laboratories in which animal housing or surgical manipulations occur are evaluated twice per year during a convened meeting of a quorum of the IACUC, using the *Animal Welfare Regulations* and the *Guide for the Care and Use of Laboratory Animals* as a basis for the evaluation. Information for this evaluation is gathered via a series of inspections conducted by IACUC subcommittees or IACUC agents. All IACUC members are invited to participate in the semi-annual facility inspection, with each subcommittee typically consisting of at least 2 IACUC members. To facilitate the inspections, the IACUC uses the Semiannual Facility Inspection Checklist provided by OLAW as a guide. All areas inspected are rated as being Acceptable or having Minor or Significant Deficiencies; if deficiencies are noted, then a reasonable, specific action plan and time table for correction is determined. Laboratories where non-surgical activities occur are monitored throughout the year via random site visits and evaluations.

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:

Following evaluation of the Program Review and Facility Inspection, the IACUC Office compiles a report summarizing the results. The *Semiannual Report to the Institutional Official* template provided by OLAW is used as a guide in preparing the report, which typically includes a description of the nature and extent of the Medical College's adherence to the *PHS Policy,* the *Guide for the Care and Use of Laboratory Animals,* and the *Animal Welfare Regulations* (including a list of approved departures from the PHS Policy and the Guide along with reasons for each); minor and significant deficiencies in the animal care and use program; minor and significant deficiencies in the animal facility; schedule and plan for correcting deficiencies; minority views; AAALAC Accreditation status; and the signatures of a majority of IACUC members. The report is reviewed and approved during a convened meeting of a quorum of the IACUC and subsequently forwarded to the Institutional Official. During the time between Semi-Annuals, the Committee considers reports from the Attending Veterinarian and IACUC Office staff

regarding program status at each IACUC meeting. During these reports, deficiencies may be identified and then reported to the Institutional Official if necessary.

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

   As stated in Medical College policy, any individual may report concerns about the care, use or general welfare of animals used in Medical College research or teaching programs to any of the following:

   - MCW Compliance Reporting Line
   - Senior Associate Dean for Research
   - Director, Biomedical Resource Center
   - Any member of the IACUC
   - Any member of the IACUC Office Staff

   Upon notification of a concern, the IACUC Chair will form a subcommittee, typically including at least one veterinarian, to investigate the report. This subcommittee will investigate the concern by interviewing involved parties and reviewing applicable approved animal use applications and institutional policies. Following the investigation, the subcommittee will present its findings during a convened meeting of a quorum of IACUC members during which the results will be discussed and a plan of action recommended. This decision will be reported to the Institutional Official in writing, and if necessary, to applicable federal agencies.

   Instructions for reporting animal welfare concerns, including available mechanisms and contacts, are posted throughout the animal facility, as well as on the Medical College website.

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:

   The IACUC Office compiles reports summarizing the recommendations of the IACUC, primarily as part of the Semi-Annual Program Review and Facility Inspection, but also on an as-needed basis. Such reports are reviewed and approved during a convened meeting of a quorum of the IACUC and subsequently forwarded to the Institutional Official.

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 as follows:

   - Submission and Pre-Review
     The Animal Use Application (AUA) is submitted to the IACUC Office. An IACUC Office staff member evaluates the AUA for completeness. The completed AUA is then forwarded to the BRC veterinarians. A veterinarian conducts a pre-review of the AUA, communicating revision requests and consulting as deemed necessary with the investigator/submitter. Following the veterinary pre-review, the AUA is returned to the IACUC Office and processed for formal IACUC review by either the Designated Member Review (DMR) or Full Committee Review (FCR) processes. [Note: The veterinary reviewer may request FCR of the AUA when routing the AUA back to the IACUC Office.]

   - Designated Member Review (DMR)
     Prior to review by DMR, the AUA is made available to all IACUC members. Any member may call for review of the AUA at a convened meeting of the IACUC, i.e., Full Committee Review (FCR; see below). If no one calls for FCR, the IACUC Office staff typically assigns one Committee member to be the designated reviewer (DR) using a

rotation method approved by the IACUC Chair. In some cases, the Chair may personally assign the DR. The DR reviews the AUA and has the authority to approve, require modifications in (to secure approval) or request full committee review of the AUA; the DR may not withhold approval. In the event that more than one DR is assigned, all DRs will review identical copies of the AUA and a decision of approval will be unanimous among DRs.

- Full Committee Review (FCR)
  The IACUC requires review of an AUA at a convened meeting in the following circumstances:

  a) When any Committee member requests FCR.

  b) When the AUA involves any of the following:
    - Multiple major survival surgeries
    - Studies involving dogs, cats, nonhuman primates
    - Unalleviated pain
    - Death as an endpoint
    - Prolonged physical restraint
    - Substantial impairment of physical or physiologic function
    - Exceptions to the recommendations of the *Guide*.

  When FCR is required or requested, a primary and a secondary reviewer are assigned to evaluate the AUA prior to the convened meeting. In addition, AUAs scheduled for FCR generally are made available to all Committee members prior to the convened meeting. At the meeting, the primary reviewer presents his/her evaluation of the AUA, providing a brief overview of the project, issues identified during the review, and recommendations to the IACUC. Likewise, the secondary and veterinary reviewers are asked to comment. All Committee members then have the opportunity for discussion of the AUA. In cases where an IACUC member has a conflicting interest (e.g., is personally involved in the AUA), the member may be asked to provide information requested by the IACUC; however, the member is recused from the meeting during the deliberation on the AUA. Following deliberations, the Committee takes one of the following actions:

    - Approve.
    - Require modifications to secure approval with the modified AUA reviewed at a subsequent convened meeting.
    - Require modification to secure approval with the modified AUA reviewed by a DR assigned by the Chair, per a written IACUC standard that was approved via a unanimous vote of the Committee. In these cases, the DR holds the same authority as during the DMR process described above. The revised AUA submitted by the investigator is made available to all Committee members before the DR is permitted to take final action; any member of the IACUC may call for FCR during that time.
    - Withhold approval.

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 according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

   Proposed amendments to previously approved AUAs are submitted to the IACUC Office. The IACUC Office staff, in consultation as needed with the Chair, other Committee members, and veterinary staff, and consistent with guidance provided by OLAW and USDA/APHIS/AC, determines whether or the amendment is "significant" or "minor". Significant amendments are reviewed by the same process described above for AUAs.

Minor amendments, i.e., those amendments that do not involve increased risk to animal welfare or the potential for increased pain/distress, do not require IACUC review and are handled administratively and reported to the IACUC as a matter of information at the next regularly scheduled meeting. Examples of minor amendments include but are not limited to the following:

- Change in source of project funding
- Removal of study staff
- Addition of information about study staff training and experience

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:

Following approval by the IACUC, the investigator receives written documentation indicating that approval was rendered by the Committee. This documentation includes the AUA number, title, date of approval and date of renewal. If modifications are requested in order to secure approval, the nature of the changes requested is documented and forwarded to the investigator for response. The investigator's response to the written documentation is posted for all IACUC members to review through either FCR or DMR as described earlier. If the IACUC withholds approval, the investigator receives written documentation indicating that approval is being withheld. This documentation includes the AUA number, title, the date of the decision and a list of the reasons why the approval is being withheld. The investigator then has the opportunity to respond in person or in writing.

All IACUC deliberations and decisions are documented in Meeting Minutes which are made available to the Institutional Official.

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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

The procedure for review of 3-Year *de novo* Renewals is the same as that described for review of new animal use applications described in Item #6. The IACUC Office notifies investigators of upcoming renewals at 30-day intervals beginning at 90 days prior to the date of the required renewal.

In addition to a complete review every three years, brief continuing reviews ("Annual Renewals") for all AUAs are conducted on or about the first and second year anniversaries of the IACUC approval date. To ensure compliance with the provision of the Animal Welfare Regulations (9 CFR), those Annual Renewals involving USDA-regulated species are completed within 1-year intervals. Reviews of all Annual Renewals are conducted via the Designated Review process (without veterinary pre-review). The IACUC Office notifies investigators of upcoming renewals at 30-day intervals beginning at 90 days prior to the date of the required renewal.

In conjunction with the IACUC conducting the required periodic reviews of animal use submissions, the Medical College has implemented additional activities to augment the other aspects of the IACUC's on-going monitoring of the animal care and use program:

- An IACUC Office staff member performs recurring visits to and evaluations of all laboratories where animal usage occurs. This lab survey program is designed specifically to ensure conformance between the IACUC-approved animal activities and

those activities actually performed. New investigators are asked to complete a "self-assessment form" prior to the scheduling of an in-lab visit, and subsequent evaluations of the laboratories are based on in-lab visits. If survival surgery is conducted in the laboratory, a BRC veterinarian accompanies the IACUC Office staff member in order to observe and discuss with the lab staff surgical and anesthesia technique and peri-operative care of the animals.

- On approximately a weekly basis, an animal care supervisor or veterinary technician visits laboratories that are approved by the IACUC to house animals longer than 24 hours.

- During the time between semi-annual evaluations, the IACUC considers reports at each regularly scheduled meeting from the AV and IACUC Office staff regarding program status; if deficiencies are identified, they will be reported to the Institutional Official if necessary.

- An *ad hoc* "animal program compliance group" consisting of the IACUC Chair, IACUC Vice Chair, AV, IACUC Manager, and the Office of Research Senior Department Administrator meet typically at weekly intervals to discuss contemporary issues of import to the animal care and use program and to formulate actions plans for matters requiring follow up.

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:

Upon notification of a concern, the IACUC Chair will form a subcommittee, typically including at least one veterinarian, to investigate the report. This subcommittee will investigate the concern by interviewing involved parties and reviewing applicable approved animal use applications and institutional policies. Following the investigation, the subcommittee will present its findings during a convened meeting of a quorum of IACUC members during which the results will be discussed and a plan of action recommended; this plan may include suspension of the activity. The decision will be reported to the Institutional Official in writing and if necessary, to applicable federal agencies. In the case of a suspension of an activity, which occurs based on a majority vote of a quorum of the Committee, the IO in consultation with the IACUC will review the reasons for the suspension, take appropriate corrective action and report that action with a full explanation to OLAW.

E. 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:

1) **Control and Prevention Strategies**

The Occupational Health and Safety Program (OHSP) for personnel exposed or potentially exposed to animals is highly proactive and consists of continual hazard assessment carried out jointly by the Occupational Health Manager (OHM) and staff from the Environmental Health and Safety Office (EHS). Risk assessment is both animal species- and facility-based and contains training and health and environmental surveillance components. Physical, chemical and biological hazards in the vivarium are evaluated on a regular basis and conservative engineering and operational controls, as well as required Personal Protective Equipment (PPE), are implemented at all times to mitigate risk to employee health. All personnel (including visitors) who enter the animal facility are grouped by the OHM with respect to animal contact type and participate in the OHSP to the extent necessary to ensure that human health is not impacted in a negative manner through animal contact. As the animal husbandry staff log the most contact time with animals, safety and animal handling instruction for the staff is overseen by a full time

training manager for the BRC. The BRC Training Specialist recruits aid from the OHS and EHS staff as needed to provide the expertise required for all classes of safety training.

2) **Hazard Identification and Risk Assessment**
In addition to the IACUC, other safety committees review all proposed use of potentially hazardous agents in animals, including infectious agents, toxins, recombinant DNA, hazardous chemicals, or radioisotopes as dictated by hazardous material use. Written approval from each committee is required before the animal project can start. The safety committees evaluate the research methodology for adherence to regulatory requirements and accepted standards and guidelines for safety. Upon safety committee approval, the IACUC is notified of the approval and all associated safety protocol documentation, including subcommittee review details, is made available to the IACUC.

After IACUC and safety committee approval but prior to implementation of an AUA involving the housing of animals exposed to hazardous agents, the investigator is required to have a hazard communication meeting with the BRC staff, at which time proper precautions in the care of the animals, personal protection, disposal of animal waste and carcasses, etc. are discussed. Staff from the Environmental Health and Safety Office is invited to this meeting to ensure that the final protocol takes into account all hazardous aspects of the proposed work.

A representative Occupational Health Services is invited to attend IACUC meetings as necessary.

3) **Facilities, Equipment, and Monitoring**
All research projects that involve the use of hazardous agents are normally conducted in the BRC biocontainment suites or other approved and secure facilities at MCW. Only authorized personnel are granted card access to these areas. The biocontainment suites are physically isolated from all other facilities and labeled as to the type of hazard in use and requirements for entry. The ABSL-2 and -3 suites incorporate numerous integrated engineering controls designed to reduce occupational exposure to hazardous substances. These engineering controls include single pass directional air flow into animal rooms (twice HEPA-filtered prior to exhaust in ABSL-3), Class 100 cage changing stations to reduce routine exposure to animal allergens in bedding and Class II Type B1 biological safety cabinets which act as primary containment for infectious and toxic particulate sources such as inoculated animal bedding and contaminated animal dander. Disposable booties/gloves and good hand hygiene are used in animal areas to limit inadvertent dissemination of hazards from 'dirty' areas to 'clean' areas. Infectious and hazardous waste is stored temporarily in double-bagged closed containers and disposed of via a licensed biohazardous or hazardous waste hauler as applicable.

4) **Personnel Training**
During the first week of employment, new employees who will be working with animals are provided an educational program to inform them about zoonoses, personal hygiene and other considerations regarding occupational health. Additional information is provided to employees on an on-going basis through the BRC in-house training program, BRC Standard Operating Procedures, BRC website and staff meetings. Specific zoonotic training is conducted by Occupational Health Services and is determined by the animal species to which an individual will be exposed (e.g. Q-fever for ungulates). EHS staff conducts occasional animal safety training sessions during staff meetings, as well as agent-specific training during hazard communication meetings. All employees who are authorized to work in ABSL-3 space must attend annual BSL3/Select Agent training carried out by OHS, EHS and Public Safety staff. BRC staff members that may be required to wear hearing protection are trained annually.

BRC staff members receive annual training by Occupational Health on hazardous agents, ergonomics, proper immunizations, universal precautions and zoonotic diseases. Lab staff

and BRC staff also receive annual training in the use of ABSL-2, ABSL-3 and ABSL-3 enhanced agents. BRC staff members receive biennial training on hazardous waste disposal.

The qualifications of research investigators and technical staff are reviewed as part of the protocol approval process. BRC staff is trained to appropriately handle animals and waste for projects that involve hazardous agents. When deemed appropriate by the safety committee, investigators may be required to obtain training for working with specific hazardous agents by visiting and training in the laboratory of an individual experienced in working with the agent. This training may require travel to another institution.

5) **Personal Hygiene**

Protective clothing including uniforms, gowns, rubber boots, safety shoes, caps, masks, gloves, safety glasses and respirators are provided for use in animal rooms when required by the risks associated with the work assignment. Work clothing is provided for all BRC personnel. BRC technical staff and animal care supervisors wear non-disposable scrubs, safety shoes, and protective eyewear as their base work attire. They don additional items, e.g., gowns, disposable gloves, respirators, etc., as required for particular agents and rooms. All BRC personnel who work with animals are trained, medically evaluated, and fitted for a N95 respirator at time of hire and annually thereafter. A laundry service provides facilities for laundering scrubs and lab coats.

Shower and change facilities for animal care personnel are located in the BRC. Some small animal holding rooms and most large animal holding rooms or anterooms have a sink, and personnel are encouraged to wash their hands when leaving the animal room. BRC personnel must wear scrubs that are left in the facility at the end of each workday. Staff is trained during ABSL-2 class to wash their hands prior to exiting an ABSL-2 animal housing room.

BRC personnel are not required routinely to change out of their work attire in order to leave the animal facility for breaks/meals, to attend training sessions, etc. However, if the scrub uniform is worn when leaving the animal facility, a clean, dedicated, light-blue lab coat must be worn over the scrubs and be fully buttoned. The veterinarians and other staff who wear white lab coats for use in the facility are not permitted to wear those lab coats outside of the animal facility.

Principal investigators are required to provide research staff with personal protective equipment (PPE) and safety equipment as required by safety committee review for inoculation and monitoring of animals during study procedures. Minimum ABSL-2 PPE requires a disposable gown and gloves, with eye protection required for any procedures that pose a splash or spray hazard, with additional PPE required in an agent-specific manner. The BRC provides approved sharps and hazardous waste containers throughout the facility to expedite immediate disposal of used sharps and solid waste. All ABSL-3 work requires disposable scrubs and gown, two pairs of booties and gloves, hair bonnet and respiratory protection to enter an agent room. A Powered Air Purifying Respirator (PAPR) with High Efficiency Particulate Air (HEPA) filtration use is mandated for aerosol inoculation of animals with Risk Group 3 agents, as well as in any spill response scenario where a particulate may be generated. Non-disposable outer clothing is not allowed into agent rooms of the ABSL-3 facility.

6) **Animal Experimentation Involving Hazards**

Initial risk assessments for research activities on-site are performed by Principal Investigators in collaboration with the Environmental Health and Safety (EHS) Office, and Office of Research staff. Protocol review is carried out by hazard-specific committees, which are administered by the Office of Research and staffed by subject matter experts. Review by the appropriate safety committee must be completed prior to final approval by the IACUC. To ensure that complex activities involving the use of multiple hazardous

agents in one animal and that multidisciplinary safety and environmental health issues are addressed in a timely manner, cross-membership of veterinary, safety and Occupational Health staff among individual committees is utilized.

The EHS Office, in association with the OHS and veterinary staff, have adopted standard operating procedures for safety precautions when using common hazardous agents such as human cell lines and selected chemical agents in research animals. These written procedures are maintained on the EHS intranet site, can be accessed by all employees, and are used as guides by principal investigators during the design of hazardous materials work in animals.

7) **Personal Protection**

All new employees undergo general laboratory safety training. The training includes: the identification of potentially dangerous, health-affecting agents in the workplace; the nature of the hazardous effects which may result from accidental exposure or over dosage; the precautions to take in handling hazardous agents; and the procedures for emergency treatment in the event of accidental exposure. In addition, all BRC employees receive instruction in zoonotic diseases; handling projects that involve the use of hazardous agents; material safety data sheets; and emergency response procedures including hazmat spill response.

In addition, the MCW Occupational Health Service and EHS staff members provide job-specific training seminars to the BRC personnel periodically, review injury/illness issues, and discuss ways to minimize future injury/illness incidents.

8) **Medical Evaluation and Preventive Medicine for Personnel**

The Occupational Health Program for all BRC personnel consists of the following: a pre-placement physical examination and medical history including an allergy assessment; PPD skin test or its equivalent; Tetanus/Diphtheria booster if more than 5 years since last booster; measles titer and vaccination if indicated; Lyme Disease titer; toxoplasmosis titer; Q fever titer; and additional vaccines as indicated, such as Hepatitis B vaccine, are provided at the time of hire. During employment, all personnel have their Lyme titer checked annually; Tetanus/Diphtheria is boosted every 5 years.

The Occupational Health Program for other MCW personnel with laboratory animal contact consists of the following: an allergy assessment; appropriate education in the form of informational handouts and counseling; and immunization with tetanus and diphtheria vaccine according to accepted recommendations is provided at the time of hire.

During employment all participants are revaccinated and serologically monitored as indicated.

The MCW Occupational Health Service conducts a risk assessment for individuals who do not work directly with animals but must enter the BRC facilities. Those individuals who are considered transient are informed of the risk of animal allergens and are offered an opportunity to enroll in the program. For all others a risk assessment questionnaire is completed by the individual and faxed or emailed to the Occupational Health Office for evaluation. If Occupational Health determines that the individual may be at risk, an appointment is scheduled immediately for further evaluation with a referral to the MCW Allergy Clinic if indicated. Occupational Health Services, the BRC, IACUC Office, and the safety committees work cooperatively to monitor the program. Periodic risk assessment is conducted at yearly intervals to determine health surveillance requirements.

An educational program to inform personnel about zoonoses, personal hygiene and other considerations regarding occupational health is achieved through the BRC in-house training program, BRC Standard Operating Procedures, staff meetings and the NRC Occupational Health and Safety in the Care and Use of Research Animals manual.

Protective clothing including uniforms, gowns, sleeve extenders, rubber boots, caps, masks, gloves, safety glasses, safety shoes and respirators are provided for use in animal rooms when required by the work assignment. Victims of on-the-job injuries such as animal bites and scratches are provided medical treatment on site at MCW Occupational Health Services or Froedtert Hospital Emergency Department (a Level 1 Trauma Center). The emergency room staff at Froedtert Hospital maintains a worksheet of all pathogenic/toxic agents in use at the Medical College, with associated OHS-mandated post exposure prophylaxis (PEP) protocols for occupational exposures off hours. All employees are urged to report any overt or potential exposures to hazardous substances via a web-based Accident/Injury Report Form maintained by OHS. OHS and EHS staff carries out incident investigation if warranted, as well as any required clinical work-up as dictated by the original approved research protocol and any applicable Occupational Health policies.

9) **Special Precautions for Personnel working with Nonhuman Primates**
There are currently no AUAs involving the use of nonhuman primates at the Medical College. However, should that status change, individuals with nonhuman primate contact would receive the same services as all other participants of the Occupational Health Program plus the following: physical exam, tuberculin skin testing or its equivalent (employees who are determined to be tuberculin converters will be advised to avoid any contact with nonhuman primates until they have received appropriate medical treatment), chest x-rays (employees working with nonhuman primates who, on initial examination or subsequent testing, are found to be tuberculin converters, will have a chest x-ray at the time of the first significant reaction, and when clinically indicated), Hepatitis A vaccinations if offered, Rubella titer and vaccination if indicated. Participants working with nonhuman primates are routinely recalled annually for tuberculin skin testing. Those individuals who are documented tuberculin converters will receive a symptoms survey annually. Additional information, including a detailed protocol for Herpes B exposure, is provided to all employees working with old world nonhuman primates. In addition, the Herpes B exposure protocol is reviewed with the Medical College Emergency Department faculty on a periodic basis.

F. 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.

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

1) **Core Certification**
All individuals from institutions covered by this Assurance and who work with animals, (e.g. study personnel on AUAs, veterinary staff, and training staff members in the BRC) are required to complete a set of core training requirements. These requirements include attendance at an Animal Care and Use Program Orientation (ACUPO) and completion of the American Association of Laboratory Animal Science (AALAS) Learning Library course entitled *Working with the IACUC: Non-VA version*.

The base ACUPO is a seminar conducted jointly by BRC and IACUC Office staff members. The orientation is designed to impart knowledge and understanding of principles of humane care and use of animals, the working relationship between the BRC and the IACUC, the implementation of AWAR, PHS Policy and the Guide within the Medical College program, and the attendees' institutional and personal responsibilities. Orientation topics include: overall goal of the Medical College Animal Care and Use Program, program oversight and organization, IACUC review and approval processes, non-compliance and

its consequences, how to report animal welfare concerns, organization of the BRC, BRC services and function, animal husbandry, veterinary care and oversight, animal ordering and tracking, safety precautions, and our training program. Attendance at the orientation is documented and only individuals who have completed the program are permitted to procure and handle animals. Refresher orientation is required at 3-year intervals.

The AALAS Learning Library course entitled *Working with the IACUC: Non-VA version* is an online course designed to provide knowledge about several key components to animal research, including but not limited to, the regulations that govern the use of animals in research and teaching, the 3 R's (Replacement, Reduction and Refinement) and how to apply them, how to avoid unnecessary duplication of research, and ways to minimize pain and distress to the animals.

In addition, individuals from institutions covered by this Assurance and who work with animals are required to provide documentation of ongoing continuing education (CE), typically on an annual basis.

2) **Other Training for Personnel Involved in the Care and Use of Animals**

a) The BRC provides training opportunities to the MCW research community on a wide variety of topics related to animal use and care, using a number of venues.

- For investigative personnel, the BRC provides practical training in a number of animal procedures/practices such as animal handling, restraint, basic biomethodology, anesthesia, analgesia, and surgical/surgical support techniques. Most frequently, the training is provided ad hoc to individuals and small groups; however, formal laboratory sessions are offered occasionally as well.

- Seminars/special topics lectures and wet labs are provided on a wide variety of topics several times per year. Topics have included pain and distress in animals, public perception of basic science research, cryopreservation of mouse embryos, breeding scenarios and recordkeeping, basic rodent surgery techniques, and animal diets and their effect on research.

- The BRC also maintains a website that provides a wide variety of information pertaining to the use and care of animals at the Medical College.

b) The IACUC Office within the Office of Research provides training opportunities to the Medical College research community on a wide variety of topics related to regulatory concerns and animal research.

- The IACUC Office offers a core curriculum of in-house training sessions designed to provide practical information about the overall animal program at the Medical College of Wisconsin and tips for working with the IACUC. These sessions, collectively entitled *IACUC Essentials*, include modules on the following topics: *Submitting a More Effective Animal Use Application, Post Approval Monitoring, Semi-Annual Program Reviews and Facility Inspections, Animal Research Training Requirements and Guidelines, Conducting a Literature Search, the MCW PHS Assurance, Grant to AUA Comparisons,* and *The Eighth Edition of the Guide.*

- In addition, the IACUC Office maintains an internal website to provide information to the Medical College research community, highlighting current research events, addressing frequently asked questions, and providing guidance regarding federal regulations, institutional standards, and the AUA approval process.

3) **IACUC Member Training**

All IACUC members are required to complete and maintain a core set of requirements. Initially, each member attends the Animal Care and Use Program Orientation, completes two (2) American Association of Laboratory Animal Science (AALAS) Learning Library courses (*Essentials for IACUC Members* and *Working with the IACUC: Non-VA version*), and attends an in-house IACUC Orientation. The IACUC Orientation is designed to explain the expectations of a Medical College IACUC Member as well as how the federal regulations and institutional standards are implemented at the Medical College. In addition, all members receive copies of the following: *Animal Welfare Act/Regulations*, *PHS Policy*, *Guide for the Care and Use of Laboratory Animals*, USDA Animal Care Policies, AVMA Guidelines for Euthanasia, PHS Assurance, IACUC Guidebook, and *What Investigators Need to Know* brochure.

In addition, IACUC members are required to provide documentation of ongoing continuing education (CE), typically on an annual basis. The IACUC periodically sets aside portions of the regularly scheduled meetings or schedules special meetings for continuing education for its members.

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, David D. Gutterman, MD.
   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 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, David D. Gutterman, MD.
   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 should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: David D. Gutterman, MD	
Title: Senior Associate Dean for Research	
Name of Institution: Medical College of Wisconsin	
Address: 8701 Watertown Plank Road Milwaukee, WI 53226	
Phone: 414-955-8495	Fax: 414-955-6565
E-mail: dgutt@mcw.edu	
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: [signature]	Date: 10/25/13

B. PHS Approving Official	
Venita B. Thornton, D.V.M., M.P.H. **Senior Assurance Officer, Division of Assurances** **Office of Laboratory Animal Welfare (OLAW)** **NIH/OD/OER** **6705 Rockledge Drive** **RKL 1, Suite 360-MSC 7982** **Bethesda, Maryland 20892-7982** **thorntov@od.nih.gov**	
Signature: Venita B Thornton	Date: Oct. 31, 2013
Assurance Number: A3102-01	
Effective Date: Oct. 31, 2013	Expiration Date: Oct. 31, 2017

VIII. Membership of the IACUC

Date: October 2013	
Name of Institution: Medical College of Wisconsin	
Assurance Number: A3102-01	

IACUC Chairperson

Name*: Bryon D. Johnson	
Title*: Professor, Pediatrics/Hematology/Oncology	Degree/Credentials*: PhD
Address*: 8701 Watertown Plank Road Milwaukee, WI 53226	
E-mail*: bjohnson@mcw.edu	
Phone*: 414-955-4123	Fax*: 414-955-6565

IACUC Roster

Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Scientist 1	PhD	Professor, Pharmacology & Toxicology	Scientist
Joseph D. Thulin	DVM, MS, DACLAM	Animal Facility Director; Attending Veterinarian	Veterinarian
Veterinarian 1	DVM, DACLAM	Staff Veterinarian	Veterinarian
Scientist 2	MD	Assistant Professor, Surgery/Surgical Oncology	Scientist
Scientist 3	PhD	Director of Core Laboratories	Scientist
Scientist 4	PhD	Assistant Professor, Pediatrics/Allergy	Scientist
Scientist 5	MD, PhD	Associate Professor, Dermatology	Scientist
Scientist 6	DVM, PhD	Professor, Medicine/Gastroenterology	Scientist
Scientist 7	PhD	Professor, Cell Biology, Neurobiology & Anatomy	Scientist
Scientist 8	PhD	Associate Professor, Physiology	Scientist
Scientist 9	PhD	Associate Professor, Medicine/Gastroenterology	Scientist
Scientist 10	PhD	Assistant Professor, Pediatrics/Developmental Biology	Scientist
Non-Scientist 1	JD	Attorney	Non-Scientist
Non-Affiliated 1	N/A	Retired Small Business Owner	Non-Affiliated

Alt 1-Veterinarian	DVM	Staff Veterinarian	Alternate, Veterinarian
Alt 2-Scientist	PhD	Assistant Professor, Physiology	Alternate, Scientist
Alt 3-Scientist	PhD	Associate Professor, Pharmacology & Toxicology	Alternate, Scientist
Alt 4-Scientist	DVM, PhD	Associate Professor, Anesthesiology/Research Support	Alternate, Scientist
Alt 5-Scientist	PhD	Assistant Professor, Microbiology & Molecular Genetics	Alternate, Scientist
Alt 6-Non-Affiliated	DVM	Graduate Student/ Relief Vet at Emergency Clinic	Alternate, Non-Affiliated Member

* 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 — a 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 — a practicing scientist experienced in research involving animals.

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

Nonaffiliated — an 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.

IX. Other Key Contacts (optional)

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

Contact #1	
Name: Sandra L. Jensen, M.S., RLATG, CPIA	
Title: IACUC Manager	
Phone: 414-955-8223	E-mail: sjensen@mcw.edu

X. Facility and Species Inventory

Date: October 2013			
Name of Institution:	Medical College of Wisconsin		
Assurance Number:	A3102-01		
Laboratory, Unit, or Building*	Gross Square Feet [*include service areas*]	Species Housed [*use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog*]	Approximate Average Daily Inventory
Facility 1	65,600	Mice	23,915
		Rats	4,600
		Zebrafish	12,400
Facility 2	35, 928	Mice	2,815
		Rats	1,115
		Cats	0
		Chinchillas	2
		Dogs	0
		Goats	3
		Ground Squirrel	1
		Guinea Pigs	13
		Hamsters	0
		Pigs	1
		Rabbits	2
		Sheep	0
		Zebrafish	30,000

*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.