

Animal Welfare Assurance for Domestic Institutions

I, Ira Block, as named Institutional Official for animal care and use at Primate Products, LLC, 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, DHHS, and or NSF (if applicable). This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
Panther Tracks Learning Center is the name of the campus. Primate Products, LLC is the sole owner and operator under this Letter of Assurance. We have dedicated areas depending on species separation requirements and client needs.
- B. The following are other institution(s), or branches and components of another institution:
None

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows: The Attending Veterinarian and The IACUC Chair have direct communication with the Institutional Official with regards to IACUC matters.

- 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. Paul W. Barras

Qualifications

- Degrees:
 - Doctor of Veterinary Medicine (LSU 1997)
 - Bachelor of Science in Animal Science (ULL 1994)
- Training or experience in laboratory animal medicine or in the use of the species at the institution: USDA accreditation, licensed in Florida, 20 years' experience working in laboratory animal medicine and management.

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

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

(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 meets at a minimum to review the facilities and program. All members are invited to participate. The Program Review is done using the template obtained from OLAW website which includes review of Occupational Health and Safety, Veterinary Care Program, PHS Policy/Animal Welfare Assurance and the training program. The *Guide* and the Animal Welfare blue book are used as reference tools for completion of the Program Review. Additional meetings are held as necessary to review protocols, discuss regulatory information, or other areas of concern regarding the welfare of the animals and staff. A report of the IACUC's evaluation of the overall animal care program

is prepared for submission to the Institutional Official. Results of the inspections and reviews are included with the minutes of the IACUC meetings.

- 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: All members are invited to participate. At least two voting members will conduct the facility review. The review shall include acceptable, minor and significant deficiencies with corrections listed and dates to be completed. A significant deficiency is one that directly affects the health and welfare of the animals. This self-assessment review must be conducted using the standards established in the most current *Guide*, PHS Policy, and the Animal Welfare Act.
- 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 uses templates provided by OLAW, the *Guide* and Animal welfare regulations when performing semi-annual Program Reviews, facility inspections and when submitting semi-annual letter to the IO. The Committee meets semi-annually to perform facility inspections and program reviews. After each separate event the minutes, draft deficiency log (for inspection), and completed program review template with deficiencies noted are sent electronically to each member of the Committee by the Chair. The Committee has a set amount of time to review, approve, approve with changes or not approve the documents provided. From these semi-annual meeting documents, protocol review meetings, post approval monitoring documents, and all other IACUC involved events that occurred since last semi-annual letter to the IO, the Chair will gather necessary information to draft letter to IO. Once draft is complete the document is sent to Committee electronically for review as stated above for other of IACUC documents. The Committee provides email approval, approval with changes or disapproval of the semi-annual report to the IO. The Committee will sign in approval once letter is final. The semi-annual report to the IO includes information on each of the following from the date of the previous report to the IO:
 - Review of the Animal Care and Use Program noting consistencies or departures from PHS Policy, the *Guide* and Animal Welfare Regulations.
 - Inspection of Animal Facilities noting consistencies or departures from PHS Policy, the *Guide* and Animal Welfare Regulations. Including list of deficiencies noted by the Committee, with designation of minor or significant, assigned personnel for corrective action and date of completion of task.
 - Departures from the *Guide*, if any, reasons for each (if any) and how approved by the Committee.
 - Minority Views
 - Status of AAALAC Accreditation
 - Protocol Review
 - Standard Operating Procedure review by the Committee
- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: The mechanisms in place to facilitate/enable individuals to report concerns involving animal care and use;
 - a. There is a suggestion box located by each time clock. There is a pre-printed pad attached that lists the name and address of the president of the company as well as the IO. A person can leave the form in the suggestion box or carry the item with them and submit the concern by U.S. mail.
 - b. Any person may at any time approach an IACUC member with a concern. In this event, the IACUC should request the concern be submitted in writing to allow the Committee to convene on the matter. If animal welfare is immediate concern, then the IACUC will respond in kind.
 - c. The procedure the IACUC uses to review such reported concerns- The Committee will meet in person or via telephone, discuss the issue and decide as to the validity of the complaint as well as outlining the steps to make the necessary corrections with the person responsible and date for completion.

- d. The IACUC then will submit in writing to the IO the incident and the corrections ordered and the person(s) responsible for making the correction with a date for completion.
- 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: If during the program review or upon receiving a written request or statement from an individual the IACUC will address issues raised concerning the program. After discussion the Committee may write to the IO via email, or of faster response is needed, call the IO making recommendations for correction of the issues. The IO and all other persons involved will be notified via telephone and writing an email of the issue and the necessary steps needed to make the change.
- 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: All projects involving the use of vertebrate animals, regardless of the source of funding or the proposed use of the animals must be reviewed by the IACUC prior to initiation. The animal research protocol review process is initiated by the investigator completing an Animal Study Proposal form, draft protocol and providing to IACUC Chairperson. The proposal form must be filled out in full and the following issues must be addressed to the satisfaction of the Committee:
 - a. statements of background and purpose of the study.
 - b. identification of the species and number of animals to be used.
 - c. rationale for involving animals, and the appropriateness of the species.
 - d. alternative to painful procedures must be addressed along with at least two literature searches using keywords and dates of searches.
 - e. Provision of veterinary monitoring of animals under procedures or criteria to assure timely intervention in assurance that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research. Analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.
 - f. A description of the method of euthanasia with doses and routes of administration as indicated.

All members of the IACUC will be provided with an electronic copy of the document that describes all proposed activities (the protocol). The Attending Veterinarian will perform a pre-review of all submitted Animal Care and Use Protocols to assure completeness of the veterinary care information provided. When the Attending Veterinarian is satisfied that the form has been filled out properly a copy is then sent to all of the committee members. If any committee member desires to have a full committee review, then the FCR (Full Committee Review) process will be followed per Standard Operating Procedure. If no member asks for a FCR within the specified time to respond then the Chair may appoint a DMR (Designated Member Review), which may consist of one or more members of the IACUC

1. If **all** members of the IACUC **are** present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by designated member review or returned for FCR at a convened meeting.

-OR-

2. If **all** members of the IACUC **are not** present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:

All IACUC members agree **in advance in writing** that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

In order to conduct reviews by DMR subsequent to FCR, the institution should specify its intention to conduct reviews in this manner in its Assurance with OLAW. (IACUCs that newly elect to utilize a standard operating procedure for DMR subsequent to FCR should provide information about this program change to OLAW in the next Annual Report.)

If an IACUC uses DMR, the approval date is the date that the designated member(s) approve the study. Animal work conducted before this date must be reported to OLAW as a serious noncompliance with the PHS Policy.

Note: [If electing to use DMR, the IACUC Chairperson appoints one or more appropriately qualified IACUC members to serve as the designated reviewer(s)].

DMR: When a DMR is used the Chair will appoint a member(s) of the IACUC to review the protocol with the study director/ principal investigator. The DMR may be made up of one or more persons (including the IACUC Chairperson). All of the designated reviewers must be unanimous in their decisions. The DMR will assemble a list of questions/modifications and send it to the study director/ principal investigator. The study director/ principal investigator should respond to the DMR with a written response and by highlighting the recommended changes on the revised protocol and appendices as applicable. This process will continue until all the DMR is satisfied that the questions /modifications have been made adequately. The DMR will communicate with the Chair for verification that the comments/ recommendations have been adequately addressed. This will be documented on the Protocol Approval Form.

The DMR, through the Chair, if no objections are raised by any other IACUC member, may give approval, a requirement for modification (to secure approval) or refer the protocol to the full committee. A DMR may not result in withholding of approval. Under DMR, all designated reviewers must either approve or require (the same) modifications for approval; failing this, they must submit the protocol for full-committee review. Approval of the protocol will be granted only after a review, at a convened meeting of a quorum of the IACUC, by an approval vote of a majority of the members present.

Protocols should not be finalized prior to IACUC review. The proposed activities will meet the following requirements:

- Procedures involving animals will avoid or minimize discomfort, distress, and pain.
- If procedures to be used will cause more than momentary pain or distress, the Study Director (SD) or Principal Investigator (PI) will provide a written narrative description of methods and sources used to determine that alternatives were not available.
- The SD or PI will have provided written assurance that the activities will not unnecessarily duplicate previous experiments.
- Procedures which may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics, or anesthetics. Withholding such agents must be justified for scientific reasons, in writing, by the SD or PI and will continue for only the necessary period of time. Planning of these procedures will involve consultation with the Attending Veterinarian, or designee, and will not include the use of paralytics without anesthesia.
- Animals which would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure.
- The animal's living conditions will be appropriate for the species in accordance with the AWA and The Guide and will contribute to their health and comfort. The housing, feeding, and non-medical care will be directed by the Attending Veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species.
- Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- Personnel conducting the procedures will be appropriately qualified and trained.
- Activities that involve surgery will include appropriate provision for pre- and post-operative care of the animals in accordance with established veterinary practices. All survival surgery will be performed using aseptic procedures. Major operative procedures in non-rodents will be conducted only in facilities intended for that purpose under aseptic conditions; non-major operative procedures do not require a dedicated facility but must be performed using aseptic procedures.
- No animal will be used in more than one major operative procedure from which it is allowed to recover unless scientific justification is provided in writing by the SD or PI. The procedure may be allowed if it is a routine veterinary procedure or is undertaken to protect the health or well-being of the animal as determined by the Attending Veterinarian, or, in other special

circumstances, as determined by the Administrator, Animal and Plant Health Inspection Service (APHIS)

- Methods for euthanasia must be in accordance with the definition set forth in 9 CFR Part 1, Section 1.1 and the AVMA Guidelines for Euthanasia, (2013) unless a deviation is justified by the Study Director for scientific reasons. This justification must be submitted to the IACUC in writing.
- 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: The IACUC will review and approve, require modifications in (to secure approval), or withhold approval, of proposed changes in the care and use of animals in ongoing activities. These modifications are reviewed/approved using the same method as the protocol, through FCR or DMR. As with full protocol review a DMR may not result in withholding of approval. Under DMR, all designated reviewers must either approve or require (the same) modifications for approval; failing this, they must submit the protocol modification for full-committee review. The following items are considered to be significant changes by the IACUC:
 - Changes in animal numbers
 - Changes in species
 - Changes in husbandry procedures such as:
 - Change in diet
 - Changes in light/dark cycles
 - Changing from one AVMA-approved euthanasia technique to another, (allowed provided personnel are qualified for both)
 - Changing anesthetic or analgesic agents (allowed after consultation with an attending veterinarian).
 - Change in immunization procedures from use of Incomplete Freund's Adjuvant (IFA) to Complete Freund's Adjuvant (CFA).
 - 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 investigators and the IO if its decisions regarding protocol review in writing via email with a request for verification of receipt of the notice. The investigator may request to address the Committee in writing or in person or resubmit the protocol.
 - 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 will conduct continuing review of activities approved by the IACUC on an annual basis. A standard form is provided to the Study Director or Principal Investigator, requiring updates on numbers of animals used, training files of personnel conducting protocol related functions, and USDA pain category classifications of animals used in protocol. The form is provided to the Study Director (SD) or Principal Investigator (PI) by the Committee via email. The SD/PI has a designated length of time to provide documents fulfilling the questionnaire. Once form is completed and returned the Committee will review answers/documents using the current protocol and amendments to ensure that all activities are occurring as stated in protocol/amendments. If the Committee review finds a deviation from the protocol/amendments the SD/PI will be notified and allowed to provide clarification, draft an amendment for approval or the Committee can cease study activities. The Protocols will be resubmitted to the IACUC every three years, with updated information and literature searches, and may be reviewed as described above in section 6.
 - 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 will be authorized to suspend any activity involving animals that was previously approved if the activity is not being conducted in the manner proposed. This will be done:

- a. Only after a review at a convened meeting of the IACUC, with a quorum present, and
- b. Only when a majority of the quorum present votes for suspension.

The Attending Veterinarian is delegated the authority by management to take any action necessary to ensure that the Animal Care Program meets all required standards.

If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the PHS Policy, Animal Welfare Act, the *Guide*, or the institution's Assurance, suspension, take appropriate corrective action, and report that action with full explanation to OLAW. The IO must be notified of any IACUC suspension of animal's protocols in writing through the IACUC Chair within five business days of the action. In the spirit of self-regulation, AAALAC is also notified.

- 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: The Occupational Health and Safety program (OH&S) for personnel involved in the care and use of animals is based on relevant topics listed in the *Guide*. Portions are as follows-
 - a. The OH&S program was developed with the consultation and assistance of our workman's compensation provider, Hendry County Regional Health, and the Centers for Disease Control and Prevention (CDC). All medical evaluations comply with state and local HIPAA regulations. Medical evaluations are kept private by health care provider; health care provider notifies Primate Products, LLC if an employee meets or does not meet the health requirements for employment.
 - b. The Chief Veterinarian oversees the program locally, but the program is ultimately monitored by the physicians at Hendry County that perform all pre-employment health screenings.
 - c. There are two primary entities that are responsible for the monitoring of the OHSP. The first such entity is the Hendry County Regional Health Center. All employees must provide medical history and submit to physical exam, tuberculosis testing, and respiratory fit testing prior to employment at PPLLC. The second entity is the Occupational Health and Safety Committee at PPLLC, which is comprised of at least one member of each department of the company and meets on at least semi-annual basis to discuss the status/efficacy of the OHSP and identify any new risks or hazards as well as to consider any novel strategies to reduce risk/exposure to hazards.
 - d. The program is based on risk assessment and hazard identification. Job specific risks and hazards are identified by the physicians monitoring the OHSP. We also have an onsite OHSP Committee that meets semi-annually to discuss risks of illness or injury as well as evaluate current practices that were set as a result of previous meetings. A site-specific Occupational Health and Safety Program Manual that details site-specific hazards/risks and how to mitigate them with appropriate engineering and administrative controls was also developed by the OHSP Committee.
 - e. The program consists of:
 - i. Pre-employment physical, all employees must provide medical history and submit to physical exam, tuberculosis testing, and respiratory fit testing from physicians at Hendry County Regional Health prior to employment at PPLLC.
 - ii. Yearly respiratory fit test, which includes respiratory health questionnaire that is evaluated by an RN. After questionnaire review by medical professional the document is destroyed or provided back to the employee for further follow up with health care provider if necessary.
 - iii. Employees are also strongly encouraged to seek medical evaluation as a result of any work-induced injury or illness.
 - f. The Occupational Health Program Manual outlines a pre-animal contact medical evaluation and testing, health surveillance during employment (requirements for Tb testing, Herpes B contact procedures, illness, and tetanus, rabies, and Hepatitis B immunizations), accident and disease prevention, biohazard training, how to treat bites, scratches and how to report an accident.
 - g. An established Safety Committee with equal membership of management and non-management representatives.

- i. The Safety Committee meets semi-annually and investigates accidents, receives and reviews safety suggestions, periodically conducts safety inspections, and acts as liaison with the IACUC, President and CEO on safety issues.
 - h. Training is provided on procedures for monitoring employees and animals for Herpes B when a human injury has occurred from an animal and/or unclean equipment that has had direct contact with an animal.
 - i. Training is provided for appropriate use of personnel protective equipment when working with nonhuman primates in quarantine and post-quarantine.
 - j. Yearly training is provided by Veterinary staff on the topic of zoonotic disease and blood borne pathogens.
 - k. Yearly training provided on biohazardous waste and proper disposal of biohazardous waste.
 - l. Yearly training is provided on Emergency Response and the Disaster Plan.
- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

New Employees/Orientation

 - New employees working directly or indirectly with nonhuman primates will be oriented on safe procedures in the workplace.
 - New employees will be required to attend training session's listed under annual training within four weeks of hire. Each Manager will schedule training with necessary trainer.
 - New employees will be provided a list of all applicable Standard Operating Procedures, and instruction on proper use of personal protective equipment (PPEs). Forms will be provided to guide as to what order SOP's should be read and these forms will be completed by employee as the SOP's are read and understood.

Annual Training

 - Zoonosis and Blood Born Pathogens- all employees regardless of title or position will attend this training on a yearly basis. The Attending Veterinarian or designated member of Vet Staff will conduct this training session.
 - Fire Safety- all employees regardless of title or position will attend a yearly fire safety training course. This course will be given by the Superintendent of Facilities or designee.
 - Bio-hazardous Waste- all employees working hands-on with nonhuman primates (NHP), NHP bio-products, or in NHP housing areas will attend this training on a yearly basis. The Operations Manager or designee will conduct this training session.
 - Institutional Animal Care and Use Committee (IACUC) – all employees regardless of title or position shall receive annual training on the purpose and function of the IACUC. This training may be performed by any voting-member of the IACUC, the Attending Veterinarian or the Institutional Official.
 - Standard Operating Procedures- all employees will receive a list of SOP's to review upon hire and as they are revised. Documentation for reading of SOP's will be maintained in each employee training file.
 - Natural History and Behaviors of Macaques- all employees working directly with nonhuman primates or around nonhuman primates will attend this training on a yearly basis. The Head of Behavioral Sciences or designee will provide this training.
 - The Three R's and Ethics in Research-all employees regardless of title or position will attend this training on a yearly basis. The Institutional Official or designee will conduct this training session.

Individual Training

 - Initiation of training for technicians and assistant technicians in Husbandry, Behavioral and Vet staff will follow the Phase Training program as attached (Form 202; attached). Each Manager will be responsible for documenting and tracking all practice sessions for his/her staff. Number of practice sessions for completion in function will be determined by employee's supervisor or manager.

Training Records

- For group training sessions the attendance list (Form 201; attached) will be used for documentation of participation.
 - The Operations Manager or designee will be responsible for placing a copy of Form 201 into each employee training file from group training sessions. The original copy of the attendance record will be maintained in an appropriately labeled binder in an administration area. Individual Training records will be maintained by each employee's manager.
- New members of the IACUC are sent to offsite training sessions such as IACUC 101. Continuing education is offered through the AALAS library, OLAW articles and NABR articles provided to members via email by the Chair. New members of the IACUC are provided orientation through direct activity with the Committee, facility inspections and program reviews. All members of the IACUC are provided copies of the *Guide*, The Animal welfare Act and Animal Welfare Regulations Blue Book and Occupational Health and Safety in the Care and Use of Research Animals.

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

- 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, Ira Block.
 5. Records of accrediting body determinations
- 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.
- 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

- 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, Ira Block.
 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: Ira Block	
Title: CEO, IO	
Name of Institution: Primate Products, LLC	
Address: (street, city, state, country, postal code) 34200 Doctors Hammock Rd Immokalee, FL 34142	
Phone: (b) (6)	Fax: (b) (6)
E-mail: info@primateproducts.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: 20 June 2019

B. PHS Approving Official (to be completed by OLAW)	
<div>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 Phone: (301) 451-4208 Fax: (301) 480-3421</div> <div>Venita B. Thornton -S Digitally signed by Venita B. Thornton -S Date: 2019.07.22 11:39:58 -04'00'</div>	
Signature:	Date: July 22, 2019
Assurance Number: D16-00590 (A4102-01)	
Effective Date: July 22, 2019	Expiration Date: May 31, 2023

VIII. Membership of the IACUC

[illegible]

* 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.

IX. Other Key Contacts (optional)

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

Contact #1	
Name:	
Title:	
Phone:	E-mail:
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

[illegible]

*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.

Primate Products, LLC Organization Chart 2019

