

D16-00554 (A3984-01)

Animal Welfare Assurance for Domestic Institutions

I, John Barton Sr. as named Institutional Official for animal care and use at Barton West End Farms, Inc., 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:
Barton's West End Farms Inc.
Location 1: 161 Janes Chapel Road, Oxford, New Jersey 07863
Location 2: 576 Townsbury Road Great Meadows, New Jersey 07838
- B. B. The following are other institution(s), or branches and components of another institution: (NA). There are currently no other covered locations or Branches-only these two locations listed above are covered under the BWEF Assurance statement.

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.

Recommended Reference:

- o [Distribution of Assurance within Institution](#)

- 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](#)).

Recommended Reference:

- o [Use of the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching](#)

- 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:

[Insert or attach a description or organizational chart for these components:

See attached ORG Chart BWEF

Chief Executive Officer- John Barton Sr.

Institutional Official- John Barton Sr.

IACUC- Dr. John Vlazny

Attending Veterinarian- Dr. Jeff Weagly

(b) (6)

BWEF is led by the CEO and Institutional Official, Mr. John Barton, Sr.

Dr. John Vlazny is Chair of the BWEF IACUC and reports directly to the IO and CEO (Mr. Barton) for all matters of a regulatory nature and for IACUC matters.

Dr. Jeff Weagly serves as the Attending Veterinarian and reports directly to the CEO and IO (Mr. Barton). Dr. Weagly has direct supervisory oversight and responsibility for the veterinarians on staff who serve in a clinical role.

An organizational chart is attached. All IACUC membership is encouraged to offer suggestions, comments and improvements either through the IACUC Chair or directly to the Institutional Official.

- 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. Jeff Weagly / Attending Veterinarian and IACUC member. Animal health and animal welfare compliance. Surgical Modeling and nonhuman primate (NHP) experience. Has 10 plus years lab animal experience. Has access and veterinary care program oversight of all species on site 7 days a week. Degree: DVM Ross University, St Kitts (2006). New Jersey State License # 29V100628200 / Fed Accredited #003216. Authority: Dr. Weagly has direct program authority and oversight responsibility for the animal care and use program including access to all animals. The A V has primary oversight of the veterinary care program. He is an independent consultant and is on site at least weekly, or more frequently if necessary. In addition, he is available on-call 24/7. The AV has unrestricted access to the animals and the vivarium. The A V has the authority to institute appropriate measures to relieve pain and distress, including euthanasia. The A V serves as a member of the IACUC. The AV is included on all clinical case correspondence and clinical cases captured by the Laboratory Animal Resources (LAR) staff or research investigators and is consulted for follow-up as necessary. The AV is responsible for reviewing and approving all surgical, anesthesia, and euthanasia procedures and for the oversight of training in these procedures. The A V approves all animal sourcing and supply. The A V consults with investigators on new animal models (e. g. animal procedures, veterinary care, anesthesia and analgesia selection, disease models) and related animal care concerns. A description of the veterinary care program is on file in the IACUC office which delineates his roles and responsibilities as the Attending Veterinarian (attached). This is a part time position. He maintains a part time position and provides 25% of his time to the animal care and use program. His direct reports for the veterinary care include Drs. Vlazny, (b) (6) and

(b) (6). All three veterinarians report direct to Dr. Weagly and work under his direct supervision and under the authority of his NJ license as they are not licensed to practice veterinary medicine in any state. They do not have ECFVG certification and are not federally accredited.

In the unusual event that Dr. Weagly is unavailable, the backup AV for him is (b) (6)

- 2) Name: Dr. John R Vlazny / IACUC Chair and Regulatory Oversight. Lab Animal Veterinarian for over 35 Years. Degree: DVM / University of Parma Italy (1981). Dr. Vlazny has extensive experience and training in surgical procedures, experience in nonhuman primates, canines and farm animal species. He maintains a full time position. As he maintains a full time position, he provides 100% of his time to the animal care and use program.

- 3) (b) (6)

- 4) (b) (6)

Recommended References:

- o [*ACLAM Guidelines on Adequate Veterinary Care*](#).(PDF)
- o *Guide*, pages ~ 114

- 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.

A current roster of the IACUC of BWEF is attached. (see Part VIII.),

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 performs a review of the program for humane care and use of animals at least once every 6 months for all aspects of the Institution's animal care program and facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual animal care program review are as follows:

Reviews of the animal care and use program and facility inspections are completed at the time of the semiannual program and facilities review. All members of the IACUC are involved with and perform the program review at a convened meeting.

We utilize our written AAALAC program description and the Guide for evaluating the content of the animal care and use program reviews. The program description is maintained and updated at least annually to ensure the program content described is current and accurate. The AAALAC program description is used as a written description of the animal care program and accompanying Standard Operating Procedures (SOP) for animal and veterinary care as part of the OLAW semi-annual program review, with an emphasis placed on animal care and veterinary care. A current version of the AAALAC Program Description is always used to review the key aspects of the animal care and use program at BWEF. The Program Description is based on the Guide for the Care and Use of Laboratory Animals (2011). In addition, the program review checklist that is attached is also used for ensuring consistency or review and for purposes of documentation. The aspects of the Program Review include: Introduction/Description (Exceptions, Contract Facilities, Animal Use Areas); Regulations, Policies, Principles, Program Management, Personnel Management (to include Training and Occ. Health), Personnel Security, Investigating Animal welfare Concerns Roles and responsibilities of the IACUC, Protocol Review, Post Approval Monitoring, Disaster Planning and Emergencies, Veterinary Care, Procurement and Transport of animals, Preventive medicine, surveillance and diagnosis of diseases, Clinical care and management, Surgery and Surgical care, Record keeping, Pain and distress, anesthesia and analgesics, Euthanasia, Physical Plant (HVAC, Maintenance, design, Construction guidelines, etc.), Special areas (Imaging, surgery).

We also use the OLAW checklist to ensure that the correct content is included for the entire program when it is reviewed. The *Guide* is used as a reference document, as well as the reference documents/reference resources listed on the AAALAC website, as needed.

The IACUC uses the OLAW based facility and program inspection checklist and the Guide to assure consistency and thoroughness in review. The semi-annual Program and Facility Review Report is prepared and then is used to organize and track information regarding deficiencies, plans, and schedules for correction. The table is then sent to the IO for review. A full report is sent to the IO in writing after the IACUC has had the opportunity to review and approve it after each semiannual review. Findings are categorized as either significant or minor, target date for completion, or a plan of action and person(s) responsible are included in the report.

The semiannual program review and the semiannual facility inspection are conducted every 6 months. Our last semiannual program and facility reviews were conducted on April 17th and October 16th 2018.

- 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:

Inspections teams for the facilities are assigned by The IACUC Chairman to inspect the facility areas during the regular semi-annual review meetings. The teams which are constituted from the entire IACUC membership. Teams always involve at least two members of the IACUC for any given area or function in the facilities. Then all animal facilities are inspected and a checklist is used as a guide for the inspection process. The use of the checklist was approved by the majority of the IACUC membership. The areas inspected include all animal procedure laboratories, surgery areas, surgery prep and post op care areas, animal holding rooms, laboratories cage washing, storage, and all ancillary support areas such as feed and bedding storage, lockers and shower space. The findings are recorded by the team members, collated and then placed on the checklist as described above. The findings are categorized as significant or minor, a schedule for correction, and responsible people determined. The report is voted upon by the IACUC, Signed, and forwarded to the IO as a formal report from the IACUC.

- 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:

Reports of IACUC evaluations distinguish between significant deficiencies and minor

deficiencies. A schedule for completion and responsible persons to perform the corrective actions are identified during each semiannual review and sent out to the entire IACUC for review. To date, we have had no significant deficiencies that threatened the health or welfare of the animals. All reports will be available to OLAW, when requested, both as hard copies and electronic versions. Any departures and reasons for departures from the Guide, PHS Policy, or Animal Welfare Act Regulations (AWAR) will be identified in the report. To date, BWEF has not had any such departures. The process as described above is precisely what BWEF does in its adherence to the Guide, PHS Policy, and AWAR. The report is signed by all of the members of the IACUC. To date, there have been no dissenting opinions. A specific call for dissenting opinions is made at the IACUC meeting and recorded in the meeting minutes allowing for and documenting the opportunity to disagree.

The IACUC Chairman reviews the reports or any responses and provides a written letter of notification to The Institutional Official of its findings and recommendations.

Both protocol approval and suspension of animal study protocols by the IACUC do require a majority vote of a quorum of the IACUC at a convened meeting. Any IACUC member's dissenting vote on these issues is recorded in the minutes, this does not constitute a minority view for reporting purposes. Any minority views, if expressed, are also recorded in the minutes. Any minority views and /or dissenting votes are discussed by the IACUC Chair and the IO and any member expressing a dissenting vote or minority view are always encouraged to discuss their views with the IO and /or the Chair of the IACUC.

Any IACUC member may submit a minority view to OLAW addressing any aspect of the institution's animal program, facilities, or personnel training.

If a minority view is expressed during a meeting, it will be noted and included in the minutes of that meeting. This will also be included in the report to the IO.

Recommended References:

- o [Departures from the Guide](#)
- o [Distinguishing between significant and minor deficiencies](#)
- o [Sample semiannual report to the Institutional Official](#)

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

BWEF has a reporting system in place which allows all membership and any BWEF employee to report any incidence or animal welfare concern anonymously. In each animal area or in the buildings of on-site locations, a box is available so that anyone can submit a written and anonymous complaint. The forms are provided in these locations and the instructions are provided. There is an assurance statement on the concern form used that states anyone may express a concern and that there is no retaliation and that the concern will be handled in a confidential and respectful manner.

These boxes are checked every week. Any complaints or concerns are sent to the IACUC chair for further action and follow up as described below. In addition, all animals are carefully monitored multiple times per day during study conduct for any signs of pain, distress, or adverse drug effects. Any deficiencies or unexpected outcomes must be reported in writing (e.g., email) as soon as possible after the event to the IACUC Chair, AV and/or LAR management. The report would include a brief description of the event and actions taken to minimize impact on animal health and welfare. The IACUC Chair, AV, or designee would contact the sponsor and study director/ investigator to identify the root cause of the deficiency, if possible, and define any follow-up actions to prevent recurrence of the event (e.g., retraining, reassignment of work, supportive measures, etc.). If severe, the study may be suspended until corrective action is completed.

A study may be suspended only after the matter is formally reviewed at a convened meeting of a quorum of the IACUC with a majority vote of the quorum voting to suspend. All suspensions must also be reviewed by the IO in consult with the IACUC, and any corrective actions taken by the IO are reported to OLAW.

Tracking: The IACUC will review and track reported deficiencies on an ongoing basis. A sign is posted in the vivarium that explains that concerns or complaints may be brought forward in an anonymous and confidential manner to any member of the IACUC, the AV, or the IO (whistleblower clause). Their contact information is listed. Should a concern be expressed by any employee, the concern will be thoroughly investigated and corrective action implemented. All concerns are handled confidentially and without retaliation or retribution. To date, no concerns have been submitted.

In the event a complaint is filed, the IACUC Chairman notifies the membership and a meeting is called to discuss the alleged complaints. Once the IACUC has met and determined the validity of the claim a report is drafted and submitted both electronically and on paper. The Institutional Official will request that the IACUC take the necessary action to report the incidence if applicable and come to an acceptable resolution. The IACUC committee has the responsibility to report any serious non-compliance or ongoing Guide deviations or exceptions (departures) of PHS policy. Significant deviations, exceptions, or departures from the Guide must be corrected within a specific timetable depending upon the decision of the IACUC and the severity or complexity of the issue. Such an incident will be reported to the appropriate agencies (OLAW, AAALAC, and USDA).

Recommended References:

- o *Guide, pages [23-24](#)*

- 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 Institutional Official (IO) and IACUC Chair work on site and are reachable by phone, email, or in person at all times. Any recommendations made to the IO are tabulated for review. A formal written report, which includes any recommendations for corrective actions, is made on a semiannual basis and sent to the IO from the IACUC. The report is signed by all IACUC members.

Signage is posted in all animal labs and animal holding areas for this policy as part of the policy to address concerns regarding animal welfare and concerns and it is emphasized that anyone may approach the IO (Mr. Barton CEO and/or the IACUC Chair) without retaliation and in confidence in training for current and any new employees. The IO and the IACUC Chair available on site for in-person meetings, by email, or telephone a daily basis. This is enabled by the fact that BWEF has a small staff who all work on one site along with the IO (CEO).

A formal statement to this effect is given by the IACUC Chair at each meeting as part of the meeting agenda.

- 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:

An animal care and use protocol is required for all research involving the use of animals at BWEF. Protocols are created by investigators using a standard template. Protocols may reference relevant SOP's, which are reviewed and approved at least every year by the IACUC, for routinely conducted studies with standard study designs and endpoints. The IACUC reviews all protocols submitted by investigators on a project-specific basis for research and training carried out at BWEF, taking into account a number of factors such as aims of the study, consideration of alternatives, and minimization of pain and distress. This includes both sponsored and non-

sponsored applications. Specifically for NIH studies, a new protocol will be submitted for each study with its own designated study number and will be reviewed by a full quorum of the IACUC. The AV reviews all protocols and provides advice and consultation, including during the planning stages, on topics such as objectives and end points of the study, consideration of alternatives, alleviation of pain and distress, surgical procedures, and the proper use of anesthetics and analgesics.

After the IACUC Chair and AV have reviewed a protocol, the protocol is forwarded to each member of the IACUC allowing adequate time for review, generally at least a week prior to the meeting. Protocol submissions must include species and number of animals to be used, a description of the use of the animals, the aims of the study, consideration of alternatives, a description of methods used to minimize discomfort and pain, and euthanasia methods. Justification of the animal model, animal numbers, and description of the procedures to which the animals will be subjected must also be included.

A full IACUC review occurs at a convened meeting with a quorum of voting members present. Meetings are only scheduled on days that allow all voting members to be present. A majority vote of the IACUC members present at the meeting is required to approve, require modifications in order to secure approval, or withhold approval. IACUC members will inform the Chair of any conflicts of interest. No IACUC member may participate in the review or approval of any activity that they may have a conflicting interest, with the exception of providing requested information or clarification. Any member with a conflict of interest may not contribute to a quorum. The investigator may be invited to an IACUC meeting to answer any questions.

The IACUC Chair will notify the investigator of the decision to approve or withhold approval or of any modifications required to secure approval. Written decisions will be electronically forwarded to the investigator. If members of the full committee vote to require modifications to be made to a protocol in order to secure approval, the modified protocol will be returned for a subsequent full committee review at a convened meeting. We do not utilize DMR at BWEF. Under no circumstances is an animal study allowed to proceed without IACUC review and approval.

Recommended References:

- o [Designated member review and full committee review](#)
- o [Electronic communications](#)
- o [Methods of IACUC review](#)
- o [Quorum](#)
- o [Tracking animal numbers](#)
- o [Use of nontraditional species](#)

- 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:

BWEF treats all revisions and amendments as a new protocol submission. Any newly revised or amended protocol is then submitted to the IACUC for a full committee review following the process for review described above.

Recommended Reference:

- o [Significant changes to approved protocols](#)

- 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.CA. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

BWEF IACUC Chairman notifies the Principal Investigator of the outcome of IACUC review

via a formal letter submitted electronically. If the IACUC notifies the Investigator of disapproval, a formal letter notifies the investigator with a general explanation as to why the protocol was not approved. The Investigator then has the opportunity to review and respond within a designated period of time as specified by the Chair. If the protocol is revised addressing the reasons for non-approval, and then resubmitted, the same review process will take place.

The IO may attend the IACUC meetings, but is a non-voting *officio* member. He attends the meetings mainly for the purpose of addressing any concerns the IACUC may have for a CRO sponsor-based study since he is most often the major point of contact with the client. The PI from the client or CRO sponsor is also available for any IACUC concerns during the reviews. If there is any conflict of interest for business or research study reasons, the IO recuses himself from the discussions so that there is no undue or unfavorable influence over the decision making or discussion by the IACUC members.

- 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.-S. The IACUC procedures for conducting continuing reviews are as follows:

BWEF Has a Post Approval Monitoring (PAM) program in place in which a designated member is appointed to conduct a visit and review of the study activities. A checklist form is provided by the IACUC chairman and a review and follow up discussion is had at the next IACUC meeting. Any deviations from the protocol will be reported to the IACUC, a decision made for a course of action, and then it would be determined if this would be reportable to OLAW.

BWEF completes a full committee review *de novo* for all protocols for all species at each semi-annual IACUC meeting. This is only possible because there are a small number of protocols performed at BWEF per year. The review of any protocol is scheduled so that no animal study is ever performed on an un-reviewed protocol because of a pending review by the IACUC.

Recommended References;

- o [Frequency of review](#)
- o [Model for performing continuing review of research activities](#)
- o [Postapproval monitoring](#)

- 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:

The IACUC may suspend an activity only after review of the matter at a convened meeting of an IACUC quorum present. A majority vote is required. The IACUC may suspend an activity if determined that the activity is not conducted in accordance of AWAR, the *Guide*, or PHS Policy IV.C.6. If a suspension is authorized, all activity will immediately cease, and the IO with the IACUC will review the reasons for suspension, take appropriate action, and report that action with a full explanation to OLAW.

If there is a suspension of activity by the IACUC, the IO cannot reverse the IACUC decision to suspend activity on a specific protocol.

- 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:

BWEF's OHS Committee is comprised of the Attending Veterinarian, a Staff Veterinarian, a Research Scientist, and the Facility Manager. Using the Occupational Health and Safety in the Care and Use of Research Animals reference and current literature as a guide, the OHS committee developed a risk assessment of both animal related hazards and non-animal related hazards for all job titles in the facility. These assessments are reviewed by: the BWEF OHS Committee at least annually; a consulting Industrial Hygienist who employs a medical professional at least every

three years; additional reviews are conducted as necessary. All employees at BWEF are considered to be "at risk" and are therefore included and then enrolled in the Occupational Health and Safety Program. All employees fill out and complete the medical surveillance questionnaire upon new employment and annually thereafter. Prior to handling a hazardous agent, all involved staff are trained in the proper handling of the agent; this includes, but is not limited to, review of: the SDS, risk related hazards of the agent, containment procedures, required PPE and personal hygiene practices.

A consulting industrial hygienist was employed to perform a complete animal program occupational health survey. The scope of the evaluation included monitoring and recording sound decibels in animal rooms during working hours as well as measuring levels of formalin exposure during simulated tissue perfusion. Radiation exposure badges are worn by those performing radiologic imaging procedures and personnel potentially exposed to anesthetic waste gases are periodically monitored to ensure there is no inadvertent exposure to anesthetic waste gases, and radiation, biosafety hazards, or chemical hazards like formalin as stated. Additional SOP's that are provided by the consultant as a result of the survey include: blood-borne pathogens, hearing conservation, biohazard protection and PPE, respiratory protection, use of formaldehyde and occupational exposure to hazardous chemicals in laboratories. The consultant also made recommendations in regards to the proper respiratory protection to wear when performing animal husbandry procedures. As part of the training, employees are advised to notify the Occupational Medicine consultant if they are planning to become pregnant or are pregnant, have a serious illness that could jeopardize their health if working with animals, or are immunocompromised so that appropriate work accommodations or restrictions can be implemented. To date there have been no personnel in any of these categories.

All employees must report all work-related injuries and accidents, to their supervisor, and an "Accident Report Form", must be completed. The OHS committee will review all reported incident(s), and determine what, if any, procedural changes and/or training should be instituted to reduce risks, and thereby reduce future similar injuries.

BWEF's OHS program is based on risk assessment and hazard identification; procedures, personal hygiene, personal protective equipment, facilities, and monitoring; and medical evaluation and preventative medicine. As stated, all employees are enrolled in the program. Employees are separated into different groupings for tracking purposes; these are: Veterinary (veterinary/husbandry), Research, Maintenance and Administrative. All BWEF employees and visitors are included in the OHS program. All employees of BWEF are included in the OHP and all employees fill out the medical surveillance questionnaire. The questionnaire is a required document that all new and existing employees must complete on an annual basis. BWEF considers all employees at the same level of risk status as part of OHP risk assessment, but are tracked separately as described above. It is under the oversight of BWEF Operations. An outside medical practice with expertise in occupational medicine has been engaged to provide review of medical questionnaires and provide guidance on medical surveillance and institutional occupational medicine issues. All surveillance questionnaires are submitted and reviewed by the medical practice. Basic PPE consists of laboratory coat or scrubs, gloves, goggles, shoe covers, and respiratory protection.

A sign listing the required PPE is posted on the door of any procedure room or animal room, which has a risk of exposure to a hazardous agent. Access is limited to appropriately trained personnel. In addition, the information for the provision of first aid and any necessary emergency health care contact information for the local hospital (Hackettstown, NJ. Community Hospital) is posted on all doors in the animal areas. Employees only work on-site when at least two people are present and a supervisor or manager are always on site when animal procedures or animal work is being performed, hence first aid and emergency responses are available through a work partner or supervisor. All employees are provided this information verbally as part of their safety training as well.

All personnel using the fluoroscope are trained in the risks associated with the fluoroscopy unit. Caution signs are posted outside the fluoroscopy room when the unit is in use and access is limited to personnel necessary to perform procedures. These personnel are equipped with lead aprons, thyroid shields. They are provided with radiation exposure badges that are sent to an outside facility quarterly for evaluation for exposure monitoring.

When working with NHP's there is a bite scratch kit provided in every NHP holding area that is available to anyone working with NHP. Instructions are included for providing immediate first aid. A log of bites and scratches is also maintained. All employees are trained and updated regularly on the importance of prevention of Macacine Herpesvirus. Should an employee be bitten or scratched, first aid is immediately administered on site and the person is then taken to the local hospital for treatment if necessary. The Occupational Health physician is immediately notified for follow up consultation and action(s). Employees are advised as part of the training to report any signs of illness or injury when working with NHP on a "no penalty" basis so that any suspect medical issues are immediately and safely addressed.

All of the procedures for reporting and contacting medical professionals are included in the bite scratch kit instructions.

- 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.

[Complete the Facility and Species Inventory table provided (see Part X.).

Note: list common names for animal species, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog.

Note: animal areas (buildings/rooms) may be represented by a number or symbol in this submission to OLAW.] See the attached form

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

[Describe training or instruction provided: people caring for or using laboratory animals in the proper and humane animal care and use.

Describe training or instruction on research or testing methods that minimize the number of animals required to obtain valid results and limit animal pain and distress.

Describe training or orientation provided to the IACUC members, including background materials and resources.

Zoonotic disease and allergy prevention training is conducted with all new employees and reviewed on an annual basis. Exposure to Allergens and surveillance of allergies is part of the annual health surveillance program. Employees are also informed and trained on the risk of animal allergies at least annually. Training is provided to each individual regardless of the level of activity i.e., animal caretaker, and maintenance or Vet staff. Each employee receives an

orientation training of our policies and an overall introduction to the BWEF SOPs. BWEF has a specific SOP for each species of animals

And each of the activities associated with animal care and handling here at BWEF. We also employ an ACLAM board certified laboratory animal veterinarian consultant with many years of lab animal experience, that trains our staff on a regular basis. Training is done using PowerPoint or video based materials. We keep a comprehensive record as well of each individuals and the training they received. We also provide AALAS training modules for those employees who would like to become AALAS certified. A copy of the Guide is used during training and is also kept in our main training conference area for the employees to reference whenever it is necessary.

All members of the BWEF IACUC, PI, and veterinary staff are made fully aware of the principles of the 3 R's and specific endpoints when they undergo training and orientation for joining the IACUC.

The concept and principles for how to reduce the use of animals, how to alleviate pain and distress, and define humane, specific and scientifically valid endpoints are included in questions on the IACUC protocol submitted. More importantly, the study director, the AV, and sponsors (PI's) are trained to perform statistical power analyses and incorporate this information as part of the study design submitted to the IACUC. Their CV's and training are on file and continuing education for these aforementioned topics are offered (e.g. scientific meeting attendance, publications, attendance at local and national AALAS, etc.).

All IACUC members and all personnel working with animals are also encouraged to take online courses or attend professional meetings such as NJABR, PSBR, or PRIM&R. BWEF supports their attendance at these courses and meetings, and provides appropriate resources to support all personnel training. The AV and IACUC Chair also provide orientation and training to all IACUC members on their roles and responsibilities at BWEF during their orientation and during training sessions. They are provided copies of the *Guide*, PHS Policy, and AWAR. They are also provided a copy of the AAALAC program description as part of their orientation and reference materials upon their appointment as an IACUC member. All personnel and IACUC training is documented in training binders, and binders are stored in the IACUC office.

For example, in 2017 we all attended a NABR hosted Q and A online webinar and discussion with USDA officials on most recent topics that affect regulations. Also in 2017, a training session on Recognizing Pain and Distress in different Species was presented. A consultant has helped us to implement a pain assessment program and trained both our Veterinarians and Animal Care staff on how to identify pain in the different species and an effective assessment and scoring of the pain levels. The assessment plan rates the level of pain and how to identify the different levels and what to do when this occurs. Other training sessions provided by the consultant were separate training sessions on Post Approval Monitoring, Changes in Expectations of AAALAC and USDA, and Oversight Roles and Responsibilities.

Recommended References:

- o [*Guide*, pages 1.:i, 17](#)
- o [*Training in the Laboratory Animal Science Community: Strategies to Support Adult Learning, 2007*](#)
- o [*Training of staff*](#)

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.

(I) This Institution is Category 1 - Fully 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.

Barton's West End Farms is an AAALAC accredited animal care and use program. BWEF enjoys Continued Full Accreditation. The most recent site visit was conducted March 13th 2018, when Continued Full Accreditation was granted.

Recommended Reference:

- o [*Sample semiannual report to the Institutional Official*](#)

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, *[Insert name or title of the Institutional Official signing the Assurance]*.
 - 5. Records of accrediting body determinations
The Institutional Official signing all regulatory documents for the AWR, AAALAC, and OLAW is Mr. John M. Barton, CEO of BWEF, and Inc. He serves as the IO and CEO in all of these instances.
- 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) BWEF enjoys Continued Full Accreditation from AAALAC.
There has been no change in status.
 - 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance.
There have been no major changes in the institution's animal care and use program.
 - 3. Any change in the IACUC membership.
There has been a recent loss of one IACUC Outside/Nonscientist Member due to a recent death. This position is under recruitment and replacement.
 - 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, John M Barton Sr. CEO and Institutional Official receives the semi-annual reports from the IACUC. The last two dates of the semi-annual reports are April 17th 2018 and October 16th 2018
John M. Barton Sr. serves in the capacity of IO and is the CEO of BWEF, Inc. and receives these reports.
 - 5. Any minority views filed by members of the IACUC.
To date, there have been no minority views expressed or recorded in the minutes of the IACUC.
 - 6. At this current time there are no major changes to report.

- B. 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 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.
To date, there have been no changes or reportable incidences of noncompliance or serious deviations from PHS policy, nor have there been any suspensions of 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: John M Barton	
Title: CEO	
Name of Institution: Barton's West End Facilities	
Address: (street, city, state, country, postal code) 161 Jane's Chapel Road Oxford, New Jersey 07863	
Phone: (b) (6)	Fax: (b) (6)
E-mail: jmbarton@bwefinc.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: JANUARY 23RD 2019

B. PHS Approving Official (to be completed by OLAW)	
Name/Title: Jane J. Na / Veterinary Medical Officer Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD USA 20892-6910 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Signature: Jane J. Na -S <small>Digitally signed by Jane J. Na -S DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, cn=Jane J. Na -S, 0.9.2342.19200300.100.1.1=2002213367 Date: 2019.01.25 09:20:17 -05'00'</small>	Date: January 25, 2019
Assurance Number: D16-00554 (A3984-01)	
Effective Date: January 25, 2019	Expiration Date: December 31, 2022

VIII. Membership of the IACUC

Date: September 26, 2018			
Name of Institution: Barton's West End Farms Inc.			
Assurance Number: D16-00554 (A3984-01)			
IACUC Chairperson			
Name*: John R Vlazny			
Title*: IACUC Chair and Regulatory oversight			Degree/Credentials*: DVM
Address*: (street, city, state, zip code)			
161 Jane's Chapel Road Oxford, NJ 07863			
E-mail*: Jvlazny@bwefinc.com			
Phone*: (b) (6)		Fax*: (b) (6)	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
John R Vlazny	DVM	IACUC Chairman	Chair / Veterinarian
(b) (6)			Member
Glenn Dobson	MS	Dir of Research	Scientist Member
(b) (6)			Member
(b) (6)			Member
Jeff Weagley	DVM	Attending Veterinarian	Attending / Vet Member
(b) (6)			NonAffiliated /Scientist
(b) (6)			Non Affiliated /Non Scientist

* 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.

All members are renewed and or appointed annually by the CEO John M Barton Sr

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

(b) (6)

Contact #2

Name:

Title:

Phone:

E-mail:

X. Facility and Species Inventory

Date: September 26 2018

Name of Institution: Barton's West End Farms Inc.

Assurance Number: D16-00554 (A3984-01)

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)	@ 360 Sq ft	Rabbits	12
	@ 650 Sq ft	Swine	8
	@ 10,000 Sq ft	Swine	183
	@ 1900 Sq ft	NHP's ? Baboon / Pigtales	25
	@ 2500 Sq ft	NHP's / Rhesus and Cynos	68
	@ 6300 Sq ft	Swine	88
	@ 1800 Sq ft	Swine	14
	@ 1200 Sq ft	Canines	6

"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.



BWEF Inc.
Organizational Chart

