



Animal Welfare Assurance for Domestic Institutions

I, Philip Downing, as named Institutional Official for animal care and use at BASi, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, and/or NSF. 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:
Bioanalytical Systems (BASi) - Evansville
- B. The following are other institution(s), or branches and components of another institution:
None

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: Philip Downing, the Senior Vice President of Preclinical Services, serves as the Institutional Official. The IACUC reports are submitted to Philip Downing. The Attending Veterinarian is Dr. Braden M. Kemmerling. Dr. Kemmerling is a member of the IACUC. The Animal Facility Staff reports to (b) (6) Christina Drennan is the IACUC Chair. The Attending Veterinarian (Dr. Kemmerling), the IACUC chair

(Christina Drennan), and the (b) (6) report directly to the Senior Vice President of Preclinical Services (Philip Downing). The BASi Senior Vice President of Preclinical Services reports to the (b) (6)

There are open lines of communication between the Attending Veterinarian, the IACUC, IACUC Chair and the IO, as is required by PHS Policy. There are only 65 employees at BAS Evansville, therefore, communication at the facility is open. The IO receives and signs off for review of the IACUC Meeting Minutes and attends IACUC meetings and discussions when appropriate.

- 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. Braden M. Kemmerling

Qualifications

- Degrees: BS Purdue University, Animal Science
DVM Purdue University, School of Veterinary Medicine
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
 - Over 5 years of experience as a licensed veterinarian. Two years of experience in a private practice, and over two years of experience as an Attending Veterinarian for laboratory animals. Three summers experience in a laboratory setting as a veterinary intern. Extensive experience with rodents, lagomorphs, swine, canines, and non-human primates.

Authority: Dr. Kemmerling has direct program authority and responsibility for the Institution's Animal Care and Use Program including access to all animals.

Time contributed to program: Full Time Employee – 100% of time is contributed to the animal care and use program.

(b) (6)



(b) (6)

- 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 conducts a review of the animal care and use program, using the Animal Welfare Act and the 8th Edition of the *Guide for the Care and Use of Laboratory Animals* as a basis for the evaluation, at least twice yearly. The review is completed by answering questions in the Program Evaluation Checklist (OLAW's Semiannual Program Review Checklist) at the April and October IACUC Meetings by all of the IACUC members present at the meeting. Each question is read, reviewed, and acknowledged in the presence of members at the meeting. If any discrepancy or disagreement is identified, it is more thoroughly discussed to ensure the issue is properly addressed. The IACUC reviews the institutional policies and responsibilities and the veterinary care. Once the checklist is complete all members of the IACUC review and sign the document.
 - 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 animal facilities are inspected, using the Animal Welfare Act and the 8th Edition of the *Guide for the Care and Use of Laboratory Animals* as a basis for evaluation, at least twice yearly. All IACUC members are invited to participate in the Facility Inspection. All aspects of buildings (animal housing, support areas, surgical sites, cage wash, etc.) in which animals are housed are thoroughly inspected including the exterior areas and entry points. Particular attention is paid to the microenvironment in which the animals are housed. Given the large size of our campus, teams of 2-3 members are assigned specific areas to inspect in order to perform the

Inspection in a timely and efficient manner. The Facility Inspection Checklist (OLAW's Semiannual Facility Inspection Checklist) is completed by all members of the IACUC present at the IACUC meeting. The findings that are noted on the facility inspection are classified as either a minor deficiency or a significant deficiency. The deficiencies are put into a work list that is given to the responsible parties. A copy of the Facility Inspection and work list are given to the Institutional Official.

- 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: Minutes of each IACUC meeting are prepared by the Committee Chair in a timely manner following each meeting and sent out for review to the IACUC before finalization. The Facility Inspection and Program Evaluation findings are summarized in a report to the Institutional Official. The format for this report is taken from the sample report form provided by OLAW. The summary report that is given to the IO contains a description of the nature and extent of the institution's adherence to the *Guide* and the PHS Policy on Humane Care and Use of Laboratory Animals, any departures from the *Guide* and the PHS Policy on Humane Care and Use of Laboratory Animals, and the reasons for each departure. All members of the committee present at the time of the inspections sign the report which must include a majority. If there are any minority opinions, they are included and listed as such. Deficiencies (minor and significant) and suggestions for improvement are included in the report with a timetable for implementation of corrections. The list of deficiencies and suggestions is also given to appropriate area managers to ensure that the listed items are corrected.
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: Any employee with concerns involving the care and use of animals at the Institution may either directly or in writing contact any member of the IACUC, the Attending Veterinarian and/or his/her supervisor. Signs are posted throughout the facility noting who to contact for animal welfare concerns. There is also notation on the signs reminding employees that there are no repercussions for reporting animal welfare concerns. The individual contacted, if not the IACUC Chair, will advise the IACUC Chair of the concern. The Chair will convene a meeting of the IACUC (a quorum must be present) to discuss the issue. The IACUC thoroughly reviews the allegations and gathers further information, if needed. Once all information is presented to the IACUC a vote would be taken on whether there is an animal welfare issue. If the IACUC finds that there was an animal welfare issue, a vote would also be taken on whether the issue should be reported to NIH/OLAW based on any serious or continuing noncompliance with PHS Policy or serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals*. The IACUC is authorized to suspend an activity involving animals in accordance with specifications set forth in the Animal Welfare Act and PHS Policy IV.C.6. If the majority of the IACUC votes the issue is not reportable, the issue will be documented in the meeting minutes but not be reported. If a majority of the IACUC votes that the issue is reportable, a second vote must be taken to determine if reporting to APHIS is also applicable. The IACUC Chair or his/her designee will then draft a response letter to the Institutional Official outlining in detail the issue as well as any corrective actions implemented. The Institutional Official will be responsible for directing the information to OLAW and APHIS (if applicable). No member of the IACUC or employee of the Institution will be reprimanded, demoted or relieved of their position as a result of reporting an issue. See section III.D.10 for procedures for suspending an ongoing study.
- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows: Recommendations set forth by the IACUC regarding any aspect of the Institution's animal program, facilities, or personnel training are presented in writing to the Institutional Official. It is generally the responsibility of the IACUC Chair to generate written recommendations and present it to the Institutional Official although any IACUC member may be delegated to do so. The written recommendation will include suggestions for implementing the recommendations of the

IACUC and, when appropriate, a required time period by which the recommendation should be undertaken.

- 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: There are two types of protocol review that are used, Full Committee Review and Designated Member Review. The protocol is submitted to the IACUC by either a Study Director or the Director of Toxicology. Each protocol is first reviewed by a representative of the IACUC for compliance with applicable regulations and statutes. At this point the IACUC representative may decide that the protocol will go through Full Committee Review directly or the IACUC representative will generate a protocol review memo from the protocol in question and distribute it to all IACUC members. If the IACUC representative sends the protocol to Full Committee Review prior to submitting the protocol review memo to the entire IACUC, it is because there is some aspect of the protocol that needs to go through a Full Committee Review, in the opinion of the IACUC representative. Rather than sending out the memo asking the entire IACUC if they approve Full Committee or Designated Review, the protocol goes through Full Committee Review.

Full Committee Review – The IACUC Chair will notify the committee of a meeting to review the protocol. The protocol will be distributed to committee members prior to the meeting. A primary reviewer may be selected to present a protocol to the rest of the members at the meeting. Approval of a protocol may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the review in which the member has a conflicting interest except to provide information requested by the IACUC. The committee may approve the protocol, require modifications to secure approval or withhold approval of the protocol. A full committee meeting may be called to review a resubmission of a protocol following modifications or a designated reviewer may be selected for the review after the entire IACUC has reviewed the required modifications and approved designated review. Work cannot begin until final approval has been obtained. The Chair will notify the Study Director in writing of the IACUC's decision. If the protocol was not approved, the reason for withholding approval must be given and the Study Director must have an opportunity to respond in writing or in person.

Designated Member Review – IACUC Chair notifies the IACUC, preferably via email, of a proposed protocol. Notification will include: protocol title, brief synopsis of protocol, selected designated reviewer, committee member reply date (within 2 working days, after reply date has expired no response is presumed to mean acceptance; if the reply time is less than two days, members that have not responded will be contacted by phone, a phone log will be generated). The designated reviewer, selected by the IACUC Chair based on qualifications and workload, may rotate periodically. For consistency, the Chair will try to assign related studies to the same reviewer.

At the end of the predetermined reply period, if a quorum of the committee has approved a designated member review and no member has called for a full review, the protocol will be forwarded to the selected designated reviewer(s) along with the review completion date. Generally, the reviewer will be given 1 – 3 working days to review the protocol. The designated reviewer(s) may approve the protocol, require modifications to secure approval or call for a full committee review. If more than one designated reviewer is selected, all participants must either approve or require (the same) modifications for approval; failing this, they must submit the protocol for full committee review. A designated reviewer may not withhold approval of a protocol- only a full committee has that authority. The Chair will notify the Study Director in writing of the designated reviewer's decision.

Designated Review, as described above, may be used for any protocol that is reviewed by the IACUC. BASi Evansville does not have any requirements that automatically trigger a protocol to go through Full Committee Review.

- 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: Each proposed significant change regarding animal care and use in ongoing protocols or activities is reviewed using the same procedure as described in question 6 above for protocols. Necessity of IACUC review and approval of protocol amendments is ultimately the responsibility of the Study Director. However, several members of the IACUC review these amendments for potential IACUC concerns but this review process is not documented. Examples of a significant change may include but are not limited to :
 - Changes in the objectives of the study
 - Proposals to switch from non-survival to survival surgery
 - Changes to the degree of invasiveness of a procedure or discomfort of an animal
 - Changing restraint device or restraint time
 - Any surgical involvement
 - Change in species or in the number of animals used
 - Changes in the protocol defined personnel involved in animal procedures
 - Changes in anesthetic agents or the use or withholding of analgesics
 - Changes in the method of euthanasia
 - Changes in the duration, frequency, or number of procedures performed on an animal
 - Increase in total volume of blood collected
 - Increase in dosing time points
 - Change in route of dose administration
 - Increase in dose volume administration
 - Change in housing
 - Use of animals in a location that is not part of the animal program overseen by the IACUC
- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows: The IACUC notifies Study Directors 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. The IACUC Chair or other designated member is responsible for generating the written notification and providing it in a timely manner to the investigator. If animal work is not approved the reason for withholding approval must be given and the Study Director has to have an opportunity to respond in writing or in person. The IO is notified about IACUC decisions relating to the care and use of animals in writing.
- 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: All ongoing protocols are reviewed by the IACUC on an annual basis rather than triennially. These reviews are generally conducted during the last quarter meeting of the IACUC by Full Committee Review. The Renewal protocols are submitted to the IACUC for a complete de novo review. Animal work is not allowed to continue past the expiration date of the protocol. This protocol review applies the same procedures as those employed for the initial reviews using the Animal Welfare Act and the *Guide* as a basis for evaluation. The IACUC does a de novo review of protocols every year instead of every three years by Full Committee Review. The expiration time for the BASi IACUC Protocols is one year rather than 3 years. The de novo review is completed prior to the expiration date for the protocol. The annual review is conducted earlier than the date of the initial approval. The review is documented in the IACUC meeting minutes and on a form for each protocol. A post approval monitoring program has also been implemented whereby approximately ten percent of the studies approved by the IACUC will be selected randomly and reviewed annually by the IACUC to ensure that the study is being carried out as per approved protocol.

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: In the event that any member of the IACUC determines that an ongoing activity involving the care and use of animals is not being conducted in accordance with the description of that activity provided by the Study Director (via the protocol) the matter will be reviewed at a convened meeting of a quorum of the IACUC. If a majority of the quorum of the IACUC members present at the meeting, after review of the matter, vote to suspend a protocol, a designated member of the IACUC (generally the Chair) would provide the Study Director and individuals conducting the activity with a written order to stop the activity. Following suspension of the activity, the Institutional Official will be notified. The Institutional Official will be responsible for reporting the suspension and the corrective actions taken to the OLAW, APHIS and any other Federal agency funding that activity, as appropriate.

- 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:

Personal Hygiene and Protection:

Personal Protective Equipment/Work Clothing Provided: Employees working in the animal colonies or diet/dosage prep labs are required to change out of street clothes into clean uniforms and shoe covers before entering those areas each day. Surgical scrub suits are provided as uniforms. Lab coats are provided to be worn over the scrub suits. The lab coats are changed as the employee moves from animal room to animal room. Lab coats and scrubs are laundered in-house. Safety glasses, surgical type masks and half-face piece respirators are provided by this institution. Personnel entering a non-barrier animal room must wear a lab coat. Lab coats, shoe covers and a surgical-type face mask are required in barrier and nonhuman primate animal rooms. Gloves are required when handling animals, test articles or related equipment/supplies, etc. Additional protective clothing and equipment used include Tyvek® suits, boots, leather "monkey gloves," face shields, ear protection devices, and respirators.

Provisions for Washing Hands, Changing Clothes, Wearing Work Clothes Outside Facility: Locker rooms and showers are provided in Buildings B, C and F. Toilet facilities including sinks equipped with hand soap dispensers are provided in the office areas of Buildings B and F, on the clean and/or dirty halls of Buildings A, B, C and L. Sinks with hand soap dispensers are also provided in the laboratory areas of all buildings. Work clothes are not worn outside BASi Evansville property.

Eating, Drinking, and Smoking Policies: Smoking is not permitted inside any of the BASi Evansville facilities. Smoking on the property is only allowed in a designated area outside of (b) (4)

Eating and drinking in the animal colonies or adjacent hallways is forbidden. Employees are furnished with 2 areas where eating and drinking are permitted:

(b) (4) This room contains a refrigerator, a freezer, a soft drink machine, a snack machine, coffee pot and 2 microwave ovens.

(b) (4) This room has tables and chairs, a refrigerator and a microwave, but no kitchen facilities.

Animal Experimentation Involving Hazards:

Description of Institutional Policies: The Safety Officer (local) and the Study Directors are responsible for monitoring the use of hazardous materials in animal studies and ensuring that proper safeguards are in place to protect the personnel involved. It is also the responsibility of those individuals to ensure that the employee(s) involved understand the instructions given them. There are comprehensive procedures and precautions for handling hazardous materials. These procedures and precautions are discussed during the pre-study start up

meeting. The study director will inform the personnel if the test article is a known hazard (i.e. teratogen, carcinogen, etc.) and further precautions may then be set in place to ensure all pertinent staff members are adequately informed.

Description of Oversight Process and Husbandry Practices: All personnel handling and caring for animals are trained and certified. Additionally, those personnel are supervised to assure there are no deviations from the process.

Containment of Hazardous Agents: This institution controls exposure of personnel to hazardous materials by enforcing strict adherence to standard operating procedures and practices for handling hazardous materials.

Hazardous Agents: All test articles tested by BASi Evansville are considered hazardous.

Biologic Agents: BASi Evansville does not conduct studies utilizing hazardous biologic agents.

Chemical Agents: All test articles received for testing at this institution are handled as known or potential hazards. Many test articles are in the earliest phases of testing and their hazard level is not known, and the purpose of testing is to determine information for Material Safety Data Sheets. Other test articles are being tested in order to generate animal safety data needed for submission to regulatory authorities. BASi Evansville's standard operating procedures require personnel to wear masks, protective clothing, and gloves when handling test articles or other chemical agents. Respirators may also be used.

Physical Agents: Various medical devices for use in humans are tested for irritation potential. Though most are known or suspected to be nonhazardous, the same precautions and procedures are taken for handling these items as for test articles known or suspected of being hazardous.

Medical Evaluation and Preventive Medicine for Personnel:

Personnel Included in the Program: BASi Evansville reserves the right to require pre-employment physical examinations of employees in positions that are considered to carry a potential health risk and for those employees whose health appears to affect their ability to perform satisfactorily. Also, Periodic Risk Based Health Evaluations may be used for employees with frequent or substantial contact with animals in order to assess the individual risks of animal users. All employees may be required to have semi-annual clinical pathology determinations. Annual Audio Testing is required of employees with frequent or substantial contact with high noise level exposure in order to assess hearing trends. Annual Respirator Fit Testing may be required for any worker who is required to use a tight-fitting respirator. Annual tuberculosis screening is made available for all employees and bi-annual tuberculosis screening is required of all personnel working with nonhuman primates. If during any examination, a medical finding is cause for concern, the examining physician will promptly notify institution management, the employee and his or her medical representative. BASi Evansville makes every effort to ensure the health and safety of all employees including those that are pregnant or immune-suppressed. Health and safety practices at this institution are such that these individuals may continue to carry out their duties without undue risk. BASi Safety and Security personnel along with Human Resources work closely with the Deaconess Occupational Medical Staff to train employees on precautions to be taken during personnel pregnancy, illness or decreased immunocompetence. There are written procedures to follow when an employee who works with animals becomes pregnant – the employee's physician is also involved in these circumstances. Should the employee's doctor advise, pregnant or immune-suppressed individuals may be transferred to another position or job function within this institution. Employees are provided training on allergies to laboratory animals. In addition, all employees are required to report any allergic reaction or suspected reaction when working with animals. The treatment of bites, scratches, or injury is dependent on the nature and severity of the injury, most medical issues are dealt with by having the employee fill out an accident form and treatment is provided by (b) (4)

(b) (4) Any bite or scratch resulting from contact with a non-human primate requires a blood draw from the animal and from the employee. These samples are sent to a laboratory to screen for Herpes B Simplex virus. A second draw is taken approximately 2 weeks later and again sent for analysis. All injuries are reported and an accident form is filled out no matter how minor the injury. All employees are required to seek medical attention/advice regardless of the severity of the injury. Those who decline are required to complete a medical waiver. Employees are offered tetanus vaccinations at the physical exam upon hiring. Employees are also offered influenza shots yearly.

Risk Assessment and Hazard Identification: BASi's Safety Committee has periodic meetings to review: risk assessment and hazard identification based on safety committee and employee input and suggestions; workplace incidents and injuries; analyze reports for possible trends; develop safety procedures and plans and training. BASi Occupational Health and Safety Standard Operating Procedures (SOPs) are periodically evaluated by the Occupational Health Professional.

Aspects Relating to Hazardous Agents: Employees are instructed to notify their supervisor if they suspect an illness or injury due to contact with an animal or hazardous agent. When necessary, the employee will be treated at a local medical center or hospital. Periodically, levels of formaldehyde and xylene are monitored at technician level in various areas to ensure the efficiency of hooded work areas. Extra precautions are taken by performing environmental and personal monitoring tests. Periodic monitoring of exposure to hazardous materials (i.e. formalin, isoflurane, etc.) is performed using the appropriate monitoring badge semi-annually or on an as needed basis.

All of our fume hoods and back/down draft table work areas are certified to compliance with OSHA regulations on an annual basis.

Special Precautions for Nonhuman Primate Users: BASi Evansville's program for personnel who work with nonhuman primates was adapted from the Recommendations for Prevention of and Therapy for Exposure to B Virus (Cercopithecine Herpesvirus 1) for employees exposed to nonhuman primate injuries. BASi Evansville has developed a detailed standard operating procedure for the procedures to be taken following a nonhuman primate related injury.

Hazard Identification and Risk Assessment: As a contract research organization, BASi Evansville considers all test articles to be hazardous or potentially hazardous. All personnel are trained, upon employment, through this institution's "Hazard Communication Program" and "Chemical Hygiene Plan." When available, Material Safety Data Sheets (MSDS) for test articles are reviewed for new and significant health/safety information. When hazardous test articles or agents are used in a specific study, the proper use and handling procedures for that agent may be noted in the protocol and discussed in pre-study startup meetings.

Description of Procedures that Reduce Potential for Injury: All personnel are instructed in the proper use of equipment, chemicals, test articles and the appropriate handling of animals. Safety equipment, described elsewhere in this outline, is required to be utilized by personnel in the conduct of their job. Additional instruction, such as proper methods of lifting, etc. is provided for personnel when required. Additionally, all personnel are supervised to assure that no one is injured due to carelessness or lack of appropriate instruction and training.

Description of Special Facilities: BASi Evansville considers all test articles to be hazardous. Animals are housed within conventional animal rooms. Entrance to the designated room(s) is limited to trained necessary personnel. At the end of the study utilizing hazardous materials, the room is thoroughly cleaned and sanitized.

Feed mixing areas are equipped with exhaust hoods to facilitate removal of aerosolized materials from potentially hazardous test articles. There are also exhaust hoods for use in various areas when necessary.

Description of Housing and Care for Animals Exposed to Hazardous Agents: BASi Evansville considers all test articles to be hazardous. Animals are kept in the same animal room for the duration of the study and are cared for by trained personnel. All animals on study housed at this institution are considered exposed to hazardous or potentially hazardous agents. The housing and husbandry of animals at BASi Evansville is described thoroughly in facility standard operating procedures.

Personnel Training:

Description of Special Qualifications and Training for Work with Hazardous Agents in Animals: BASi Evansville considers all test articles as hazardous. Therefore, all personnel are trained, upon employment, in the handling of all test articles as hazardous agents. Specifics pertaining to the proper use and handling of hazardous agents are described in the study protocol and discussed during pre-study protocol meetings.

Description of Educational Programs: Employees are informed of occupational health and safety considerations through BASi Evansville's "Hazard Communication Program" and "Chemical Hygiene Plan." After attending the training class, each employee will sign a form to verify that they attended the training and understood the information presented. Additionally, all employees must read and sign a form to verify that they have read and understood this institution's standard operating procedures pertaining to zoonotic diseases and the protection of employees from other known and potential hazards associated with handling research animal species. Training is provided in the areas of zoonosis, allergies, and hazards. Zoonosis training is provided by the veterinary staff. The allergy and hazard training is covered by the Safety and Security staff with some specialized training provided by supervisors as on the job training.

Occupational Health and Safety Program Personnel: The planning and monitoring of the program is done by the Facility Safety Officer and the veterinarian on staff. The personnel listed above also work closely with the Occupational Health Professional at Deaconess COMP Center. The Occupational Health and Safety Program is monitored by the BASi Safety and Security Department. All employees at the Evansville site are covered by the Occupational Health and Safety Program to the extent that is warranted by the job function of each individual employee. The employees are enrolled in the program and training is initiated during the orientation week after being hired. All BASi employees, including maintenance, housekeeping, safety, and/or interns, receive training on animal welfare, B-virus and animal allergy awareness, safety upon employment.


- 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:
 - The Institution's scientists, research technicians, animal care technicians, IACUC members, and other personnel involved in animal care and use upon employment, receive training and instruction regarding humane and scientifically acceptable use of animals in research. The training also includes the use of a minimum number of the appropriate species to obtain valid results and the avoidance and minimization of discomfort, distress and pain to the animals. The AALAS Learning Library is used to aid in the training session, specifically the areas concerning Regulatory Compliance Training and the Animal Welfare Act. All employees are made to understand that abuse or mistreatment of any animal is grounds for immediate dismissal. Documentation of training is maintained in the employee's training file.
 - Literature concerning humane animal care and use and alternatives to animal testing is made available for the use of all employees and IACUC members in the conference room in Building B. An electronic resource library has been created on the Institution's local network. The library includes such documents as the Animal Welfare Act, the Guide, PHS Policy on Humane Care and Use of Lab Animals, etc...The Attending Veterinarian or his/her representative will

conduct annual training session(s) on the humane care and use of animals. All employees are instructed to immediately report any concerns about the humane care and treatment of any animal at this institution to a member of the IACUC, the attending veterinarian, or their supervisor.

All new IACUC members attend a training session provided by the IACUC Chair. At this training session, the roles and responsibilities (protocol review, facility inspections, program evaluation, etc...) of the IACUC are explained. The documents pertaining to the animal welfare are discussed; the location of the documents on the computer network is given at the training session. New members are also given a list of documents (all BASi SOPs relating to the care and use of animals, the Animal Welfare Act and Regulations, AAALAC International Position Statements, Institutional Animal Care and Use Committee Position Statements, OLAW/ARENA Institutional Animal Care and Use Committee Guidebook, Report of the AVMA Panel on Euthanasia, Guide for the Care and Use of Lab Animals, Animal Welfare Policies, BASi Emergency Operations Plan, Occupational Health and Safety Program for Individuals with Animal Exposure, Occupational Health and Safety in the Care and Use of Research Animals, PHS Policy on Humane Care and Use of Lab Animals, the approved Animal Welfare Assurance and the OLAW On-line Tutorial) that are required reading for IACUC members, a form is completed indicating the reading of these documents. Periodically, IACUC members will receive training either off-site at conferences or on-site by consultants. IACUC members also attend webinars provided quarterly by OLAW.

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, Philip A. Downing.
 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, Philip A. Downing.
 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: Philip Downing

Title: Senior Vice President of Preclinical Services

Name of Institution: BASi

Address: (street, city, state, country, postal code)
10424 Middle Mt. Vernon Road, Mt. Vernon, IN 47620

Phone: (b) (6)

Fax: (b) (6)

E-mail: pdowning@basinc.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: (b) (6)

Date:

23 AUG 2017

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

Doreen H. Bartlett
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
bartletd@mail.nih.gov

Signature: (b) (6)

Date:

8/24/17

Assurance Number:

D16-00571 (A4058-01)

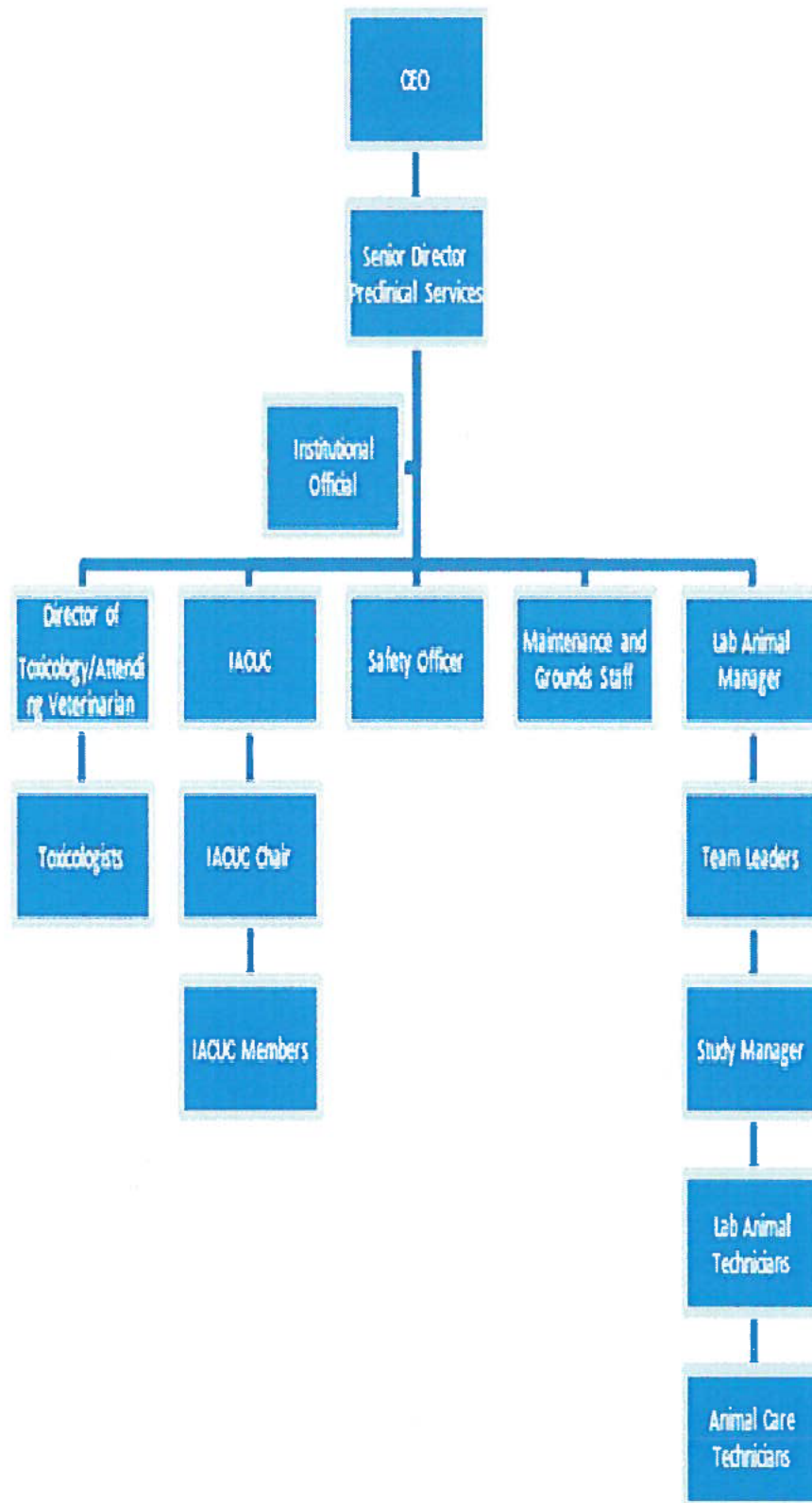
Effective Date:

9/1/17

Expiration Date:

9/30/21

Animal Care and Use Program Key Roles





VIII. Membership of the IACUC

Date: 13 April 2017			
Name of Institution: BASi			
Assurance Number: A4058-01			
IACUC Chairperson			
Name*: Christina M. Drennan		PHS Policy Membership Requirement: Member	
Title*: Data resource Manager		B.S. – Biology, LAT	
Address*: (street, city, state, zip code) BASi 10424 Middle Mt. Vernon Rd. Mt. Vernon, IN 47620			
E-mail*: cdrennan@basinc.com			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Braden M. Kemmerling/(V)	DVM	Attending Veterinarian	Veterinarian
(b) (6)			Scientist
			Nonscientist
			Nonaffiliated
			Non-voting member
			Member
			Member
			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 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.

Nonscientist

practicing scientist experienced in research involving animals.

Nonaffiliated

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

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. Mr. Rohlfer meets all of the requirements of a nonaffiliated member of the IACUC.

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:	
Title:	
Phone:	E-mail:
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

Date: 13 April 2017			
Name of Institution: BASi			
Assurance Number: A4058-01			
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
(b) (4)	15,055	Dogs, Pigs	61 Dogs 1 Pigs
	29,975	Rats, Mice, Rabbits	582 Rats 5 Mice 3 Rabbits
	6,550	Rats, Mice	463 Rats 552 Mice 12 Rabbits
	7,955	Dogs, pigs	8 Dogs
	4,656	Monkeys	94 Monkeys
	4,471	Dogs, Pigs	Not in use
	1,002	Dogs, Pigs, Monkeys	2 Monkeys
	3,316	Monkeys	Not in use

*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.

**Each building has animal rooms which may be configured to house these animal species. Listing each species should not be construed as to imply all are housed in the building simultaneously.