Form
OMB Control No. 0920-XXXX
Expiration Date: XX/XX/XXXX

Application For Registration as an Importer of Nonhuman Primates*

Organizational Name: Telephone No.:

Address:

Person Responsible for Requested Record Keeping and Reporting

1. Estimated number of nonhuman primates to be imported or to be received within 31 days of importation in the period covered by this registration:

2. If currently registered, number of nonhuman primates imported or received within 31 days of importation in the previous 2-year period*

3. Animal Holding Facilities:

a. Attach sketch of facility indicating rooms or area where newly acquired nonhuman primates are held and the relationship of these rooms or areas to offices, laboratories and other animal rooms in the same building.

b. Air handling procedures in rooms or areas where newly acquired primates are held:

(1) Air pressure in holding rooms ◯ is higher than ◯ same as ◯ lower than adjacent corridors and other immediately adjoining areas.

(2) Is exhaust air filtered? ◯ Yes ◯ No If yes, specify the type of filtration:

c. Usual number of animals per cage in the quarantine area:

Prosimians: Old World Species: New World Species: Great Apes:

d. Waste disposal procedures for animal feces:

e. Waste disposal procedures for liquid waste (provide a description of how potentially contaminated liquid waste is treated/disinfected):

f. Waste disposal procedures for animal carcasses:

4. Have you developed standard operating procedures for:

a. Animal transport to your facility ☐ *Yes* ☐ *No*	b. Intake procedure for arriving animals ☐ *Yes* ☐ *No*
c. Animal husbandry ☐ *Yes* ☐ *No*	d. Laundry ☐ *Yes* ☐ *No*
e. Worker protection/use of personal protective equipment ☐ *Yes* ☐ *No*	f. Necropsy ☐ *Yes* ☐ *No*
g. Considerations for B virus exposures ☐ *Yes* ☐ *No*	h. Statement of intended use ☐ *Yes* ☐ *No*
i. Communication with CDC ☐ *Yes* ☐ *No*	j. TB testing on NHPs in quarantine ☐ *Yes* ☐ *No*
k. Outdoor quarantine space* ☐ *Yes* ☐ *No*	l. Group housing* ☐ *Yes* ☐ *No*

*If applicable

5. Are newly acquired nonhuman primates held in rooms or areas with dedicated air-handling systems? ☐ *Yes* ☐ *No*
6. *Are all animals that died during the quarantine period necropsied?* ☐ *Yes* ☐ *No*
7. *Is entry to the area where newly acquired nonhuman primates to only those personnel who are essential to its operation?* ☐ *Yes* ☐ *No*
8. *Is a veterinarian retained to provide or supervise case of nonhuman primates?* ☐ *Yes* ☐ *No*

Name: *Telephone No.:*

Address:

9. *Personnel Health Program*

a. *Are all employees given a pre-employment tuberculin test?* ☐ *Yes* ☐ *No*

b. *Routine interval between tuberculin tests of employees after employment:*

Number or months: *or* ☐ *Not Done*

c. *Do you have a respiratory control program, as required by OSHA 29 CFR 1910.134 Respiratory Protection – Standards.* ☐ *Yes* ☐ *No*

d. *Are workers fit-tested and trained annually?* ☐ *Yes* ☐ *No*

e. *Is an occupational health clinic or physician retained to supervise health care programs?* ☐ *Yes* ☐ *No*

Name: *Telephone No.:*

Address:

10. **Assurance Statement**

As a condition of registration I, (we) assure the Director, Centers for Disease Control and Prevention that I (we) will import live nonhuman primates into the United States only for bona fide scientific, educational, or exhibition purposes. I (we) shall not subsequently sell, resell, or otherwise distribute the nonhuman primates to any other person or organization without clear evidence that these animals will be used solely for bona fide scientific, educational, or exhibition purposes. I (we) understand that "nonhuman primates" are defined as all nonhuman primates of the Order Primates including but not limited to animals commonly known as monkeys, chimpanzees, orangutans, gorillas, gibbons, apes, baboons, marmosets, tamarins, lemurs, and lorises.

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11. **Signature of Person Completing this Form:** **Date:**

Registration Form for NHP Importation (Part 2 – Standard Operating Procedures)

Importer's Contact Information			
Date of Application: _ _ _ _ / _ _ _ _ / _ _ _ _ _ _ _ _ *M M D D Y Y Y Y*			
Name:	*Institution:*		
Address:	State abbr.	County	Zip Code
Email:	*Phone Number ( ) -*		

Standard Operating Procedures
In sections 1-6, please include the elements of your standard operating procedures (SOPs) that address each regulatory requirement for importing nonhuman primates. You may copy and paste applicable sections of your SOPs or reference the SOP (name AND page number/section) that addresses each element in the spaces provided. Please attach copies of your SOPs.

Section 1: Documentation		
Regulation 42 CFR §71.53 (h)		**Standard Operating Procedure Meeting Regulation**
1. *Describe your procedures to collect or create a record of the intended purpose of importation for each imported NHP. The purpose must comply with one of the regulatory permitted purposes (science, education, or exhibition), as defined in 42 CFR§71.53 (a).*		
2. *Describe how you will ensure that written certifications demonstrating that the NHPs and their offspring will continue to be used for permitted purposes are maintained for three years after the distribution or transfer of the NHP. Each record must include the identity of any recipients, the number and identity of each NHP in each shipment or sale, and the dates of each shipment or sale, for three years after the distribution or transfer of the NHP.* *An importer must maintain these records in an organized manner, either electronically or in a central location that is at or in close proximity to the NHP facility to allow HHS/CDC to easily inspect the records during HHS/CDC site visits during regular business hours or within one hour of such visits. If records are maintained electronically, they must be time-dated in a manner than cannot be altered, and redundant back-up copies must be made in a manner that protects against loss.*		
3. *Explain how, before distributing or transferring an imported NHP, you will:*	*i. Communicate to the recipients of NHPs, in writing, the restrictions and definitions of permitted purposes; and*	
	ii. Obtain written certifications from the intended recipient that the NHPs will be used and	

	distributed only for permitted purposes.	

Section 2: Worker Protection Plan and Personal Protective Equipment	
Regulation 42 CFR §71.53 (i)	**Standard Operating Procedure Meeting Regulation**
Note: In addition to complying with the requirements of this section, an importer must comply with all relevant federal and state requirements relating to occupational health and safety.	
1. *Please verify that you have a written worker protection plan for anyone whose duties may result in exposure to NHPs, including procedures for appropriate response measures in the event of an emergency. An importer must adhere to the plan and SOPs and must ensure that each worker covered under the plan also adheres to it and all pertinent SOPs.*	
2. *An importer must contact HHS/CDC immediately by telephone, text, or email, as specified in the importer's SOP, to report any instance of a worker exposed to a zoonotic illness and must include instructions for contacting HHS/CDC in its worker protection plan. Please describe your procedures to contact CDC.*	
3. *Describe the elements of your worker protection plan that address the following:*	
i. *Procedures to protect and train transport workers in how to avoid and respond to zoonotic disease exposures associated with NHPs, including procedures for appropriate responses in the event of a vehicle crash or other emergency during transport;*	
ii. *An infection-prevention program, including infection-prevention methods requiring, at a minimum, PPE and workplace practices for preventing infection among workers whose duties may result in exposure to NHPs and;*	
A. *SOPs that include requirements for preventing workplace infection from potentially contaminated needles or other sharp instruments and that, at a minimum, prohibit workers from recapping used needles by hand; removing needles by hand; or otherwise bending, breaking, or manipulating used needles by hand.*	
B. *SOPs requiring that used disposable syringes and needles, scalpel blades, and other sharp items be placed in puncture-resistant containers kept as close to the work site as practical and disinfected and/or disposed of as hazardous waste.*	
C. *SOPs requiring that removable, disposable PPE be autoclaved, incinerated, or otherwise disposed of as*	

	biohazardous waste.	
	D. Nondisposable clothing worn in the quarantine facility must be disinfected on site before laundering. Please provide a detailed description of how quarantine laundry is handled.	
	E. Describe your infection-prevention program that requires NHP handlers to cleanse all bites, scratches, and/or mucosal surfaces or abraded skin exposed to blood or body fluids immediately and thoroughly.	
	F. Describe your infection-prevention procedures that require workers to immediately flush their eyes with water for at least 15 minutes following an exposure of blood or body fluids to the eye.	
iii. *Describe your post-exposure procedures that provide potentially exposed workers with direct and rapid access to a medical consultant including:*		
	A. Procedures ensuring that exposed workers have direct and immediate access to a medical consultant who has been previously identified in the SOPs to HHS/CDC.	
	B. For potential exposures to herpes B virus, post-exposure procedures that require the routing of diagnostic specimens to the National B Virus Resource Center located at Georgia State University in Atlanta, Georgia, or another location as specified by HHS/CDC.	
iv. *How do you document worker training, including for those working in the quarantine facility?* *v.* *What is the frequency of quarantine worker training?*		
4. Describe how your worker protection program addresses hazard evaluation and worker communication procedures that include the following:		
i. *A description of the known zoonotic disease and injury hazards associated with handling NHPs*		
ii. *The need for PPE when handling NHPs and training in proper use of PPE, including re-training and reinforcement of appropriate use*		
iii. *Procedures for monitoring workers for signs of zoonotic illness, including procedures that ensure reporting to HHS/CDC by telephone, text, or email within 24 hours of the occurrence of illness in any worker suspected*		

	of having a zoonotic disease	
	iv. Procedures for disinfection of garments, supplies, equipment, and waste.	
5. As part of your worker protection plan, you must identify the PPE required for each task or working area. Please describe your procedures for ensuring the following (be sure to describe in detail the steps for donning, doffing, and discarding or disinfecting PPE):		
	i. Any required PPE must be available to workers when needed	
	ii. Workers in direct contact with NHPs must wear the following	
	A. Gloves of sufficient thickness to reduce the risk of cuts, scratches, and punctures	
	B. At a minimum, disposable NIOSH-approved N95 respirators, in compliance with OSHA 29 CFR §1910.134, which requires a respiratory protection program	
	C. Face shields or eye protection	
	D. Outer protective clothing when opening crates, removing foreign materials from crates, feeding NHPs, removing dead NHPs, or handling bedding materials	
	iii. Workers handling crates or pallets containing NHPs must wear the following	
	A. Elbow-length, reinforced leather gloves or equivalent gloves that prevent penetration of splinters, other crating materials, or debris	
	B. Outer protective clothing	
	C. Waterproof shoes or boots	
	D. NIOSH-approved respiratory protection that is compliant with OSHA regulations at 29 CFR 1910.134	
	E. Face shields or eye protection	
	iv. Workers whose faces may come within 5 feet of an NHP must wear disposable NIOSH-approved N95 respirators and either face shields or eye protection to protect against aerosol or droplet transmission of pathogens;	
	v. Workers must remove disposable PPE and discard as a biohazard	
	vi. Describe procedures to ensure workers do not drink, eat, or smoke while physically handling NHPs or cages, crates, or other materials from such NHPs	
6. Describe your procedures for ensuring that each item listed below regarding tuberculosis (TB) is addressed:		
	i. Workers in a facility housing NHPs must have a baseline evaluation for TB prior to working with NHPs and an evaluation at least	

		annually	
	ii.	*Personnel must have prompt and direct access to a medical consultant who is capable of performing the evaluation and maintaining records for such tests*	
	iii.	*If an NHP is found to have laboratory-confirmed TB, any worker who had previously entered any room where a confirmed NHP has been housed must promptly undergo a post-exposure TB evaluation and*	
		A. If that test is negative, the worker must undergo another TB evaluation 3 months later; and	
		B. If either test is reactive, the worker must be referred for medical evaluation; and	
		C. The HHS/CDC must be immediately notified of the results of the medical evaluation by telephone, text, or email as specified in the importer's SOPs	
	iv.	*Describe how you ensure compliance with exposure-control planning elements under 29 CFR 1910.1030 for workers who will have parenteral and other contact with blood or other potentially infectious material from NHPs.*	
	v.	*Describe how you will ensure compliance with the respiratory protection requirements in 29 CFR 1910.134.*	
7.	*For importation of macaques, an importer must develop, implement and adhere to a written PPE program to prevent herpes B virus transmission. The program must be based on a thorough hazard assessment of all work procedures, potential routes of exposure (e.g., bites, scratches, or mucosal exposures), and potential adverse health outcomes. If you intend to import macaques during the 2-year registration period, please provide a description of your program addressing herpes B.*		
8.	*Describe how you will ensure the following requirements are met:* *a. An importer must keep records of all serious febrile illnesses (fever greater than 101.3 degrees Fahrenheit [38.5 degrees Celsius] for more than 48 hours) in workers having exposure to NHPs in transit or in quarantine. The record must be kept by the importer as part of the worker's administrative records.* *b. The importer must promptly notify HHS/CDC by telephone, text, or email if such an illness occurs.* *c. An importer must ensure that the medical consultant providing care is informed that the patient works with and/or has been exposed to NHPs.*		

Section 3: Crating, Caging, and Transport	
Regulation 42 CFR §71.53 (j)	**Standard Operating Procedure Meeting Regulation**
Equipment standards for crating, caging, and transporting live NHPs must be in accordance with USDA Animal Welfare regulation standards (9 CFR parts 1, 2, and 3) and International Air Transport Association standards. Additionally, importers must establish, implement, maintain, and adhere to SOPs that ensure the items listed below are met. Describe the elements of your SOPs that will ensure the following:	
1. *Any crate used to transport NHPs must be free of sharp projections that could scratch or otherwise injure workers or NHPs*	
2. *Glass items must not be used for feeding or watering NHPs during transport.*	
3. *NHPs must only be removed from crates in an approved quarantine facility under the supervision of a licensed veterinarian.*	
4. *NHPs must not be removed from crates during transport*	
5. *Upon arrival into the United States, only an importer or an authorized representative may receive the NHPs from a conveyance (e.g., airplane, ship). The importer must establish an emergency contingency plan in the unlikely event they are unable to meet the shipment.*	
6. *All reusable items must be decontaminated between uses.*	
7. *At all times during transport, crates containing NHPs must be separated by a physical barrier from workers, other individuals, and all other animals and cargo, or by a spatial barrier greater than 5 feet, that prevents contamination of cargo or individuals with bodily fluids, feces, or soiled bedding.*	
8. *At all times during transport, individuals traveling with the shipment must be protected from shared air of NHPs to prevent the transmission of zoonotic diseases. Airflow must be unidirectional from NHP transport workers to NHPs or, if any air is recirculated to the NHP transport workers, it must be HEPA-filtered. If a ventilation system is not in place, all NHP transport workers must wear respiratory protection.*	
9. *If traveling by plane, crates containing NHPs should be loaded in the cargo hold last and removed first, must be placed on plastic that prevents spillage onto the deck of the plane, and must be placed on pallets or double crated to ensure separation from other cargo.*	
10. *Workers, as well as NHPs, must be protected from communicable disease exposures at any facility used en route, including transportation holding facilities. An importer must maintain a description of any transportation holding facilities and document the communicable disease prevention measures taken to protect workers at facilities used en route*	
11. *For each import, documentation must be made of the communicable disease-prevention procedures to be carried out in every step of the chain of custody, from the time of*	

embarkation of the NHPs at the country of origin until arrival at the quarantine facility.	
12. *Procedures to ensure that aircraft, ship, vehicles, and related equipment are decontaminated following transport.*	
13. *Used PPE, bedding, and other potentially contaminated material must be removed from the ground transport vehicle upon arrival at the quarantine facility and disposed of as biohazardous waste.*	

Section 4: Ground Transport Vehicles	
Regulation 42 CFR §71.53 (k)	**Standard Operating Procedure Meeting Regulation**
An importer must establish, implement, maintain, and adhere to SOPs for ground transport vehicles transporting NHPs that meet the following requirements. Provide a description of ground transport vehicles you intend to use for transportation of imported NHPs under CDC-mandated quarantine. You may also attach diagrams or photographs.	
1. *Ground transport vehicles must have a separate cargo compartment with separate heating, ventilation, and air-conditioning systems.*	
2. *The interior surfaces of ground transport vehicle cargo compartments must be of smooth construction, easy to clean and disinfect.*	
3. *Ground transport vehicle cargo compartments must be large enough to allow safe stowage of NHP crates in a manner that allows ready access to each NHP during transit without unloading any crates.*	
4. *Verify that used PPE, bedding, and other potentially contaminated material will be removed from the ground transport vehicle upon arrival at the quarantine facility and disposed of as biohazardous waste by a licensed facility.*	
5. *Describe procedures to notify HHS/CDC in writing, text message, or email, after transport of the NHP shipment from the port of entry to the quarantine facility. Notification must occur within 48 hours of the time the shipment arrived at the quarantine facility.*	
6. *As part of the notification of arrival in number five (5) above, an importer must inform HHS/CDC whether suspected or confirmed transmission or spread of communicable disease occurred during transport, including notification of NHPs that died, became ill, or were injured during transport, or malfunctions associated with disease-mitigation procedures or equipment. Please describe your SOPs to ensure this notification occurs.*	

Section 5: Quarantine Facilities	
Regulation 42 CFR §71.53 (l)	**Standard Operating Procedure Meeting Regulation**
An importer must maintain a quarantine facility for holding a cohort during the required quarantine period. NHPs must be quarantined for 31 days after arrival at the importer's quarantine facility. HHS/CDC may extend the quarantine period if an importer or HHS/CDC finds or suspects that an NHP is infected with, or has been exposed to, a zoonotic disease, or if an importer or HHS/CDC finds a need for additional	

diagnostic testing.	
1. *For any quarantine facility established or maintained under this section, an importer must establish, implement, maintain, and adhere to SOPs that meet physical security requirements. Please describe the security measures to ensure the following at your quarantine facility:*	
i. *The facility must be locked and secure, with access limited to authorized, trained, and knowledgeable personnel.*	
ii. *An importer must limit access to NHP quarantine areas to authorized personnel who are responsible for the transport, study, care, or treatment of the NHPs.*	
2. *Describe your procedures to keep the number of workers involved in the care, transport, and inspection of NHPs to the minimum necessary to perform these functions.*	
3. *Explain how the facility is designed and operated in such a manner as to allow for adequate disinfecting.*	
4. *Please provide a written description or attach diagrams/photos to support that your facility meets these requirements.* a. *The facility must have adequate equipment and space for discarding and disinfecting all equipment, clothing, and caging.* b. *Each heating ventilation and air-conditioning unit in the quarantine facility must be designed so that there is no mixing of air among quarantine rooms.* c. *Each quarantine room must remain under negative air pressure in relationship to the common hallway or anteroom(s) adjacent to the quarantine room.* d. *Each quarantine room must have air flow indicators (pressure gauges or visual flow indicators) that are affixed outside the quarantine room that indicate the direction of airflow into or out of quarantine rooms and adjoining common hallways and anterooms.*	
5. *An importer must establish, implement, maintain, and adhere to SOPs for handling, monitoring, and testing NHPs in quarantine. Please describe the elements of your SOPs that ensure the following requirements are met:*	
i. *An importer must ensure that all NHPs are identified individually with a unique number or alphanumeric code permanently applied to the NHP by tattoo, microchip, or other permanent identifier before importation or after the 31-day quarantine. Tattoos, microchips, or other permanent identifiers must not be applied during the quarantine period.*	
ii. *Health certificates, shipping documents, and NHP health records must include the NHP's identification number, age, sex, and species.*	
iii. *An importer must ensure NHPs are confined in a squeeze-back cage whenever possible and that any individual NHP is anesthetized, tranquilized, or otherwise restrained before handling.*	

	iv.	*A description of handling and transporting samples. For any procedure involving the use of a syringe, a separate, disposable needle and syringe must be used, including a sterile needle and syringe for withdrawing medication from any multi-dose vials (e.g., ketamine).*	
	v.	*Before any contaminated item is removed from a quarantine facility, an importer must ensure that all NHP waste, bedding, uneaten food, or other possibly contaminated items are disinfected, autoclaved, or double-bagged for disposal as biomedical waste by a licensed facility.*	
	vi.	*All cages, feeding bottles, reusable items, and other contaminated items must be disinfected between uses and before disposal.*	
	vii.	*Any equipment used for infusion of NHPs must be autoclaved or incinerated, as appropriate.*	
	viii.	*During the quarantine period, an importer must monitor NHPs for signs of any zoonotic illness, including signs consistent with yellow fever, monkeypox, or filovirus disease.* *A. If any NHP appears ill during quarantine, an importer must monitor that NHP for signs of zoonotic illness, including filovirus disease, and ensure appropriate treatment.* *B. If an Old World NHP displays signs suggestive of filovirus infection (e.g., diarrhea with melena or frank blood, bleeding from external orifices or petechiae, or suffusive hemorrhage), and survives, an importer must collect serum samples on day 31 of quarantine and test these samples for antibodies to filovirus while the entire cohort remains in quarantine. An importer must test the serum for immunoglobulin G (IgG) antibodies to filovirus by using an ELISA methodology, or other method approved by HHS/CDC.* *C. An importer must not knowingly request a release from HHS/CDC of any ill NHP from quarantine.*	
	ix.	*Describe your procedures for administering at least three tuberculin skin tests (TSTs) on the eyelid of each imported NHP using old mammalian tuberculin (MOT), with at least 2 weeks between tests, before the NHP is released from import quarantine. TSTs must be read and recorded at 24, 48, and 72 hours, and a grading scale for interpretation of these tests must be listed in an SOP for testing.*	

		A. Please verify that any cohort with positive or suspicious TST reaction will remain in quarantine and receive at least five additional TSTs (each administered at least two weeks apart) following removal of the last affected NHP. *B. The validity of TB test results may be compromised if during quarantine an NHP contracts a viral illness, including measles; is treated with steroids; or is immunized. Please provide a written procedure for ensuring such occurrence(s) will be documented and the affected NHPs will be held until they have recovered from the illness or are no longer on treatment, and for a recommended time after recovery (to be determined in consultation with HHS/CDC, depending on the illness or treatment in question) before TB tests are performed.* *C. An importer must retain records of all TSTs performed during the lifetime of each NHP at the facility housing the NHP until the NHP is transferred to another facility. These records must accompany the NHP during moves to other facilities.*	
	x.	*Please describe how you will ensure that different cohorts of NHPs are quarantined in separate quarantine rooms, along with procedures to address the following:* *A. If mixing of cohorts should occur, an importer must treat the mixed cohort as a single cohort.* *B. All NHPs within that mixed cohort must remain in quarantine until each NHP in that mixed cohort has completed the minimum 31-day quarantine period.* *C. Quarantined NHPs must be housed in such a manner that they do not expose non-quarantined NHPs to non-filtered air and other potentially infectious materials, including soiled bedding, caging, and other potentially contaminated items.*	
6.	*Before requesting release of a NHP from quarantine, an importer must obtain written permission from HHS/CDC. Provide a protocol for providing written documentation to HHS/CDC that all the following conditions have been met when requesting release from CDC-mandated quarantine:*		
	i.	*The 31-day quarantine period, including any required extension of quarantine, has been completed.*	
	ii.	*The importer must provide written notification of the health status of the NHPs in the shipment from the quarantine facility's licensed veterinarian.*	
	iii.	*The importer has addressed and resolved to*	

	HHS/CDC's satisfaction any NHP or worker communicable disease issues that were reported to HHS/CDC during shipment.	
7.	*If HHS/CDC notifies an importer of any evidence that NHPs have been exposed to a zoonotic disease, the importer must, at the importer's expense, implement or cooperate in the HHS/CDC's implementation of additional measures to rule out the spread of suspected zoonotic disease before releasing a shipment from quarantine, including examination, additional diagnostic procedures, treatment, detention, isolation, seizure, or destruction of exposed animals.*	
8.	*An importer must establish, implement, and adhere to SOPs for safe handling and necropsy of any NHP that dies in quarantine. Please describe elements of your SOPs that ensure the following:*	
	i. The carcass of the NHP must be placed in a waterproof double-bag and properly stored for necropsy, specimen collection, autoclaving and/or incineration, and disposal;	
	ii. A necropsy must be performed by a veterinary pathologist or state-licensed veterinarian.	
	iii. Each necropsy report must address all major organ systems and incorporate the following: *a. Clinical history* *b. Exam findings before the animal died* *c. Complete description of the gross appearance of all major body system at the time of necropsy. Major body systems include:* *i. Nervous system (including brain if indicated by clinical signs)* *ii. Cardiovascular system* *iii. Respiratory system* *iv. Digestive system (including ancillary organs such as liver and pancreas)* *v. Genitourinary system* *vi. Lymphatic system (including spleen)* *vii. Musculoskeletal system* *viii. Endocrine system* *ix. Integumentary system* *d. Laboratory findings, including the following:* *i. Histopathology results from, at a minimum, samples of tracheobronchial lymph nodes, liver, lung, spleen, and any tissue that exhibited lesions during gross necropsy examination.* *ii. For any tissues where histopathology results suggested evidence of infection, results of appropriate microbiological cultures.* *e. A pathologic diagnosis must be included on each necropsy report. If cause of death cannot be determined, an explanation regarding how an infectious disease was ruled out must be included in the report.*	

	f. If an infectious cause of death is suspected, the necropsy report must document tests conducted to establish the exact etiology of the infection (e.g., for a pathologic diagnosis of pneumonia, the necropsy report must include results of histopathological and microbiological tests conducted to determine the type of pneumonia, and, if infectious, the etiologic agent). *g. The printed name, state license number, state in which licensed, and signature of the veterinarian who conducted the necropsy.*	
	iv. Necropsy and appropriate laboratory testing of the NHP must document the cause of death and/or rule out zoonotic illness;	
	v. Necropsy must be performed under biosafety level 3 (BSL3) or enhanced biosafety level 2 "plus" (BSL2 +) to protect against exposure to highly infectious agents;	
	vi. Any samples of tissues, blood, serum, and/or transudates (bodily fluid) collected during necropsy must be retained until the NHP shipment has been released from quarantine by HHS/CDC, in case other testing is required by HHS/CDC;	
	vii. Fresh and formalin-fixed tissue specimens, including tracheobronchial lymph node, liver, lung, and spleen, regardless of necropsy findings, must be collected for laboratory examination;	
	viii. Any granulomatous lesions found in any NHP at necropsy, regardless of whether TB in the NHP was previously suspected, must be submitted to a laboratory for laboratory examination for acid-fast bacilli and for mycobacterial culture; and	
	ix. In the event that an Old World NHP dies or is euthanized for any reason other than trauma or unexpected adverse environmental conditions during quarantine, liver tissue for filovirus antigen by using the antigen-capture ELISA method must be submitted to a qualified laboratory for testing. The laboratory should provide documentation of test validation and records of ongoing quality assurance.	

Section 6: Health Reporting for NHPs	
Regulation 42 CFR §71.53 (m)	**Standard Operating Procedure Meeting Regulation**
An importer must notify HHS/CDC of the events listed in this section (Section 6) by telephone, text, or email. Please provide elements of your SOPs that ensure the following:	
1. An importer must notify HHS/CDC within 24 hours of the occurrence of any morbidity or mortality of NHPs in quarantine facilities, or following a zoo-to-zoo or laboratory-to-laboratory transfer.	
2. For any morbidity or mortality from time of embarkation from country of origin to release from HHS/CDC quarantine, an importer must report the circumstances to HHS/CDC promptly, including the cause of death for each NHP.	

3. *Upon completion of the quarantine period and before an importer releases any NHP, cohort, or mixed cohort from quarantine, the importer must ensure that the quarantine facility's licensed veterinarian notifies HHS/CDC in writing of the health status of the shipment.*	
4. *An importer must notify HHS/CDC within 24 hours if any NHP tests positive for filovirus virus antigen or antibody.*	
5. *An importer must report to HHS/CDC within 24 hours, any positive or suspicious TST results, necropsy findings, or laboratory results. Any report required under this section must include a copy or summary of the individual NHP's health records.*	