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 describe your standard operating procedures (SOPs) that address each regulatory requirement for importing nonhuman primates under a Lab-to-Lab registration . 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. *Workers must 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. *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 will 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.* *9. 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: 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 5) 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. *An importer must notify HHS/CDC within 24 hours if any NHP tests positive for filovirus virus antigen or antibody.*	
3. *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.*	

Section 6: Laboratory to Laboratory Transfers	
Regulation 42 CFR §71.53 (q)	**Standard Operating Procedure Meeting Regulation**
In addition to the requirements listed in Sections 1-5 above, if a lab is receiving one or more NHPs for purposes related to an ongoing research project from another established research facility outside the United States, the recipient facility must, before the transfer, submit the following to HHS/CDC for approval:	
1. *A copy of each NHP's veterinary medical records, including regular testing for TB from the previous lab for HHS/CDC's approval. The medical record should include a positive identification of the NHP, such as a tattoo, microchip, or photograph.*	
2. *A copy of a current health certificate(s), including documentation of a negative TST, signed by a state-licensed veterinarian within 14 days of the transfer stating that the NHP(s) appear healthy and are free from communicable diseases; and*	
3. *Documentation of the ongoing IACUC-approved research project and the reason the NHP needs to be transported to the U.S. laboratory facility.*	

4. *A specific itinerary with names, dates, flights, times, airports, seaports, and responsible parties to contact at every step of travel, including all ground transportation. This must be provided in writing (by email) to HHS/CDC at least 7 days before shipment arrival.*	

Note: Only laboratories transferring NHPs on established research protocols from their foreign-based facilities to their U.S.-based laboratories are eligible to apply to transfer NHPs from lab to lab under 42 CFR §71.53 (q).