

# Attachment 5: Revisions to the Application for Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease

Old Form Section A:

SECTION A – PERSON REQUESTING PERMIT IN U.S.A.			
1. Last Name of Permittee (Applicant)	2. First	3. MI	4. Organization
5. Address (NOT a post office box)		6. City	7. State
			8. Zip Code
9. Telephone	10. FAX	11. E-mail	

New Form Section A:

SECTION A, Person Requesting Permit in US (Permittee)			
1. Permittee's Last Name	2. First Name	3. MI	4. Permittee's Organization
5. Physical Address (NOT a post office box)		6. City	7. State
			8. Zip Code
9. Telephone	10. Fax	11. Email	
12. Will the permittee be the courier of the imported biological agent? <input type="checkbox"/> a Yes <input type="checkbox"/> b No	13. Will other members of the organization listed above, in Section A Block 4, be authorized to use the approved permit?  <input type="checkbox"/> a No <input type="checkbox"/> b Yes if Yes →	14. Check here <input type="checkbox"/> if you have included a Continuation Form to list others authorized to use this permit	

- Added item 12 to the new form: Will the permittee be the courier of the imported biological agent?
- Added item 13 to the new form: Will other members of the organization listed above, in Section A Block 4, be authorized to use the approved permit?
- Added item 14 to the new form: Check here  if you have included a Continuation Form to list others authorized to use this permit.

Old Form Section B:

SECTION B – SENDER OF MATERIAL					
1. Last Name of Sender	2. First	3. MI	4. Organization (☑ Check here if additional sheets are attached for multiple senders)		
5. Address (NOT a post office box)		6. City	7. State/Prov	8. Postal Code	9. Country
10. Telephone	11. FAX		12. E-mail		

New form Section B:

SECTION B, Sender of Imported Biological Agent(s)				
1. Sender's Last Name ( <input type="checkbox"/> Check if same as Sec A)	2. First Name	3. MI	4. Sender's Organization	
5. Physical Address Outside of the US (NOT a post office box)	6. City	7. State/Prov.	8. Country	9. Postal Code
10. Telephone	11. Fax	12. Email		13. Check here <input type="checkbox"/> if you have included a Continuation Form to list multiple senders

- Added item 13 to the new form: Check here  if you have included a Continuation Form to list multiple senders.

Old form Section C:

**SECTION C – DESCRIPTION OF MATERIAL**

1. Provide a detailed description of the material ( Check here if additional sheets are attached):

2. Country of origin of the material:

3. Address where the human pathogen is to be used if different from Section A (NOT a post office box):

4. City

5. State

6. Zip Code

7. Is the material known or suspected to contain human pathogens?  Yes  No (If no, then see instructions: an import permit may not be required)

8. If yes, give the name of the etiologic agent(s) known or suspected to be present:

9. Natural host(s) for this etiologic agent(s):

10. Type of material:  Fluids or tissues (List species samples are from: \_\_\_\_\_)

Isolate(s)  Bacterial toxin(s)  Host or vector

Other

(Describe): \_\_\_\_\_

11. Does this material contain a select agent (specified in 42 C.F.R. Part 73)?  Yes  No

If yes, provide your CDC or APHIS facility registration number: \_\_\_\_\_ Expiration date of registration: \_\_\_\_\_

12 Are these materials for laboratory use only?  Yes  No

If no, will the materials be used for the production of biologics for humans or animals?  Yes  No

13. Estimated completion date of work:

14. Proposed use of material:  Research  Diagnostics  Production  Other (Describe: \_\_\_\_\_)

15. Describe objective of work (Additional sheets attached):

16. Final disposition of material(s) after completion of work:

Long-term storage onsite

Transfer to another location  
 (Describe: \_\_\_\_\_)

Destroyed on site (Method of destruction: \_\_\_\_\_)

Other  
 (Describe: \_\_\_\_\_)

New form Section C:

SECTION C, Shipment Information			
1. Method(s) of Shipment	2. Number of Shipments	3. Shipment Temperature(s)	4. Anticipated U.S. Port(s) of Entry
<input type="checkbox"/> Commercial Carrier (e.g., FedEx) <input type="checkbox"/> Hand-carried by (provide name of person): _____	<input type="checkbox"/> Single Shipment <input type="checkbox"/> Multiple Shipments i. Estimated # of shipments: ____	<input type="checkbox"/> Ambient <input type="checkbox"/> Frozen/Refrigerated	

- Removed item 1 from old form: Provide a detailed description of the material ( check here if additional sheets are attached):
- Removed item 2 from old form: Country of origin of the material
- Removed item 3 from old form: Address where the human pathogen is to be used if different from Section A (NOT a post office box)
- Removed item 4 from old form: City
- Removed item 5 from old form: State
- Removed item 6 from old form: Zip Code
- Removed item 7 from old form: Is the material known or suspected to contain human pathogens? Yes No (If no, then see instructions: an import permit may not be required)
- Removed item 8 from old form: If yes, give the name of the etiologic agent(s) known or suspected to be present:
- Removed item 9 from old form: Natural host(s) for this etiologic agent(s):
- Removed item 10 from old form: Type of material  
 Fluids or tissues (List species samples are from: \_\_\_\_\_)  
 Isolate(s) Bacterial toxin(s) Host or vector Other  
 (Describe): \_\_\_\_\_


- Removed item 11 from old form: Does this material contain a select agent (specified in 42 C.F.R. Part 73)? Yes No  
If yes, provide your CDC or APHIS facility registration number:\_\_\_\_\_ Expiration date of registration:\_\_\_\_\_
- Removed item 12 from old form: Are these materials for laboratory use only? Yes No  
If no, will the materials be used for the production of biologics for humans or animals? Yes No
- Removed item 13 from old form: Estimated completion date of work:
- Removed item 14 from old form: Proposed use of material: Research Diagnostics  
Production Other (Describe:\_\_\_\_\_)
- Removed item 15 from old form: Describe objectives of work ( Additional sheets attached):
- Removed item 16: from old form Final disposition of material(s) after completion of work:  
Long-term storage onsite  
Transfer to another location  
(Describe:\_\_\_\_\_)  
Destroyed on site (Method of destruction: \_\_\_\_\_)  
Other (Describe:\_\_\_\_\_)
- Added item 1 to the new form: Method(s) of Shipment  
Commercial Carrier (e.g., FedEx)  
Hand-carried by (provide name of person):\_\_\_\_\_
- Added item 2 to the new form: Number of Shipments  
Single Shipment  
Multiple Shipments  
i. Estimated # of shipments:\_\_\_
- Added item 3 to the new form: Shipment Temperature(s)  
Ambient  
Frozen/Refrigerated
- Added item 4 to the new form: Anticipated U.S. Port(s) of Entry

Old form Section D:

<b>SECTION D – TYPE OF PERMIT AND SHIPMENT INFORMATION</b>	
1. Importation into U.S.: <input type="checkbox"/> Single <input type="checkbox"/> Multiple No. of shipments expected to be made within the next 12 months: _____	
2. Transfer within the U.S.: <input type="checkbox"/> Single <input type="checkbox"/> Multiple <input type="checkbox"/> None No. of shipments expected to be made within the next 12 months: _____	
3. U.S. port(s) of entry (if known):	4. Total volume (indicate units, ml, mg, liter):

New form Section D:

<b>SECTION D, Final Destination of Imported Biological Agent</b>
--

1. Is final destination of biological agent(s) different from address in Section A? <input type="checkbox"/> No (skip to Section E) <input type="checkbox"/> Yes 		2. Last Name of Recipient at Destination		3. First Name		4. MI	
5. Destination Organization		6. Final Destination Address (NOT a post office box)		7. City		8. State	9. Zip Code
10. Telephone		11. Fax		12. Email		13. Check here <input type="checkbox"/> if you have included a Continuation Form to list multiple final destinations	

- Removed item 1 from old form: Importation into U.S.: Single Multiple No. of shipments expected to be made within the next 12 months: \_\_\_\_\_
- Removed item 2 from old form: Transfer within the U.S.: Single Multiple None No. of shipments expected to be made within the next 12 months: \_\_\_\_\_
- Removed item 3 from old form: U.S. port(s) of entry (if known):
- Removed item 4 from old form: Total volume (indicate units, ml, mg, liter):
- Added item 1 to new form: Is final destination of biological agent(s) different from address in Section A? No (skip to Section E) Yes
- Added item 2 to new form: Last Name of Recipient at Destination
- Added item 3 to new form: First Name
- Added item 4 to new form: MI
- Added item 5 to new form: Destination Organization
- Added item 6 to new form: Final Destination Address (NOT a post office box)
- Added item 7 to new form: City
- Added item 8 to new form: State
- Added item 9 to new form: Zip Code
- Added item 10 to new form: Telephone
- Added item 11 to new form: Fax
- Added item 12 to new form: Email
- Added item 13 to new form: Check here  if you have included a Continuation Form to list multiple final destination

Old form Section E:

<b>SECTION E – ISOLATION AND CONTAINMENT FACILITIES AND TECHNICAL PERSONNEL</b>
1. Description of applicant laboratory facilities, containment equipment, and personal protective equipment ( <input type="checkbox"/> Additional sheets attached):
2. Biosafety level (See instructions): <input type="checkbox"/> Biosafety level 1 <input type="checkbox"/> Biosafety level 2 <input type="checkbox"/> Biosafety level 3 <input type="checkbox"/> Biosafety level 4
3. Describe the qualifications, experience, and training of technical personnel handling the material ( <input type="checkbox"/> Additional sheets attached):

New form section E:

**SECTION E, Description of Imported Biological Agent**

<p>1. Intended use(s) of imported agent(s)</p> <p><input type="checkbox"/> a Diagnostic</p> <p><input type="checkbox"/> b Research</p> <p><input type="checkbox"/> c Clinical trials</p> <p><input type="checkbox"/> d Education</p> <p><input type="checkbox"/> e Production</p> <p><input type="checkbox"/> f Other (please describe):</p>	<p>2. Provide a detailed description of the work to be accomplished with the imported agent(s) (Describe your work clearly &amp; simply. Include background, purpose, objectives, methods, etc.)</p>	<p>5. Check here <input type="checkbox"/> if you included a Continuation Form to list additional agents to be imported with this Permit.</p>
--	--	--

3. Scientific name of known/suspected biological agent(s)		4. Type(s) of Biological Agent							
Genus	Species		Bacteria	Virus	Fungi	Toxin	Parasite	Prion	Recombinant Genetic Material
a		a	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b		b	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c		c	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d		d	<input type="checkbox"/>						

- Removed item 1 from old form: Description of applicant laboratory facilities, containment equipment, and personal protective equipment ( Additional sheets attached):
- Removed item 2 from old form: Biosafety level (See instructions): Biosafety level 1  
Biosafety level 2 Biosafety level 3 Biosafety level 4
- Removed item 3 from old form: Describe the qualifications, experience, and training of technical personnel handling the material ( Additional sheets attached):
- Added item 1 to new form: Intended use(s) of imported agent(s)  
Diagnostic  
Research  
Clinical trials  
Education  
Production  
Other (please describe):
- Added item 2 to new form: Provide a detailed description of the work to be accomplished with the imported agent(s) (Describe your work clearly & simply. Include background, purpose, objectives, methods, etc.)
- Added item 3 to new form: Scientific name of known/suspected biological agent(s)

Genus	Species
a	
b	
c	
d	

- Added item 4 to new form: Type(s) of Biological Agent

Bacteria	Virus	Fungi	Toxin	Parasite	Prion	Recombinant Genetic Material
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>						

- Added item 5 to the new form: Check here if you included a Continuation Form to list additional agents to be imported with this Permit.

Old form section F:

SECTION F – SIGNATURE OF PERMITTEE				
1. APPLICANT (Print Name)	2. SIGNATURE:	3. TITLE:	4. DEGREE(S)	5. DATE SIGNED (MM/DD/YYYY)

New form section F:

SECTION F, Description of Material(s) Containing the Biological Agent(s) to be Imported	
1. Source of material(s) being imported <i>(Check all that apply)</i> <input type="checkbox"/> Infected or suspected infected human <input type="checkbox"/> Infected or suspected infected vector <i>(APHIS permit may be required)</i> <i>i (please describe)</i> _____	2. Description of material(s) containing biological agent(s) <i>(Check all that apply and provide description below)</i> <input type="checkbox"/> Field-collected specimen <input type="checkbox"/> Tissues/organs <input type="checkbox"/> Laboratory isolate/culture <input type="checkbox"/> Body parts <input type="checkbox"/> Blood/blood products <input type="checkbox"/> Vector



<p>ii Vector viability:    <input type="checkbox"/> 1 live    <input type="checkbox"/> 2 dead</p> <p><input type="checkbox"/> c Environment (please describe): _____</p> <p><input type="checkbox"/> d Other (please describe): _____</p>	<p><input type="checkbox"/> Other body fluids    <input type="checkbox"/> Other</p> <p>i Provide a detailed description of the material containing the biological agent:</p>
<p>3. Does the material contain animal products or byproducts (e.g., Fetal Calf Serum or Bovine Serum Albumin)?</p> <p><input type="checkbox"/> a No    <input type="checkbox"/> b Yes (APHIS Import Permit may also be required)</p>	

- Removed item 1 from old form: APPLICANT (Print Name)
- Removed item 2 from old form: SIGNATURE
- Removed item 3 from old form: TITLE
- Removed item 4 from old form: DEGREE(S)
- Removed item 5 from old form: 5. DATE SIGNED (MM/DD/YYYY)
- Added item 1 to new form: Source of material(s) being imported (Check all that apply)

Infected or suspected infected human

Infected or suspected infected vector (APHIS permit may be required)

i (please describe) \_\_\_\_\_

ii Vector viability:                      live                      dead

Environment (please describe): \_\_\_\_\_

Other (please describe): \_\_\_\_\_

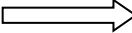
- Added item 2 to new form: Description of material(s) containing biological agent(s) (Check all that apply and provide description below)
  - Field-collected specimen      Tissues/organs
  - Laboratory isolate/culture      Body parts
  - Blood/blood products              Vector
  - Other body fluids                      Other

i. Provide a detailed description of the material containing the biological agent:
- Added item 3 to new form: Does the material contain animal products or byproducts (e.g., Fetal Calf Serum or Bovine Serum Albumin)?

No    Yes (APHIS Import Permit may also be required)

New form section G:

**SECTION G, Receiving Laboratory Capabilities**

<p>1. Laboratory Biosafety Level (Check all that apply)</p> <p><input type="checkbox"/> ABSL-1      <input type="checkbox"/> BSL-1</p> <p><input type="checkbox"/> ABSL-2      <input type="checkbox"/> BSL-2</p> <p><input type="checkbox"/> ABSL-3      <input type="checkbox"/> BSL-3</p> <p><input type="checkbox"/> ABSL-4      <input type="checkbox"/> BSL-4</p> <p><input type="checkbox"/> Other (please describe):</p>	<p>2. Primary Containment to be used (Check all that apply)</p> <p><input type="checkbox"/> None (open bench)</p> <p><input type="checkbox"/> Class I</p> <p><input type="checkbox"/> Class II, Type _____</p> <p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Fume Hood</p> <p><input type="checkbox"/> Other (please describe):</p>	<p>3. Personal Protective Measures to be used (Check all that apply)</p> <p><input type="checkbox"/> Gloves</p> <p><input type="checkbox"/> Protective Clothing</p> <p><input type="checkbox"/> Goggles and/or Face Shield</p> <p><input type="checkbox"/> Facemask</p> <p><input type="checkbox"/> Respirators: Type <input type="checkbox"/> N95/100 <input type="checkbox"/> PAPR</p> <p><input type="checkbox"/> Immunizations</p> <p><input type="checkbox"/> Other (please describe): _____</p>	<p>4. Personnel Training provided (Check all that apply)</p> <p><input type="checkbox"/> Risk(s) associated with the imported biological agent(s)</p> <p><input type="checkbox"/> Hazardous Material Packing/Shipping</p> <p><input type="checkbox"/> Laboratory Standard Practices</p> <p><input type="checkbox"/> Hazardous Waste Handling/Disposal</p> <p><input type="checkbox"/> Emergency Response Procedures</p> <p><input type="checkbox"/> Spill Procedures</p> <p><input type="checkbox"/> Other (please describe): _____</p>
<p>5. Anticipated disposition of Biological Agent(s) (and material containing it) when work is completed</p> <p><input type="checkbox"/> Will be <b>retained</b> at address listed in SECTION A</p> <p><input type="checkbox"/> Will be <b>transferred</b> to location listed in SECTION D</p> <p><input type="checkbox"/> Will be <b>destroyed</b> (please complete Block 6)      </p>		<p>6. If Agent(s) will be destroyed, list expected method(s) of destruction</p> <p><input type="checkbox"/> Thermal: (describe method): _____</p> <p><input type="checkbox"/> Chemical (describe chemical): _____</p> <p><input type="checkbox"/> Irradiation (describe energy source): _____</p> <p><input type="checkbox"/> Other (please describe): _____</p>	

- Section G did not exist on the old form
- Added item 1 to new form: Laboratory Biosafety Level (Check all that apply)
  - ABSL-1      BSL-1
  - ABSL-2      f BSL-2
  - ABSL-3      BSL-3
  - ABSL-4      BSL-4
  - Other (please describe):
- Added item 2 to new form: Primary Containment to be used (Check all that apply)
  - None (open bench)
  - Class I
  - Class II, Type \_\_\_\_\_
  - Class III
  - Fume Hood
  - Other (please describe):
- Added item 3 to new form: Personal Protective Measures to be used (Check all that apply)
  - Gloves
  - Protective Clothing
  - Goggles and/or Face Shield
  - Facemask

Respirators:

Type i N95/100 ii PAPR

Immunizations

Other (please describe): \_\_\_\_\_

- Added item 4 to new form: Personnel Training provided (Check all that apply)  
Risk(s) associated with the imported biological agent(s)  
Hazardous Material Packing/Shipping  
Laboratory Standard Practices  
Hazardous Waste Handling/Disposal  
Emergency Response Procedures  
Spill Procedures  
Other (please describe): \_\_\_\_\_
- Added item 5 to new form: Anticipated disposition of Biological Agent(s) (and material containing it) when work is completed  
Will be retained at address listed in SECTION A  
Will be transferred to location listed in SECTION D  
Will be destroyed (please complete Block 6)
- Added item 6 to new form: If Agent(s) will be destroyed, list expected method(s) of destruction  
Thermal: (describe method): \_\_\_\_\_  
Chemical (describe chemical): \_\_\_\_\_  
Irradiation (describe energy source): \_\_\_\_\_  
Other (please describe): \_\_\_\_\_

New form section H:

SECTION H, Signature of Permittee		
1. Requestor's Signature ( <b>REQUIRED</b> )	2. Requestor's Printed Name ( <i>Print name</i> )	3. Date Signed ( <i>mm/dd/yyyy</i> )

- Section H did not exist on the old form
- Added item 1 to new form: Requestor's Signature (**REQUIRED**)
- Added item 2 to new form: Requestor's Printed Name (Print name)
- Added item 3 to new form: Date Signed (mm/dd/yyyy)