

**Charles River Laboratories**  
**Research Models and Services**  
D16-00496 (A3863-01)

## **Animal Welfare Assurance for Domestic Institutions**

I, James C. Foster, as named Institutional Official for animal care and use at Charles River Laboratories, Research Models and Services (CR-RMS), provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy). I have given signatory authority to Kathleen A. Murray, DVM, MS, DACLAM, Executive Director, Global Preclinical LAM to sign OLAW documents (annual report, interinstitutional agreements) when I am absent from the office.

### **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, DHHS, and/or NSF (if applicable). 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:  
Charles River Laboratories Research Models and Services: all activities as defined above that take place in the facilities located in Wilmington, MA, Cambridge, MA, Shrewsbury, MA, Kingston, NY, Hollister, CA, San Diego, CA, Raleigh, NC, and Frederick, MD.
- B. The following are other institution(s), or branches and components of another institution:  
Not applicable

### **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:

James C. Foster is the Chairman, President, CEO and Institutional Official.

Allison M. Williams, D.V.M., DACLAM, Director, Veterinary & Professional Services, is the Attending Veterinarian for all sites with the exception of two business units. Bernard M. Flynn, D.V.M., DACLAM, Divisional Director, CR Insourcing Solutions Government Operations is the Attending Veterinarian for the Insourcing Solutions business unit facility located in Frederick, MD. Sera K. Mallette, D.V.M., Sr. Staff Veterinarian, Charles River Massachusetts (CR-MA) is the Attending Veterinarian for the Discovery and Safety Assessment business unit located in Shrewsbury, MA. All three AVs are IACUC members. Drs. Williams and Flynn are members of the IACUC located at the Wilmington MA site and Dr. Mallette is a member of the IACUC located at the Shrewsbury site. The CR-MA IACUC has oversight of all animal care and use activities conducted at the Shrewsbury MA site. The Wilmington based IACUC has oversight of all animal care and use activities conducted at all other sites covered by this Assurance (Wilmington, MA, Cambridge, MA, Kingston, NY, Hollister, CA, San Diego, CA, Raleigh, NC, and Frederick, MD). Kathleen A. Murray, D.V.M., M.S., DACLAM, Executive Director, Global Preclinical Laboratory Animal Medicine serves as the IACUC Chair for both IACUCs.

Michael Broadhurst, Sr. Site Director, CRL-MA, is the senior person located in Shrewsbury MA and is responsible for this site. Mr. Broadhurst serves as the Local Administrative Official (LAO).

The IACUC members are appointed by the Institutional Official (IO), Mr. James Foster. Both the IACUC, through the IACUC Chair, Dr. Murray, and the Attending Veterinarians (AV), Dr. Williams, Dr. Flynn and Dr. Mallette report and communicate regarding the animal care and use program to the Institutional Official, Mr. Foster. The IACUCs submit their semiannual program evaluation and facility inspection report to Mr. Foster (and the LAO, Mr. Broadhurst, for CR-MA). In its semiannual report the IACUC advises the IO and LAO of the status of the institution's compliance, establishes plans and schedules for correcting deficiencies necessary to either maintain or achieve compliance, and makes recommendation to the IO and LAO regarding any aspect of the institution's animal program, facilities, or personnel training.

There are direct and open lines of communication between the IO, LAO and the AV as well as between the IO, LAO and the IACUC. The communication between the IO and IACUC are generally conducted through the IACUC Chair, but any member of the IACUC may also communicate directly with the IO if desired.

Please refer to the organizational diagram depicting these reporting relationships in the attachment section **(Appendix 1)**.

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

1) Name: **Dr. Allison M. Williams, Director, Veterinary & Professional Services**

Qualifications

- Degrees: D.V.M., DACLAM
- Training and/or experience in laboratory animal medicine: Allison, a graduate of Mississippi State University School of Veterinary Medicine, has over 20 years of experience in laboratory animal medicine. Allison became a diplomate of the American College of Laboratory Animal Medicine in 2010. She joined Charles River in 2014. Prior to joining CR, she was a clinical veterinarian at Boehringer Ingelheim in Ridgefield, CT.

Authority: Dr. Allison Williams, as the attending veterinarian, has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. She serves on the IACUC.

Time contributed to program: Full time employee, 100% of time contributed to the animal care and use program.

2) Name: **Dr. Bernard (Mike) M. Flynn, Divisional Director, Insourcing Solutions Government Operations**

Qualifications

- Degrees: D.V.M., DACLAM, DACVPN
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Mike, a graduate of Oklahoma State School of Veterinary Medicine, has over 35 years of experience in laboratory animal medicine. Mike became a diplomate of the American College of Laboratory Animal Medicine in 1989.

Responsibilities: Dr. Mike Flynn has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. He serves on the IACUC.

Time contributed to program: Full time employee, 100% time contributed to the animal care and use program.

3) Name: **Dr. Sera K. Mallette, Sr. Staff Veterinarian, CR-MA**

Qualifications

- Degrees: D.V.M, M.S.
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Sera, a graduate of Tuft's University School of Veterinary Medicine, has over 12 years of experience in laboratory animal medicine. Sera is a member of the first group to graduate from the combined Master's in Science in Laboratory Animal Medicine and DVM program at Tufts. She joined Charles River in 2006. Prior to her current role, she served as a staff veterinarian at the CR site in Shrewsbury MA. She is licensed and accredited in Massachusetts.

Responsibilities: Dr. Sera Mallette has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. She provides clinical veterinary medicine support which includes supervision of a veterinary technician group. She also serves on the IACUC.

Time contributed to program: Full time employee, 100% time contributed to the animal care and use program.

(b) (6)



In addition, Charles River Laboratories, Research Models and Services has access to and seeks consultation and advice as needed from Charles River Laboratories large professional staff of veterinarians. These include members of Professional Services (Guy B. Mulder, D.V.M., M.S., DACLAM, Executive Director, Veterinary and Professional Services; Kathleen A. Murray, D.V.M., M.S., DACLAM, Executive Director, Global Preclinical Laboratory Animal Medicine, Theresa Albers, D.V.M., DACVP. Director, Pathology) and the Animal Welfare and Training Department (Patricia Turner, D.V.M., M.S., DACLAM, DECLAM, Corporate Vice President, Animal Welfare and Training and Michele Wilkinson, D.V.M., DACLAM Director of Animal Welfare, Global Animal Welfare and Training).

- 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 IACUC may delegate a subcommittee of at least two full voting members to review the program. No committee member is excluded from participation and all committee members are notified prior to the program review so that they may participate if desired. Subcommittee findings are then discussed as a full committee at a convened IACUC meeting. *Ad hoc* or other specialized staff may be invited to participate in the subcommittee review and/or the full committee IACUC meeting to provide additional information or to present supporting materials, if warranted. As part of the full committee discussion, any deficiencies found in the program review are categorized (minor, significant, suggestion for improvement) and documented as part of the semiannual report, including a corrective action plan with a time line for completion of the corrective action. The IACUC uses the Guide, 9CFR and facility SOPs as the basis for evaluation as well as the OLAW checklist. The program review covers all categories listed in the OLAW checklist including IACUC membership and Function, IACUC Records and Reporting Requirements, Veterinary Care, Personnel Qualifications and Training, Occupational Health and Safety, Veterinary Medical Care, Preventive Medicine/Animal Procurement and Transportation, Surgery, Pain, Distress, Anesthesia and Analgesia, Euthanasia, Drug Storage and Control, and Animal Environment, Housing and Management including Enrichment and Behavioral Management programs.

- 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: The facility inspection is scheduled prior to the full committee meeting where the program review is conducted. The IACUC delegates subcommittees of at least two full voting committee members to inspect the facility. No committee member is precluded from participation and all committee members are notified prior to the scheduled inspections so that they may participate, if desired. At a minimum, the facility inspection addresses the following:

Physical Facilities:

- General Structure/Construction
- Surfaces and Cleaning
- Utilities/Washrooms/Storage
- General Drainage and Waste Disposal
- Temperature/ventilation/Lighting
- Interior Surfaces
- Interior Drainage
- Primary Enclosures (space and additional requirements)
- Storage

During the semiannual facility inspection, members of the IACUC inspect all animal rooms, holding areas, procedure rooms, surgery, x-ray and laboratories where animal work occurs. During that process, animals that are present are observed for apparent health. If an animal is noted to be abnormal, the committee members investigate to ensure that this condition has been noted and that appropriate personnel (e.g. veterinary services staff, study director, etc.) have been made aware of the situation and that appropriate action is being taken. In addition, observations are made regarding the husbandry standards, including availability of feed, water, bedding (as appropriate based on type of housing), and environmental enrichment. Findings are then discussed at a full Committee meeting. Any deficiencies found in these areas are categorized (minor, significant, suggestion for improvement) and documented as part of the semiannual report, including a corrective action plan with time line for completion of the corrective action.

- 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: The findings of both the program review and facility inspection are discussed at a full Committee meeting. The IACUC Chair (or delegate) and the IACUC administrator compile the report. The semi-annual report contains a description of the nature and extent of the facility's adherence to the PHS policy and the Animal Welfare Act and identifies any IACUC-approved departures, including the reason for the departure, from the provisions of the Guide, PHS Policy or AWA. Minor and significant deficiencies, as determined by their potential to be a threat to the health and/or safety of animals, are distinguished. The report contains a reasonable and specific plan and schedule with dates for correcting cited deficiencies. It is the responsibility of the facility to develop the action plan including target dates to address cited deficiencies. The IACUC has the authority to determine if corrections are adequate. The IACUC may also elect to include suggestions for improvement (SFI) in the report. SFIs are a mechanism by which the IACUC's recommendations may be used to implement continuous improvement and promote best practices.

The report is reviewed and signed by a majority of the IACUC members. It includes any minority views. Results of the facility inspection and program review are reported in writing to the Institutional Official. A standing agenda item for IACUC meetings is the status report for correction of deficiencies as noted in the semi report to the IO. Uncorrected deficiencies remain open on the IACUC agenda until they are resolved. This status report ensures that all deficiencies are corrected as stated and agreed to (both the plan and the date for correction) in the semi report.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: Animal welfare training, including how to report a concern, is part of the required new hire training for all employees. Charles River has a corporate policy for reporting animal welfare concerns, investigation and implementing corrective action for animal welfare concerns. Any full or part-time employee, temporary employee, contractor, member of the public or other individual may report concerns verbally or in writing. Concerns may be reported to local or corporate management including the IO, Human Resources, any Veterinarian, any member of the IACUC or to the Animal Welfare Specialist at the site. The corporation also has a toll free phone number used exclusively for reporting animal welfare concerns. The toll free number is managed by a third party and concerns may be made anonymously. The company has a no reprisal policy for any employee expressing a concern (anonymous or otherwise). Posters are placed prominently throughout the facility and public areas which list phone numbers and staff to whom animal welfare concerns may be reported.

All concerns, incidents and non-compliance issues are reviewed at a Full Committee IACUC meeting. All concerns are initially investigated by an Animal Welfare Team consisting of the IACUC Chair, the Attending Veterinarian, Site/Department Management, the Animal Welfare Specialist, Human Resources and the Corporate Vice President of Animal Welfare and Training or their designee. Results of these investigations are then reviewed with the IACUC. Any areas of concern that are raised during this review are addressed and reported back to the IACUC at the next regularly scheduled IACUC meeting (or sooner if the issue is urgent and requires immediate action) for review, discussion and approval.

There is a standing section of the semi-annual report to the Institutional Official for animal welfare concerns. The general mechanisms for reporting and reviewing of concerns are described. If any concerns were reported since the last semi-annual report, they would be summarized in the report. The summary would include the general nature of the concern, the results of the investigation and any actions that were taken. In addition, the IACUC chair may elect to communicate to the IO, either in writing or in person, a specific concern, based on the nature of the concern and/or results of the investigation, and not wait until the next semi-annual report.

It is company policy that there shall be no reprisal for reporting concerns related to animal care. The name of the person bringing forth the concern is not used during or after the investigation.

- 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 is empowered to make recommendations to the IO regarding any aspect of the animal care and use program, facilities or personnel training. Should the IACUC need to make an immediate recommendation to the IO, the Chairperson acts on behalf of the Committee and submits a formal written recommendation. For less immediate issues, these would generally first be discussed at convened IACUC meeting which would then be followed up with a written document that is submitted to the IO. On a routine basis, needs for animal care and use program are described in the semi-annual facility inspection and program review report which is submitted to the IO.
- 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: The study director (principal investigator) submits the IACUC proposal form (IPF which is equivalent to an Animal Use Protocol) and draft study protocol if one exists to the IACUC Administrator. At that time they undergo an administrative review for completeness of documents. Should omissions be found during the initial review, the submitter is informed that the committee may require such information for a complete review and the submitter is requested to provide an addendum that includes this information. The submitter of the protocol is encouraged to attach any detailed information he/she feels is important to the committee's understanding of the proposed project. The pre-review process may also include review by a veterinarian as well as the Safety Officer if



hazardous agents are involved. Once the protocol is satisfactory it is ready for submission to the full IACUC.

Copies of the complete protocol are submitted to all IACUC members via e-mail. All IACUC members, including community members have readily available access to e-mail. Designated member review is the most common method for protocol review. Following submission of materials to IACUC members, each member has at least 48 hours (two working days) at the CR-MA site (and at least 5 business days at Wilmington) to review the proposal and draft study protocol. During this time, any IACUC member has the option to call for full-committee review. If full-committee review is not requested, a minimum of 48 hours (or 5 business days for Wilmington) has elapsed since distribution to the IACUC and a quorum of committee members have responded that designated review is acceptable, one designated reviewer assigned by the IACUC Chairperson conducts the review of the proposed activity. Note: When using the designated review process, if 100% of the Committee members respond unanimously for assignment to the designated review process and all responses are made in less than two working days (or 5 working days for Wilmington), then the protocol can proceed to designated review at that point in time.

When the protocol is reviewed by an assigned designated reviewer, the only options available in the review are "acceptance of the protocol", "require modifications (to secure approval)" or "referral to full committee review". During the designated review process, the option of requiring modifications in order to secure approval ultimately leads to either approval/acceptance of the protocol (when the required modifications are completed), or referral to full committee (when the required modifications are not completed and/or agreed upon, and the designated reviewer is unable to reach an agreement with the investigator that results in an acceptable/approvable protocol). Once the review has been completed, the IACUC Administrator notifies the study director of the outcome (approved or require modifications (to secure approval) or has been referred to full committee review).

If a member calls for a full committee review of a protocol, the IACUC Administrator schedules an IACUC meeting for that purpose. The meeting invitation and all materials to be reviewed at the meeting are distributed in advance via email to all IACUC members, and all members have access to email and the teleconferencing platform used for meetings. In order to review and approve protocols, a quorum must be present and any Committee members with a conflict of interest cannot be counted towards that quorum. Members may participate in person or by telephone. Members choosing to participate in the meeting via teleconference are able to interact with attendees that are physically present in real time and can therefore participate in discussion and voting as if they were physically present. Committee members with a conflict of interest are allowed to be present during the initial review and discussion process but are asked to leave the room for final discussions and motion and subsequent vote to approve or with-hold approval. In order to vote to approve or with-hold approval, a quorum must be present (no one with a conflict of interest can be counted as contributing to the quorum). A motion is made regarding action to be taken with regard to approval. A majority of those present must vote in favor of the motion, in order for the motion to pass. After the motion has been acted upon, those with a conflict of interest are invited back into the Committee meeting room so that they may participate in the rest of the meeting. Written meeting minutes are prepared and maintained by the IACUC administrator.

- 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:

A significant change to an approved animal activity follows the same process as a new proposed animal activity as described above. The study director submits a request for modification of the approved animal activity to the IACUC Administrator. The IACUC Administrator does an

administrative review for completeness of document and then distributes the document to the entire IACUC as described in the section above for new animal activity review and approval. IACUC review and approval of the significant change must occur prior to the change in animal activity being implemented.

Items that the IACUC defines as significant are:

- Change in the objective(s) of the study
- Change from non-survival to survival surgery
- Change resulting in greater discomfort or in a greater degree of invasiveness
- Change in the species or in approximate number of animals used
- Change in anesthetic agent(s) or the use or withholding of analgesics
- Change in the method of euthanasia
- Change in duration, frequency, or number of procedures performed on an animal
- Change in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC
- Change that impacts personnel safety
- Change in Principal Investigator that is not covered by IACUC approved trained & certified study director list

- 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:

Written notification is made to the submitting investigator of all decisions regarding IACUC review. If the IACUC withholds approval of a protocol the written document contains the reason(s) the IACUC has withheld approval and recommends that the investigator contact the IACUC Chair for further discussion, if desired. The IO receives a list of all approved activities with the IACUC meeting minutes.

- 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:

For long term (more than 12 months) animal activities, the investigator is required to submit an annual review form before the end of each year. These annual forms are sent to all Committee members by e-mail and are reviewed and approved following the same procedures described in section III.D.6 (above) for new protocol review. In addition, *de novo* reviews are conducted prior to the end of the three year period in accordance with the new protocol review procedures described in section III.D.6 (above).

Additional means of ongoing assessment of animal use activities and the Program include the following: IACUC semi-annual program review and facility inspection, daily observation of animals by trained technical staff and communication with the veterinary staff for follow-up of abnormal observations, regular vivarium rounds conducted by the veterinary services team, active program for reporting and addressing any animal welfare concerns as well as recommendations for improvements/refinements, facility monitoring by facility maintenance personnel and appropriate communication with management and the veterinary staff for abnormal observations, robust hands on training program in animal procedures with regularly scheduled refresher training, and appropriate reporting of incidents involving occupational health and safety.



- 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:

Written notification will be provided to the investigator, management personnel and other responsible individuals of the decision to suspend an activity involving animals. This action may only be taken after review by a convened meeting of a quorum of the IACUC and a vote for suspension by a majority of the members present. The Institutional Official, in consultation with the IACUC, will review the reasons for the suspension, take appropriate corrective action and report that action within 14 days with a full explanation to OLAW, APHIS and any federal agency funding that activity. The IACUC will also report to OLAW any serious or continuing noncompliance with PHS policy or serious deviation from the Guide

- 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:

All Charles River Laboratories, Inc. (CR) sites have a Workplace Safety and Occupational Health Program administered by the Environmental Health and Safety (EH&S) Engineer who is responsible for the overall administration and monitoring of the program. The Workplace Safety and Occupational Health Program outlines safety responsibilities for management, supervisors, employees and the safety committee. It also outlines the safety training required, gives safety rules and disciplinary action, how to identify and evaluate workplace risks, and effective safety communication and reporting of any hazards or safety concerns. Included in this program is the Occupational Health Program, which includes a contracted urgent care facility located in close geographic proximity to each CR site to administer medical assessment and treatment for ill or injured employees. The physicians at the urgent care facility work closely with the EH&S and Human Resources departments in risk assessment and medical preventives. The Occupational Health Program also outlines pre-employment medical evaluation and testing, health surveillance during employment (specific requirements are based on species at the site including TB testing (NHP only), periodic medical re-evaluation, Herpes B procedures (NHP only), allergens and illnesses), termination testing, accident and disease prevention, and availability of emergency equipment throughout the facilities. All employees are included in the occupational health program.

The identification of risks associated with different job classifications dictates the level, extent and type of training programs the employees undergo when hired, and on a continual schedule thereafter. Personnel are introduced to the various hazard categories including zoonotic diseases and allergy awareness, personnel hygiene, general principles of biosafety and biosecurity during Initial-On-Boarding (IOB) training. In addition, through job specific training, employees are introduced to the hazards associated with working in the vivarium (if applicable) including chemical, biologic, physical or ergonomic hazards that are present. IOB training is managed and organized by the site training coordinator as well as department management. Subsequent on-the-job and Standard Operating Procedure (SOP) training is conducted and coordinated at all levels of management from supervisors to team leaders.

In the event of personal personnel illness, decreased immune-competence or pregnancy, a personal physician would provide written instruction to the employee, who in turn would work with the human resource department and their supervisor to comply with all medical instruction.

Pre-study meetings are conducted to cover hazardous materials being tested, as applicable. General safety training is provided annually, hazardous communication is provided every two years, hazardous materials training is provided every three years and respirator training is provided once a year to appropriate personnel.

Employees are given training with respect to proper use of protective clothing, zoonotic diseases and allergy awareness, hygiene, and injury / contamination exposure reporting. For sites with NHPs, special focus is given to CHV-1 possible transmission, signs and potential consequences of human infection. Bite wound kits are maintained throughout the facility where animals or blood products are handled. Reporting procedures and management of a contamination exposure are on file for review.

Allergen training is provided at in-house meetings and training sessions as part of zoonoses training. All employees are provided with, and trained in the use of protective clothing. Laboratory coats, disposable Tyvek coveralls, scrub suits, disposable gloves, disposable caps, eye protection, disposable face shields, site shoes/boots and respirators (N95) are provided for each employee, as needed, based on their job function, work being performed and species interaction.

Each site has a Safety Committee with approximately equal membership of management and employee representatives. The committee meets regularly and investigates accidents, receives and reviews safety suggestions, periodically conducts safety inspections, and acts as liaison with the Site/Facility Head and Corporate EHS staff on safety issues.

Other written safety related programs may include, based on activity conducted at each specific site are:

- Hazard Communication or Right to Know
- Emergency Management Plan
- Emergency Management and Business Continuity Plan
- Respirator Protection
- Lockout/Tag out Safety
- Chemical Hygiene
- Confined Space Entry
- Laboratory Bio Safety
- Forklift Safety
- Fire Extinguisher Use and Training
- Bloodborne Pathogens
- Hot Works
- Workplace Safety
- Biohazardous Waste Plan
- Spill Prevention Control and Containment
- Hazardous Materials Management Plan

- 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:

Many of the CR sites covered under this assurance predominantly involve rodent breeding and production. Therefore, training is heavily oriented toward the humane practice of animal care and use as it relates to breeding, housing and handling animals at all facilities. Part of the new hire orientation program includes extensive Humane Care Initiative training for all employees. Topics include detailed information on animal care orientation, animal ethics, minimization of pain and distress, the role/function of the IACUC and the 3 R's: reduction, refinement and replacement of animals. Those employees with direct animal contact participate in mandatory annual animal welfare training that is prepared by the corporate department of Animal Welfare and Training. Examples of recent annual training topics include reporting an animal welfare

concern, biology and care type materials for the different species that we work with and the role of the IACUC.

Animal care technician training is conducted by the production department at each facility. Specific operating procedures that outline each phase of animal care and use have been developed, and employees are given individual, as well as group, instruction in each facet of these day-to-day animal care matters. Supervisors within each barrier production room monitor employee compliance with these animal care practices and provide additional instruction as warranted. Employees at all sites are encouraged to participate in the AALAS certification process, and the company facilitates this process by making facilities available for training and providing other incentives. This opportunity is available to all employees including those not directly involved in the care and use of laboratory animals.

Those employees engaged in the limited research activities (primarily at the Wilmington, MA site) are given direct training in animal care and use matters as well as the proper methods for utilizing animals in specific research settings by the veterinary staff and trained supervisors or department trainers. Individual research projects are administered by laboratory animal veterinarians and/or Ph.D level scientists, fully qualified to provide such training.

At CR-MA, scientists, animal technicians, research technicians and other personnel involved in animal care, animal use or treatment receive the majority of their training on the job by the technical training department, senior staff, or technical training assistants. The technical training department performs a comprehensive orientation program for all new employees (husbandry, technical, veterinary and scientific staff) prior to working directly with the animals including animal welfare and GLP training. Also, additional annual animal welfare training courses presented at CRL-MA are developed by Dr. Patricia Turner, Corporate Vice President, Animal Welfare and Training. This training, entitled Bringing Ethics, Morals and Values to our Use of Animals and Animal Welfare Concerns, is required of all employees and includes detailed information on animal care orientation, animal ethics, minimization of pain and distress, the role/function of the IACUC and the 3 R's: reduction, refinement and replacement of animals.

CR-MA's training program for animal care and use is tailored to the types of responsibilities our research technicians have in supporting our animal research program. Our staff is either dedicated to a specific role or they may even fulfill multiple roles which typically fall into three categories:

- Technical – involving duties of caring for the animals and performing basic, intermediate, or advanced technical procedures involved in study conduct as defined in SOPs;
- Veterinary Care – providing medical support to animals as directed by the Veterinarian, Study Director, or Veterinary Staff;
- Training – Technical Trainers, Training Assistants, Supervisors and Study Directors provide training services for research and animal care staff.

Training is documented in each employee's training file. Documentation includes training records prepared by the trainer, reviewed by the supervisor and signed by the employee; certifications; syllabi; or group training sessions conducted by Charles River. AALAS certification is encouraged and recognized by a one-time certification bonus and/or promotion to higher technical levels.


Our training program's intent centers upon being able to stimulate changes in each individual's knowledge, attitudes, and behaviors that will insure regulatory compliance, technical competence, and humane care and use of the animals used in our research. Training for essential knowledge and skills to perform assigned tasks is one of our most important priorities. Our training program was devised with built-in mechanisms such as new technologies, regulatory changes/updates, new bi methodologies or processes, new capabilities, and novel types of research.

Those employees engaged in the limited research activities (principally at the Wilmington, MA site) are given direct training in animal care and use matters as well as the proper methods for utilizing animals in specific research settings by the veterinary staff and trained supervisors or department trainers. Individual research projects are administered by laboratory animal veterinarians and/or Ph.D level scientists, fully qualified to provide such training.

Additionally, new IACUC members receive training from either the IACUC Administrator or the Chair of the IACUC. Training includes but is not limited to, a discussion of the IACUC members' roles and responsibilities for assuring animal welfare, a review of AWA/9CFR regulations, a review of SOPs, the Guide, PHS policy, regulatory inspections and reporting to regulatory agencies, AAALAC accreditation requirements and process, voting, literature searches, protocol reviews, conducting facility inspections, reviewing animal welfare concerns, and local and corporate policies. New members are provided access to the AALAS learning library and participate in the annual animal welfare training provided by Corporate Animal Welfare and Training department. In addition, CR supports the attendance at external IACUC training such as IACUC 101, enrollment in MSMR on-line New IACUC Member Training Course, participation in other external webinars provided by organizations such as NABR, OLAW, NJABR, AALAS and PRIM&R.

#### **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.

- (1) 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**

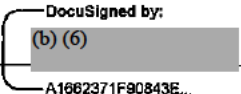
- A. This Institution will maintain for at least 3 years:
  1. A copy of this Assurance and any modifications made to it, as approved by the PHS
  2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
  3. Records of applications, proposals, 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, Mr. James C. Foster.
  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, Mr. James C. Foster.
  - 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

<b>A. Authorized Institutional Official</b>	
Name: Mr. James C. Foster	
Title: Chairman and CEO	
Name of Institution: Charles River Laboratories	
Address: (street, city, state, country, postal code) 251 Balliardvale Street Wilmington, MA 01887	
Phone: (b) (6)	Fax: NA
E-mail: james.c.foster@crl.com	
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: 	Date: 30-Jul-2018

<b>B. PHS Approving Official</b> (to be completed by OLAW)	
<b>Venita B. Thornton, D.V.M., M.P.H.</b> <b>Senior Assurance Officer, Division of Assurances</b> <b>Office of Laboratory Animal Welfare (OLAW)</b> <b>NIH/OD/OER</b> <b>6705 Rockledge Drive</b> <b>RKL 1, Suite 360-MSC 7982</b> <b>Bethesda, Maryland 20892-7982</b> <b>thorntov@od.nih.gov</b>	
Signature: 	Date: July 30, 2018
Assurance Number: D16-00496 (A3863-01)	
Effective Date: July 30, 2018	Expiration Date: July 31, 2022



## VIII. Membership of the IACUC

Date: June 30, 2018			
Name of Institution: Charles River Laboratories, Research Models and Services			
Assurance Number: D16-00496 (A3863-01)			
<b>IACUC Chairperson</b>			
Name*: Kathleen A. Murray (1)			
Title*: Executive Director, Global Preclinical LAM		Degree/Credentials*: DVM, MS, DACLAM	
Address*: (street, city, state, zip code) 251 Ballardvale Street Wilmington, MA 01887			
E-mail*: kathleen.murray@crl.com			
Phone*: (b) (6)		Fax*: NA	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)			Scientist
Allison Williams (3)	DVM, DACLAM	Director, Professional Services	Attending Veterinarian
(b) (6)			Non-Affiliated Member & Non-scientist
			Veterinarian
			Member
			Member
			Member
			Member
			Member
			Alternate member for (3)

<b>Date:</b> June 30, 2018
<b>Name of Institution:</b> Charles River Massachusetts
<b>Assurance Number:</b> D16-00496 (A3863-01)

<b>IACUC Contact Information</b>			
Address: [street, city, state, zip code] 334 South Street Shrewsbury, MA 01545			
E-mail: Kathleen.murray@crl.com			
Phone: (b) (6)		Fax: NA	
<b>IACUC Chairperson</b>			
Name: Kathleen A. Murray, DVM, MS, DACLAM (1)			
Title: Exec. Director, Global Preclinical LAM		Degree/Credentials: DVM, MS, DACLAM	
PHS Policy Membership Requirements***: Chairperson			
<b>IACUC Roster</b> [Provide below or attach]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
(2) Sera Mallette	DVM, MS	Sr. Staff Veterinarian	Veterinarian
(b) (6)			Member & Vice-Chair
			Non-scientist
			Scientist
			Scientist
			Non-affiliated & Non-scientist
			Alternate for member 2
			Alternate for member 4
			Alternate for member 5
			Alternate for member 6

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

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

\*\*\* [PHS Policy](#) Membership Requirements:

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

*Scientist*          practicing scientist experienced in research involving animals.

*Nonscientist*      member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy).

*Nonaffiliated*      individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate

family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

*[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]*

\* 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:

<i>Veterinarian</i>	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.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	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.

*[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]*

## IX. Other Key Contacts (optional)

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

<b>Contact #1</b>	
Name:	Kathleen A. Murray, DVM, MS, DACLAM
Title:	Executive Director, Global Preclinical LAM
Phone:	(b) (6)
E-mail:	Kathleen.murray@crl.com

**Contact #2**

(b) (6)

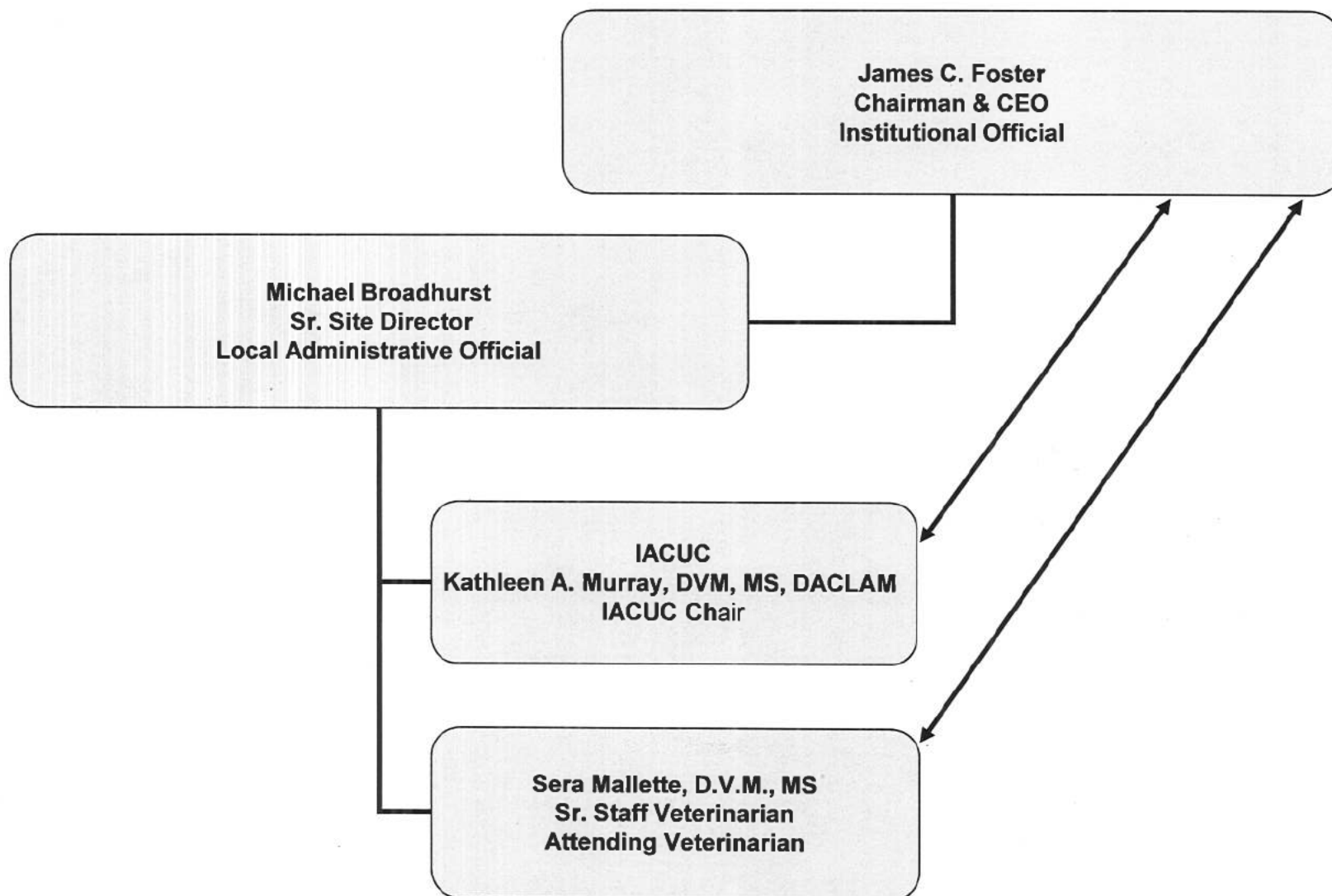


## X. Facility and Species Inventory

Date: June 16, 2014			
Name of Institution: Charles River Laboratories Research Models and Services			
Assurance Number: A3863-01			
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
Wilmington, MA	95,700 sq ft	Mice, rats, Peromyscus mice, hamsters, guinea pigs	Mice – 142,000 Rats – 9,000 Peromyscus – less than 30 Hamsters – 120 Guinea pigs-150
Cambridge, MA	2,000 sq ft	Mice, rats	Mice – 962 Rats – 25
Hollister, CA	29,807 sq ft	Mice, rats	Mice – 116,200 Rats – 23,500
Raleigh, NC	32,900 sq ft	Mice, rats	Mice – 166,850 Rats – 85,300
Kingston, NY	39,607 sq ft	Mice, rats, guinea pigs, hamsters, gerbils	Mice – 177,400 Rats – 61,100 Guinea pigs – 3,600 Hamsters – 10,200 Gerbils – 1,500
San Diego, CA	21,560 sq ft	Mice, rats	Mice – 38,250 Rats – 1,200
Frederick, MD	1,500 sq ft	Mice, rats, guinea pigs, hamsters, gerbils, rabbits	Mice- less than 20 Rats –less than 20 Guinea pigs – less than 20 Hamsters- less than 20 Gerbils –less than 20 Rabbits – less than 20
Shrewsbury, MA	70,000 sq ft	Mice, rats, beagles, macaques, hamsters, rabbits,	Mice – 700 Rats – 1,000 Beagles- 220 Macaques- 350 Hamsters- less than 50 Rabbits – less than 25

\*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.

**Charles River Laboratories, Inc. - Massachusetts**  
**IACUC Organizational Chart**  
**Animal Care and Use Program Management Structure**





## Charles River Laboratories, Inc. – Research Models & Services

### IACUC Organizational Chart

#### Animal Care and Use Program Management Structure

