Marshall Farms Group, Ltd. d/b/a Marshall BioResources
D16-00836 (A4621-01)

Animal Welfare Assurance for Domestic Institutions

I, Andy Smith as named Institutional Official for animal care and use at Marshall Farms Group, Ltd. d/b/a Marshall BioResources, 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, DDHS, and/or NSF (if applicable). This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
Marshall Farms Group, Ltd. d/b/a Marshall BioResources only ferret buildings R1 & BF 38.

B. The following are other institution(s), or branches and components of another institution:
Not applicable.

II. Institutional Commitment

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

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

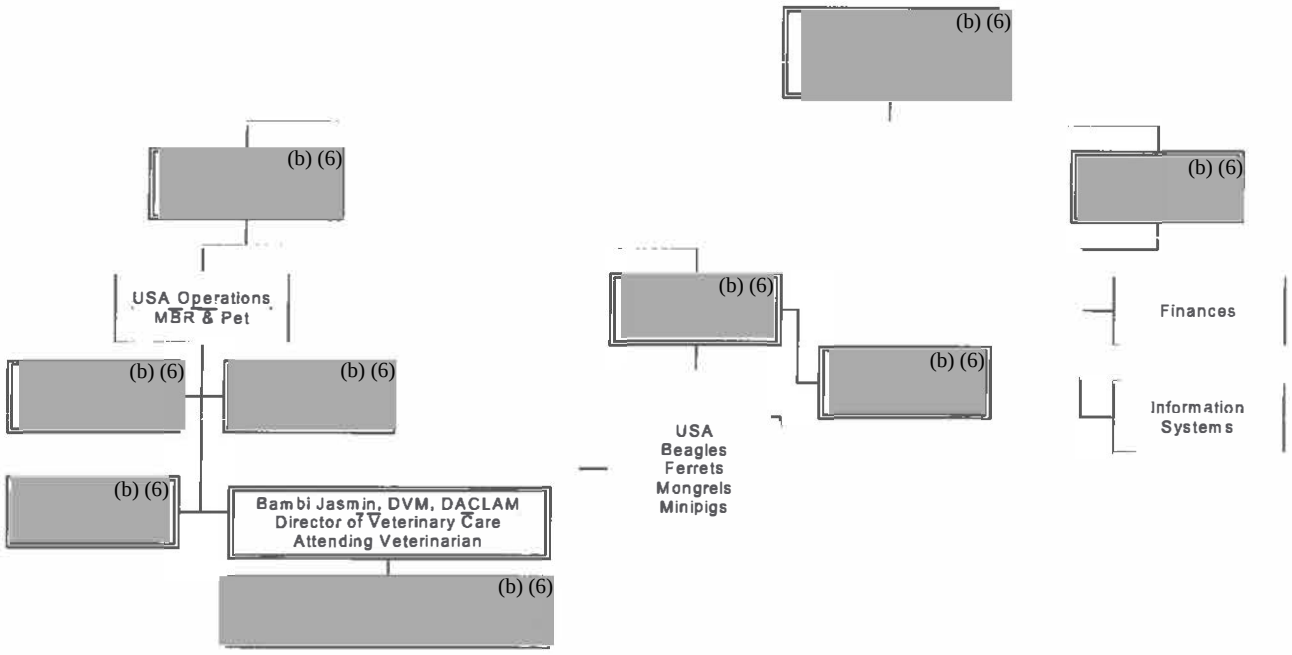
C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.

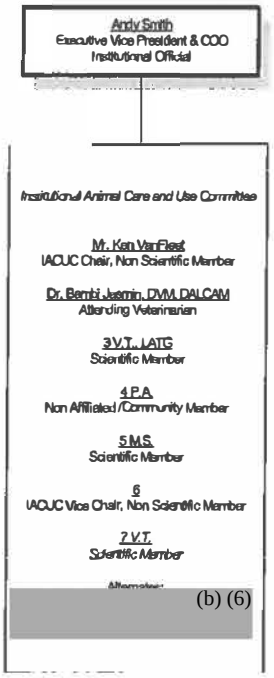
D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* (*Guide*).

E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

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





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. Bambi Jasmin

Qualifications

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

Dr. Bambi H. Jasmin is a 2006 graduate of Ross University School of Veterinary Medicine. After graduation she completed a one-year internship in Food Animal Medicine and Surgery at Colorado State University in Fort Collins, CO (2006-2007) and then a three-year residency program in Laboratory Animal Medicine from 2007-2010 at the University of Pennsylvania in Philadelphia, PA. Dr Jasmin successfully sat for the American College of Laboratory Animal Medicine (ACLAM) boards in June 2011 and served as a facility veterinarian at Marshall BioResources. In September 2011, Dr Jasmin was re-titled as Director of Veterinary Care, Attending Veterinarian and appointed as the alternate for the Veterinarian Representative on the IACUC. In November 2012, Dr Jasmin was appointed as the Veterinarian Representative on the IACUC.

Authority: Dr. Jasmin 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 with 100% of time contributed to the animal care and use program.

2) (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 will review the Program for Care and Use of Animals once every six months at convened meetings using the Guide, the Policy/ Animal Welfare Assurance, the Animal Welfare Act and Regulations and the OLAW Semiannual Program Review and Facility Inspection Checklist as a basis for evaluation and include but not limited to occupational

health and safety, veterinary care program, PHS Policy/Animal Welfare Assurance, The Guide, and training program. Each program element is reviewed by members during program review. The IACUC will categorize any program deficiency as minor or significant and develop a plan and schedule correction for any deficiency.

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 IACUC will inspect at least once every six months all of the animal facilities, including satellite holding facilities and areas in which surgical manipulations are performed. The IACUC uses the Guide, the Policy, the Animal Welfare Act and Regulations (AWARs) and the OLAW Semiannual Program Review and Facility Inspection Checklist to guide them during the facility inspection. All IACUC members are invited to participate in and any IACUC member can attend an inspection of any facility. At a minimum, two voting IACUC members conduct the facility inspections to include all facilities where USDA-covered species are housed or used. Facility inspection findings are presented at convened IACUC meetings. The IACUC will categorize any facility deficiencies as minor or significant and develop a plan and schedule correction for any deficiencies.

3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

- The IACUC develops reports of the IACUC evaluations addressing the requirements outlined in the Guide, the Policy, and the AWARs; listing the dates when program evaluation and facilities inspections were conducted and containing a description of the nature and extent of the institutions adherence to the Guide, the Policy and the AWARs. The IACUC identifies any deficiency as significant or minor. When a significant deficiency is noted by the IACUC, the deficiency is addressed immediately in a manner such that the threat to the animal's health or safety is removed immediately. The IACUC assigns reasonable and specific plans and schedules for correction of all deficiencies. Owners are assigned to each deficiency and both the owner and the IACUC are responsible for ensuring timely correction of the deficiency. Any minority views or a statement that there were no minority views are also included. The IACUC reviews and approves departures, including reason for departure, from the Guide, the Policy, and AWARs prior to implementation. During semi-annual program review, the IACUC considers any departure previously approved and ensures that the departure continues to be warranted. A list including any departure, the reason for departure and a comment regarding continued approval or disapproval is noted in IACUC records and reported to the Institutional Official in the IACUC evaluations. The IACUC evaluations are reviewed and approved at an IACUC meeting; the IACUC submits reports to the Institutional Official. The reports are signed minimally by a majority of IACUC members and 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:

Marshall's policy requires all employees to safeguard animals in Marshall's care by reporting any concerns of substantiated or suspected cases of adverse conditions, animal mishandling or abuse. Complicity or shared guilt through tolerance of such behavior or actions is perceived by failure to report an incident.

Posters noting the process for reporting, as well as the Standard Operating Procedure (SOP) titled, "Care and Use of Animals - Reporting Concerns" are placed in high traffic areas. The SOP may also be accessed via the Marshall Document website. In addition, during training, employees are instructed to report an animal concern if they observe, have evidence or knowledge of an adverse condition, animal mishandling or animal abuse, or if they are unsure if an action or condition could be considered as adverse, mishandling, or abuse.

Animal welfare concerns are directed verbally or in written form to the Institutional Official, IACUC Chair, Director of Production, Director of Human Resources and/or the Attending Veterinarian.

The following information is requested:

- Name(s) of animal caregiver(s) or technician(s) or other individual(s) involved;
- Time, date and location of alleged incident or condition;
- Description of action or condition;
- Specific animal(s) involved (if possible); and
- Witnesses, if any.

Though reports that are directly submitted from named individuals generally allow for better fact-finding, anonymous reports of animal welfare concerns are investigated as thoroughly as possible given the information provided. Anonymous reports may be directed to the same individuals and include the same information as listed above. Also, reports may be submitted anonymously through a computer program with computers available to all employees in the employee break room.

The animal welfare concern information is forwarded to a committee composed of the Institutional Official, IACUC Chair, the Director of Production, the Attending Veterinarian and the Director of Human Resources. At that time, the Committee will investigate the issue. This committee is charged with investigating concerns or alleged event(s) and recommending disposition to the Institutional Official.

Upon review of the evidence, the Animal Care Review Committee will issue a finding that may dismiss the concern as unfounded, suggest remedial training, suggest progressive discipline, or corrective action based on evidence, nature of incident, prior history and company policy. Regardless of determination, the Institutional Official will receive a written report detailing the concern, investigation and suggested disposition. The Institutional Official will receive the Animal Care Review report and recommended disposition along with any other evidence and determine final disposition. The results of the Animal care Review Committee's investigation and the final disposition by the IO will be discretely communicated to both the employee(s) raising the issue (if known) and the employee(s) alleged to have mishandled animal(s). Confidentiality will be maintained in all cases and there will be no reprisals against any individual that reports concerns of animal welfare. All investigations of complaints will be carried out in a discreet, thorough and fair manner. The IACUC Chair and Attending Veterinarian will report all concerns to the IACUC at the next convened.

5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

   The IACUC may evaluate a particular aspect of the animal care program, facilities, or personnel training at a convened meeting and vote to approve the minutes of the meeting. The Institutional Official receives the minutes. In addition, the IO is invited to all IACUC meetings.

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:

   IACUC Review of Protocol
   In order to approve a protocol or significant change in an approved protocol the IACUC must review all components of the activities related to care and use of animals, determine that the proposed activities meet and comply with the AWA regulations and standards and internal policies and guidelines, as applicable. The written protocol must

be submitted and approved by the IACUC prior to the start of any animal use activity. The PI will consult the veterinarian regarding proper use of anesthetics and pain relieving medication for any painful procedure as well as consult regarding proper use of any veterinary drugs listed in the protocol that are not included in standard SOPs. When complete the veterinarian signs PIs may submit a protocol to the IACUC Chair, IACUC Vice Chair or Attending Veterinarian for IACUC consideration. The Veterinarian completes

Conflicting Interest
To avoid the perception of conflict of interest, IACUC members who would substantially benefit either financially or by other means from the outcome of the vote or those who are participants in the protocol (e.g., is personally involved in the project) being reviewed do not participate in the review, deliberations and decisions on those protocols except to provide information requested by the IACUC. The member with conflicting interest will not contribute to the constitution of a quorum and will not be present for the review or approval of the protocol. The Chair will ensure a quorum of the IACUC is maintained when a member abstains from voting due to conflict of interest. If the quorum is lost, all IACUC activities will be suspended.

Designated Member Review
Any protocol may be reviewed through Designated Member Review (DMR). The IACUC receives a copy of the protocol (or a list of protocols) typically via e-mail and are given the option of calling for a Full Committee Review (FCR) by contacting the IACUC Chair. If full IACUC review is requested, it is conducted. A time period to allow the committee to call for full IACUC review is set. In addition, an affirmative response is requested. If all members provide affirmation, the DMR may proceed. If after a designated time period of minimally 24 hours, not all members have provided an affirmation but no IACUC member has requested Full Committee Review, the IACUC Chair appointed qualified designated member may proceed with designated member review of the protocol. Only one designated member will be assigned by the Chair. The Designated Member can approve, require modifications to secure approval, or request full Committee review. The Designated Member, assigned by the Chair, may call for Full Committee Review by contacting the IACUC Chair. Regardless of pain classification, a Full Committee Review is required to disapprove or deny an animal protocol. Any member may call for FCR at any time.
All animal use protocols brought before the IACUC via Designated Member Review are approved as submitted, require modification in (to secure approval), or referred to the full committee for review. Designated review may not result in withholding of approval.

Full IACUC Review
Any member of the IACUC may request full IACUC review by contacting the IACUC Chair directly. Any protocol may be reviewed as Full Committee Review however those determined by DMR to require FCR must be reviewed at a meeting of the IACUC, defined as a quorum of the total membership. A majority of that quorum must vote in favor for it to be officially approved. All animal use protocols brought before the IACUC are approved as submitted, require modification in (to secure approval), or withhold approval with recommendations for major revisions.

A quorum will be a majority (>50%) of the voting members of the IACUC. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. Protocols shall be approved, require modification in (to secure approval) or withhold by the majority vote of the quorum present. When substantive modifications are required in a protocol to secure approval, the resubmitted protocol will be reviewed using either FCR or DMR.

Full IACUC Review followed by Designated Member Review
Note that if during Full Committee Review substantive information is lacking from a document presented for IACUC approval, the committee may have questions requiring a response from the PI. In such situations, the IACUC, whether or not all members of the IACUC are present at the meeting, may use Designated Member Review subsequent to

FCR when the members present at a convened meeting decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. All members have agreed in advance to this procedure as indicated by written approval signature within the Policy on Animal Care and Use SOP. However, any member of the IACUC may at any time request to see revised document and/or request FCR of the document by contacting the IACUC Chair directly. Again the IACUC Chair appointed designated member (or members) can approve, require modifications to secure approval, or request full Committee review by contacting the IACUC Chair. If full IACUC review is requested, it is conducted. Regardless of pain classification, a Full Committee Review is required to disapprove or deny an animal protocol. Members agree to allow DMR following FCR when approved by unanimous vote by the quorum present at a convened IACUC meeting.

Approve
The IACUC has determined that, for a particular animal use and teaching protocol, appropriate justification for animal use has been made, a search for acceptable alternatives to animal use has been demonstrated as required, and methods described are within standard and acceptable guidelines. The IACUC signifies its approval of a research protocol by issuing a letter to the PI and IO that the research protocol has been reviewed, approved, and may be conducted. Protocols involving little risk to the subjects may be approved even if the benefit to be gained is likewise small. Protocols having higher degrees of risk to the species must demonstrate both sound methodology and an importance to the information that would be gained. The IACUC or designee will write a letter to the PI indicating approval date and required dates for annual and triennial reviews. The approval date is the date the study is approved by full committee for FCR or designated member for DMR. No protocol approval will extend beyond 3 years from the approval date.

Require Modification in
Protocols with a review status of Require Modification in (to secure approval) are most typically in need of one or more minor corrections or clarifications. The IACUC or designee will write a letter to the PI indicating that to receive approval for the protocol certain minor revisions must be made to the protocol. The letter will detail the items or questions requiring attention. Alternatively, when the PI is in attendance at FCR, record of modifications to secure approval will be documented in the IACUC minutes of that meeting. In certain cases the IACUC Chair might also elect to contact the PI directly to insure that the needed revisions are understood or to discuss ways the PI might meet the requirements of IACUC. If the PI responds to these minor issues raised in the letter to the satisfaction of the IACUC Chair, the IACUC Chair, as designated reviewer, or an assigned designated reviewer may approve the protocol as revised. If no revisions are made, or the revisions are not satisfactory to the IACUC Chair, the protocol will be maintained as Require Modification in and will be scheduled for presentation and discussion at the next regular meeting of the IACUC committee. More substantive changes to a protocol with a status of Require Modifications in may result in a re-review by the IACUC.

Withhold Approval
At Full Committee Review, the IACUC has determined that, for a particular research protocol, the risks outweigh the benefits to be gained by conducting that research. Research protocols may also be identified as Withhold Approval because:
The protocol is overly confusing or convoluted and not understood by the IACUC (e.g., poorly written or excessive technical language or jargon);
Procedures described are not considered acceptable according to current standards and justification made was not sufficient to endorse deviation.
The PI has not convinced the IACUC of his or her capacity (training and experience) to conduct the proposed research; or the methods being proposed are inadequate for the research, lack sufficient rigor or merit, or are unlikely to provide data that would allow the PI to answer the main questions driving the research. The IACUC signifies it's withhold and reason for withhold of a research protocol by issuing a letter to the PI stating that the protocol approval has been withheld, the reasons for withhold and that no research related to the protocol may be conducted. The PI may respond in person or

in writing. In which case, the IACUC will weigh the information provided by the PI and may reconsider its decision. Decisions are documented in Committee meeting minutes.

Protocol Approval Period
The PI may enact research protocols approved under this procedure for a period not to exceed the approval period. The starting and ending dates of the approval period will be stated on the approval letter sent to the PI. The approval period will not extend beyond three years. In certain cases the IACUC may require a shorter approval period and will require interim protocol status reports on the progress of the research and the status of the animals as a condition of approval. The exact period of approval, and any conditions, will be stated on the approval letter. Copies of the approved protocol will be readily available as a reference tool.

Questions and Appeals
Any PI may request an appointment with the IACUC Chair, or an opportunity to address the IACUC at a regular or special meeting, for any purpose related to the business of the IACUC. The reasons may be to answer questions concerning protocols in development or research in progress, or to resolve difficulties related to the approval of a protocol. Concerns should be brought to the IACUC Chair. If resolution cannot be reached with the IACUC Chair, the PI may be scheduled to present his/her case before the IACUC at the next regular meeting or at a special meeting called by the IACUC Chair. The decision of the IACUC, however, is final.

IACUC Requested Revisions/Changes to Proposed Protocols prior to Approval
Investigators should note that it is not uncommon for protocols received by the IACUC to require revisions. The goals of the process are to ensure humane care and use of animals, sufficient and accurate documentation in protocols, compliance with all applicable animal use regulations, and that the methods and practices proposed reflect the highest in current standards. To facilitate the protocol development and review process, it is highly recommended that investigators work closely with the AV and the IACUC Chair in advance of protocol submission. The Marshall Protocol Form is also a useful guide to ensure that protocols are as complete as possible prior to submission.

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:

In approving a protocol, the IACUC has indicated that the animal use protocol is consistent with the regulations and standards. Any change to the approved protocol must be submitted as an amendment to the IACUC and approved prior to instituting the change. Such a request must be in writing and may be in the form of a simple letter detailing the reasons for the modification and the proposed modification. This letter and any supporting documents should be sent directly to the IACUC Chair. Please note that, as the individual responsible for the overall conduct of the protocol, only the PI is permitted to request approval for modifications to protocols. Co-investigators and other research staff are not permitted to submit amendments to protocols.

The IACUC Chair is empowered to approve requests for modification that are minor in nature. Minor modifications are those that do not change the basic nature of the research effort. These include those changes identified as administrative changes; changes in research personnel (other than the PI) and changes in animal numbers less than 10% of that approved by the IACUC.

Requested modifications that are not minor in nature will initiate a review of the revised protocol using the same methods noted above. This modification review will involve review by the IACUC. As with an initial review, the requested modification may be approved, require modification in (to secure approval), or denied at full committee

review. If approved, the revised protocol will carry the same approval period as the original approval.

Significant changes to animal activities that must be approved by the IACUC include

- From non-survival to survival surgery
- Resulting in greater pain, distress, or degree of invasiveness
- Housing and/or use of animals in a location that is not part of the animal care program overseen by the IACUC
- In species
- In study objectives
- In PI (transfer of a Protocol to Another Investigator)
- Administrative Changes to an Approved Protocol

The IACUC at Marshall has approved the administrative handling of protocol changes related to

- an increase in previously approved animal numbers of up to 10% without further protocol approval
- additions of personnel other than the PI (refer to *Transfer of a Protocol to Another Investigator* section for changes in PI)

The IACUC at Marshall approves the administrative handling of an increase in previously approved animal numbers of up to 10% without further protocol approval. The IACUC must be notified of this change to document animal numbers for regulatory reporting. Any change in numbers above 10% must be IACUC approved through DMR or FCR.

The IACUC has approved the administrative handling of changes to personnel (other than the PI) associated with animal activities in the protocol. This administrative change would track personnel in attachment and approve administratively however the PI is informed that procedure specific training, including Occupation Health and Safety Training, must be complete and documented prior to undertaking animal activity.

Veterinary Verification and Consultation of Specified Significant Changes to Protocols (VVC)

There are specified significant changes for which an amendment to an Animal Protocol (AP) may be verified by administrative review with Veterinary Verification and Consultation (VVC) This policy is to be used in conjunction with the IACUC Policy on Modifications to Approved Protocols for the purpose of clarifying circumstances in which administrative review with veterinary consultation may be used. IACUC Veterinarians or alternates to the IACUC Veterinarians are authorized by the IACUC to verify such changes. Specified significant changes that may be verified by administrative review with veterinary consultation include:

- Anesthesia, analgesia, sedation, or experimental substances
- Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals
- Duration, frequency, type, or number of procedures performed on an animal,

Provided that these changes do <u>not</u>:

- change procedures from non-survival to survival surgery
- result in greater potential pain, distress, or degree of invasiveness
- add/alter procedural/housing location(s) that have not been previously approved by the IACUC for the described purpose(s)
- change species, study objectives, Principal Investigator, or personnel safety

Amendments describing changes described above may be handled administratively in consultation with an IACUC veterinarian and documented. The veterinarian is not conducting IACUC Designated Member Review (DMR), but is serving as a subject matter expert to verify that the changes requested meet the criteria listed above, are appropriate for the animal in this circumstance and meets the parameters outlined above and/or is consistent with the existing IACUC approved Animal Care and Use Policy or IACUC approved Standard Operating Procedure. The veterinarian consulted may refer any request to IACUC review at any time and for any reason. In addition, the administrative reviewer and/or veterinarian consulted will refer any request to IACUC review that does not meet the parameters outlined above and/or is not consistent with the existing IACUC

approved Animal Care and Use Policy or IACUC approved Standard Operating Procedures. The PI and IO will be notified of VVC results of amendments describing changes and verified by the veterinarian through VVC in writing and changes and verification will be documented within the protocol file. The IACUC will be notified at the next IACUC meeting.

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 the Principal Investigator and the IO via written notification typically delivered via email and/or notification of meeting minutes describing actions taken regarding Full Committee Review and status including approval, disapproval and/or modifications required for approval of the protocol. DMR results (including Chair assignment of an IACUC member for DMR) are documented on the IACUC Protocol Review Letter. If at FCR, the IACUC withholds approval, the notification includes the reasons for the IACUC's decision and the investigator is afforded the opportunity to respond either in person or 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:

The IACUC completes a continuing review of each previously approved, ongoing activity covered by PHS Policy through full committee review or designated member review (as described in Part III.D.6 of this document) at least annually. A complete review is done by the IACUC at least once every 3 years according to PHS Policy IV.C.1.-5. This review is completed through full committee review or designated member review (as described in Part III.D.6 of this document). The approval date is the date the study is approved by full committee for FCR or designated member for DMR. No protocol approval will extend beyond 3 years from the approval date.

Additionally, post approval monitoring (PAM) is conducted for research protocols and standard operating procedures (SOPs) that have been approved and designated by the IACUC as requiring PAM. PAM will be conducted by a minimum of one IACUC member or one alternate IACUC member who will consult with individuals involved in the process when completing the PAM. The PAM will be a sampling of the activity which may be accomplished through varied means at the discretion of the assigned monitor and may be announced or unannounced. A written summary of the PAM will be reported to the IACUC (at a convened meeting), Institutional Official (IO), the Director of Production and the Owner of the SOP/Principal Investigator with the IACUC requiring corrective action.

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 must review the matter at a convened meeting of a quorum of the IACUC and after review; the suspension must be approved by a majority vote of the quorum present. The reasons for suspension are reviewed with the Institutional Official and appropriate corrective actions implemented. A full report is submitted to the Institutional Official, who then submits a written report to OLAW for PHS supported activities, USDA, and other relevant entities, 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:

CONTROL AND PREVENTION - The Animal Care Health and Safety Program (ACHSP) is administered through the Occupational Health & Safety Group. The ACHSP provides information and safeguards for personnel working with animals and hazardous agents. In

addition, Marshall BioResources maintains relationships with various safety and healthcare experts to identify potential worksite hazards including hazardous biologics, chemical, physical agents (including ionizing radiation), and ergonomics. Once a hazard is identified, appropriate health and safety experts are utilized to assess the risk and to develop suitable procedures to manage the risk to an acceptable level and the employees are trained to minimize that risk. Covered personnel are those who work directly with animals, animal tissues or body fluids, and those who work in animal housing areas including investigators, students who work with animals, the facility manager or supervisor and anyone else involved in the care and use of animals. Personnel participate via a risk-based program. The level of participation is dependent upon the level of risk through the assignment with two risk groups noted; those with regular contact with animals, animal tissue or body fluids and those that are considered non-contact occasional visitors. Marshall performs no animal experimentation and thus has no animal experimentation involving hazards. All hazards at Marshalls are related to animal production. Animal production at Marshalls does not include non-human primates.

Procedure for reporting and treating injuries (e.g., bites, scratches) include instructing personnel to contact Security personnel via a paging system or a direct phone line. In an emergency, the appropriate emergency response individuals (including EMTs) are notified by Security, including the Emergency Response Manager. For a situation that isn't life threatening, medical treatment and follow-up are sought, as needed. Employees are instructed to report injuries in the workplace or suspected illness due to animal contact and seek medical attention from their health care professional. Personnel are instructed to:

- Notify their supervisor of illness, injury (including but not limited to bites and scratches) or if symptoms develop that could be associated with zoonotic disease or other hazardous materials.
- Inform their physician that they work with animals and may be exposed to zoonotic diseases. Physicians are requested to contact the Occupational Health Provider regarding illness or injury.
- Notify the Occupational Health Provider for advice on direct and indirect animal exposure if they become immunocompromised.
- An investigation team consisting of individuals from Safety and Human Resources department are notified as appropriate for follow up & corrective action.

PERSONNEL HYGIENE – Personnel hygiene includes the provision or requirement of appropriate clothing (as outlined in "Biosecurity Best Practices") depending on the area in which animal care personnel are working, or species working with, such as: ear protection, safety glasses or face shields; site-dedicated outerwear, lab coats or coveralls, masks, gloves, hoods/hair covers and booties, chemical resistant aprons, boots and gloves. Appropriate protective equipment and/or clothing are provided. Work clothing is not worn home or from home. Company policy details designated eating areas and frequency of hand washing/sanitizing including, but not limited to personnel thoroughly washing their hands with appropriate sanitizing hand wash after handling animals (including at home, before coming to work), after handling tissue/blood samples, after removing gloves, before eating, before and after using the restroom, before leaving the animal facility. Employees are instructed to not eat, handle contact lenses or apply cosmetics in work areas & to wash hands before engaging in any of these activities.

ANIMAL EXPERIMENTATION INVOLVING HAZARDS – Hazards are identified within the protocol which is reviewed as necessary by a subject matter expert consultant who reviews the protocol to provide input regarding health, safety and environmental issues. The consultant delivers a Plan which identifies known potential hazards and facilitates communication and control measures to prevent employee injury or harm. The PI and IACUC ensure appropriate training based on the consultants recommendations prior to experimentation.

HAZARD IDENTIFICATION AND RISK ASSESSMENT - Hazards are identified by review of Standard Operating Procedures (SOPs), performing facility walk-throughs and semi-annual program reviews and facility inspections, review of animal disease and health surveillance information, review of medical evaluations and annual medical histories of personnel by the Occupational Health Provider and review of accident reports and occupational illnesses. Risk assessments are conducted using various streams of information including job hazard analysis, employee assessments, Safety Committee assessments and review of worksite accidents and occupational illness history. Risk assessment is conducted by OH&S and the IACUC. Hazards are based on the nature of the procedure, the species of animal, the existence of known zoonotic diseases or potential pathogens, conditions within the work environment and the nature of the job responsibilities. Risk characterization is assigned (low risk – to high risk) based on the condition in a normal healthy adult and on the probability that an adverse health effect will occur in a given situation. All personnel exposed to chemical, physical or biological hazards, and those with direct or indirect animal contact are identified as moderate. Moderate risk individuals are exposed to a small number of moderate-severity, typically non-life threatening, well-defined hazards that can be effectively postured for. Requirements include:

a. Provide tetanus and/or flu immunizations (strongly recommended);
b. Provide pre-placement exams (strongly recommended);
c. Provide informational handouts that are relevant to the individual based on their specific risks
d. Provide information on special procedures to manage or monitor exposure to these hazards
e. Provide annual health history reviews and medical surveillance procedures;
f. Provide information for immunocompromised individuals to contact the Occupational Health Provider or their personal health care professional

A hazard that could be defined as "in animal" use is diagnostic radiography for clinical purposes. Individuals under the age of 18 years and pregnant women are not permitted to work with radiation equipment or procedures. Individuals are trained in the hazards associated with radiation exposure, are required to wear monitoring badges to ensure safe exposure levels, and are trained in the proper use of protective equipment and apparel. Pregnant woman will not be allowed to work with x-ray equipment or assist with radiographic exposures. They must notify their supervisor that they are pregnant. Upon receipt of the written notification, the employee is classified as a "declared pregnant worker." Because of the woman's right to privacy, no action can be taken until the formal notification is received. The declared pregnant worker must undeclare pregnancy in order to return to normal occupational worker status.

PERSONAL PROTECTION – Personal protection for personnel working with animals includes the issuance of appropriate clothing, the provision of appropriate facilities for maintaining personal hygiene, first aid equipment and training in safe techniques, including emergency responses in the event of an incident. Employees are required to use personal protective equipment (PPE) when working in certain conditions or when performing job functions that could place an employee's health or safety at risk. PPE will be worn in any area that has risk of employee exposure to viable material (saliva, blood, tissue, urine, and fecal matter), especially if the potential for material to become aerosolized or airborne exist. Appropriate selection and use of PPE is included as part of our regular safety training. Required PPE consist of, but is not limited to

- Lab coats or scrubs, coveralls, and shoe coverings or dedicated shoes when working with animals;
- Gloves, respirators, hair bonnet and a face mask may also be necessary in some areas; and
- Hearing Protection (Hearing Conservation Program).

Coveralls/lab coats and other "facility use only" outerwear are required when handling animals. Dedicated coveralls/lab coats are provided to employees to wear in animal production buildings. Soiled coverall/lab coats are turned in for laundry service. Coveralls/lab coats with extreme contaminants are placed in a plastic bag, and disposed of in a dumpster; they should not be placed in the soiled laundry receptacle for laundering. Dedicated footwear will be used in animal production areas.

FACILITIES, PROCEDURES AND MONITORING - To support a high level of personal cleanliness with personnel, all production facilities have been equipped with suitable facilities for washing and showering. Facilities, equipment and procedures are designed, selected and developed to provide ergonomically sound and safe operations. Ongoing evaluation of environmental conditions, incident reporting and Safety Committee findings ensures that risk assessment is a dynamic and ongoing process.
Standard Safe Work Practices and Procedures (detailed within Marshall's Biosecurity Best Practices document)

- Maintain restricted access to the animal facilities.
- Follow any posted entry requirements.
- Minimize splashes and aerosols.
- Use good hygiene.
- Separate sick or infected animals; handled by dedicated staff and/or in designated areas.
- Decontaminate equipment and work surfaces at least once a day and always after any spill of viable material.
- Dispose of waste appropriately. Contaminated bedding, animal carcasses, animal products, or items contaminated by animal products are disposed of by following recommended guidelines. Personal Protective Equipment (lab coat/gloves) should be worn at all times when disposing of animal carcasses.
- Contaminated sharps are always disposed of in a Biohazard Sharps Container.

PERSONNEL TRAINING - Marshall BioResources and the Marshall Occupational Health & Safety Group maintain a personnel training program that defines various work activities and associated workplace hazards. Workers receive both formal classroom and structured on-the-job training that emphasizes appropriate safeguards and protections for job functions within their respective areas. Training of personnel (e.g., on zoonoses, allergies, hazards, special precautions for pregnancy, illness, immune suppression, handling of animal waste) is provided through targeted in-service training and information programs, seminars and education programs. These programs emphasize the specific risks associated with different animals and provide guidance to personnel on appropriate methods of exposure control, protection and reporting of incidences.

MEDICAL EVALUATION AND PREVENTIVE MEDICINE – Pre-placement Medical Evaluations are required of all Marshall BioResources animal care employees considered being of moderate risk, including but not limited to the investigators, students who work with animals, the facility manager/supervisor and anyone else involved in the care and use of animals. Medical Evaluations are reviewed by Occupational Medicine, Clifton Springs Hospital & Clinic. This program meets all federal, state and local HIPPA regulations.

The Medical Surveillance Program is managed by the Occupational Health Provider, Clifton Springs Hospital & Clinic. Marshall BioResources animal care employees are required to participate. The Medical Surveillance Program allows Marshall BioResources to monitor employee level of risk in animal care, offer appropriate prophylactic protection from diseases associated with animal care, assess current health status of employees and monitor employee health during employment.

Potential Work Related Illness forms are available for the employee to take to their primary care physician to notify the doctor that the employee works in an animal environment. This form is to help the employee communicate work related risks to the doctor. In the event that the risks are related to the animal environment, the doctor has

the ability to communicate this information to our Occupational Health Provider, Clifton Springs Hospital & Clinic.

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 IACUC provides oversight and evaluation of the institutional training program through the use of various animal care program monitoring and assessment activities. Institutional professional training and educational records are maintained by the Human Resources Department using electronic training record file systems. Employee training records include copies of educational certificates and a list of internal safety and vocational training classes that have been successfully completed. The electronic training record system is also capable of tracking recurring training requirements and assisting with related scheduling of refresher classes.

Approximately 50 technicians are directly involved in the animal care and treatment programs at Marshall BioResources. Though each technician usually maintains a primary specialty, our work environment encourages use of cross-functional teams to optimize animal care. An example of this requirement is that all technicians are trained to recognize and report or initiate action to address incidents of sick/injured animals, adverse conditions and other significant issues to the appropriate department. This approach also creates a beneficial level of redundancy that ensures animal care is paramount in our day-today operations.

All employees charged with animal care and treatment responsibilities receive initial area training with on-the-job peer or supervisory oversight. This training follows defined training requirements for specific positions that are recorded and maintained by the Human Resources Department. Employees are not allowed to work independently until they demonstrate competence in the performance of their job's essential task.

Marshall BioResources encourages Continuing Education for all animal care workers to expand the technician's knowledge base and allow them to stay-up-to-date on new developments within their respective areas. This training is typically given by Marshall BioResources Veterinary staff or other qualified instructors on an as-needed basis when topics arise. In addition to this, employees that work in a licensed profession, which includes Veterinarians, Veterinary Technicians and a Clinical Laboratory Technologist are required to receive accredited continuing education training through professional seminars, conferences, or other formal training sessions. Marshall BioResources is fully committed to supporting continuing education and encourages its technical staff to attend AALAS branch meetings and to seek out other relevant educational opportunities to keep their skills and qualifications current. Continuing education expenses are typically fully paid for by the company and conducted as part of the regular work day.

The veterinary staff and/or designee oversee the surgical training program by discussion, supervision, and verification of skill acquisition. Training may include discussion of morbid conditions requiring treatment/surgery, and preferred methods of repair/resolution. Personnel-in-training work with experienced staff to first observe, and subsequently perform, major and minor operative procedures. Personnel are not allowed to perform procedures independently until approved to do so by the veterinary staff or designee.

All personnel that administer anesthesia are fully trained. This includes veterinary staff, veterinary technical staff, and specially designated technical staff. All training in administration of anesthesia, regardless of species, is conducted under the supervision of

the veterinary staff. Training consists of type of anesthetic, method of administration, monitoring of depth of anesthesia, and anesthetic recovery most of which is outlined in SOPs which are required training prior to commencement of hands-on training. Staff that is on-the-job trained for this task must work with already-trained personnel. Competency must be demonstrated to a veterinarian or designee prior to performing anesthesia independently. Continuing/refresher training takes place on an on-going basis. This is typically in the format of "treatment meetings" where designated technicians meet with the veterinary staff. The content is review of procedures and discussion of any questions or observations relevant to anesthesia and peri-procedural care.

All procedures, including euthanasia, are conducted only by trained personnel. Skill sets necessary for the conduct of euthanasia include morbidity assessment, handling and restraint for performance of euthanasia, dose volume calculations, injections by the appropriate route of administration and confirmation of death. Technicians are trained to make decisions regarding when to perform humane euthanasia. Any animal in extremis is immediately euthanatized; this includes animals that are comatose/moribund and/or non-responsive. Any animal that is in persistent acute, severe or unremitting pain or distress is immediately euthanatized. Acute situations that may be resolved by prompt, aggressive treatment are managed by the veterinary staff. Animals that are in moderate pain or distress as the result of disease or injury that are non-responsive to analgesics and treatments for primary conditions, such as infection or injury, receive a veterinary evaluation to determine whether treatments should be continued, or euthanasia should be performed. Training in the conduct and decision-making for humane euthanasia is restricted to designated technical staff, and is administered through the veterinary staff. Training includes recognition of clinical signs that dictates immediate performance of humane euthanasia, as well as the appropriate methodology. Any questions regarding the need for performance of euthanasia is immediately directed to the veterinary staff. No physical methods of euthanasia are used at Marshall BioResources. All euthanasia is performed in accordance with the AVMA Guidelines for the Euthanasia of Animals.

All employees are given proper user safety training on equipment and personal protective equipment required to do their job safely. All heavy equipment operators are given classroom operation/safety training and tested to assure they have the knowledge to operate equipment. They also must go through on-the-job training on the equipment and take an operators/drivers test prior to being issued an operator's license. All equipment licensed drivers must be re-certified based on the Safety Training Program.

All new IACUC members undergo some form of formal training prior to participating in IACUC activities. Training requirements are determined by the IACUC Chair and the IACUC Veterinarian and may vary based on the new member's background and previous experience. Training includes in-house Animal Welfare Act/Animal Welfare Regulations (AWA/AWR) training and may include AALAS Learning Library Courses and/or other accredited online training specific to the IACUC organization, responsibilities and operations. Participation in seminar training such as IACUC 101/201 and IACUC Advanced sessions is encouraged. Members' continuing education is achieved through participation in activities such as AAALAC, AALAS and Massachusetts Society for Medical Research webinars. In addition, the IACUC Veterinarian periodically provides training on contemporary topics. All IACUC members are provided access to copies of the PHS Policy, OLAW/Arena IACUC Guidebook and this approved Animal Welfare Assurance.

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, Andy Smith.
   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, Andy Smith.
   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: Andy Smith

Title: Executive Vice President and Chief Operating Officer; Institutional Official

Name of Institution: Marshall Farms Group, Ltd. d/b/a Marshall BioResources

Address:
5800 Lake Bluff Road
North Rose, NY 14516

Phone: (b) (6) Phone: (b) (6)

E-mail: asmith@marshallbio.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.

(b) (6)

Signature: Date: 22 OCT 18

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

Venita B. Thornton, DVM, MPH
Senior Assurance Officer
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive
Suite 2500 - MSC 6910
Bethesda, Maryland 20892
Email: thorntov@od.nih.gov
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Fax: (301) 480-3421

Venita B. Thornton -S

Digitally signed by Venita B. Thornton -S
Date: 2018.10.24 12:08:58 -04'00'

Signature: Date: October 24, 2018

Assurance Number: D16-00836 (A4621-01)

Effective Date: October 24, 2018 Expiration Date: October 31, 2022

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at the institution.

Scientist practicing scientist experienced in research involving animals.

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

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

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

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: Ken Van Fleet	
Title: Director of Compliance & Support Services; IACUC Chair	
Phone: (b) (6)	E-mail: kvanfleet@marshallfarms.com
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

Date: June 13, 2018			
Name of Institution: Marshall Farms Group, Ltd. d/b/a/ Marshall BioResources			
Assurance Number: D16-00836 (A4621-01)			
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)	4200	Ferret	158
	15145	Ferret	2358

*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.