

Registration Form for NHP Importation (Standard Operating Procedures for Zoo-to-Zoo Transfers of NHPs)

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
<p>In sections 1-6, please describe your standard operating procedures (SOPs) that address each regulatory requirement for importing nonhuman primates under a Zoo-to-Zoo registration. 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.</p>

Section 1: Documentation	
Regulation 42 CFR §71.53 (h)	Standard Operating Procedure Meeting Regulation
<p>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).</p>	
<p>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 that cannot be altered, and redundant back-up copies must be made in a manner that protects against loss.</p>	

Public reporting burden of this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30329; ATTN: PRA 0920-XXXX.

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 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	

<i>communication procedures that include the following:</i>		
i.	<i>A description of the known zoonotic disease and injury hazards associated with handling NHPs</i>	
ii.	<i>The need for PPE when handling NHPs and training in proper use of PPE, including re-training and reinforcement of appropriate use</i>	
iii.	<i>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</i>	
iv.	<i>Procedures for disinfection of garments, supplies, equipment, and waste.</i>	
5. <i>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>		
i.	<i>Any required PPE must be available to workers when needed</i>	
ii.	<i>Workers must remove disposable PPE and discard as a biohazard</i>	
iii.	<i>Workers must not drink, eat, or smoke while physically handling NHPs or cages, crates, or other materials from such NHPs</i>	
6. <i>Describe your procedures for ensuring that each item listed below regarding tuberculosis (TB) is addressed:</i>		
i.	<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</i>	
ii.	<i>Prompt and direct access to a medical consultant who is capable of performing the evaluation and maintaining records for such tests</i>	
iii.	<i>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</i>	
	A. <i>If that test is negative, the worker must undergo another TB evaluation 3 months later; and</i>	
	B. <i>If either test is reactive, the worker must be referred for medical evaluation; and</i>	
	C. <i>The HHS/CDC must be immediately notified of the results of the medical evaluation by telephone, text, or email</i>	

		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: <ul style="list-style-type: none"> 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. 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.	
4. 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	
5. 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.	
6. Procedures to ensure that aircraft, ship, vehicles, and related equipment are decontaminated following transport.	

Section 4: Ground Transport Vehicles	
Regulation 42 CFR §71.53 (k)	Standard Operating Procedure Meeting Regulation
1. After transport of the NHP shipment from the port of entry to the quarantine facility, the importer must notify HHS/CDC in writing, text message, or email as specified within the SOP, within 48 hours of the time the shipment arrived at the quarantine facility.	
2. As part of the notification of arrival in paragraph (k)(5) of this section, 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.	

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	

<p>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.</p>	
Section 6: Zoo-to-Zoo Transfers	
Regulation 42 CFR §71.53 (p)	Standard Operating Procedure Meeting Regulation
<p>If a CDC-registered zoo is importing one or more NHPs into the United States from another zoo, the recipient zoo must, before the transfer, submit the information listed below for approval by HHS/CDC. Please describe your written procedures for ensuring the following information is provided to HHS/CDC for approval:</p>	
<p>1. A copy of each NHP's veterinary medical records, including regular testing for TB from the previous zoo for HHS/CDC's approval. The medical record should include a positive identification of the NHP, such as a tattoo, microchip, or photograph.</p>	
<p>2. A copy of a current health certificate, including documentation of a negative TB test, 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;</p>	
<p>3. Documentation which verifies that the recipient zoo is registered to import NHPs for zoo-to-zoo transfer; and</p>	
<p>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.</p>	

Note: CDC-registered zoo-to-zoo importers must be accredited by the Association of Zoos and Aquariums. Please submit evidence of AZA accreditation with your registration application.