U.S. DEPARTMENT OF
HEALTH & HUMAN SERVICES
Public Health Service

APPLICATION FOR PERMIT TO IMPORT OR TRANSPORT ETIOLOGIC AGENTS, HOSTS, OR VECTORS OF HUMAN DISEASE

FORM APPROVED
OMB NO. 0920-0199
EXP DATE 1/31/2011

Read instructions before completing. Answer all items completely and type or print in ink. Let us know if you have already faxed your application. Use additional sheets if necessary. Complete and submit original signed application to: Centers for Disease Control and Prevention, Etiologic Agent Import Permit Program, 1600 Clifton Road NE, Mailstop A-46, Atlanta, GA 30333; Telephone: 404-718-2077; FAX: 404-718-2093.

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		

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		

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:_____

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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 objectives 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*:_____)

SECTION D – TYPE OF PERMIT AND SHIPMENT INFORMATION

1. Importation into U.S.: Single Multiple No. of shipments expected to be made within the next 12 months:_____

2. Transfer within the U.S.: Single Multiple 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):

SECTION E – ISOLATION AND CONTAINMENT FACILITIES AND TECHNICAL PERSONNEL

1. Description of applicant laboratory facilities, containment equipment, and personal protective equipment (*Additional sheets attached*):

2. Biosafety level (*See instructions*): Biosafety level 1 Biosafety level 2 Biosafety level 3 Biosafety level 4

3. Describe the qualifications, experience, and training of technical personnel handling the material (*Additional sheets attached*):

I hereby certify that the information submitted in this application is complete and accurate to the best of my knowledge and belief. I agree to comply with the conditions listed in the application and all restrictions and precautions that may be specified in the permit, in addition to all applicable regulations which govern this transfer. I understand that failure to comply with the importation requirements may subject me to criminal penalties pursuant to 42 U.S.C. 271. I understand that any false statement made in this application may subject me to criminal penalties pursuant to 18 U.S.C. 1001.

SECTION F – SIGNATURE OF PERMITTEE

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

CDC 0.753
REV. 02/04

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GUIDANCE DOCUMENT FOR THE APPLICATION FOR PERMIT TO IMPORT OR TRANSPORT ETIOLOGIC AGENTS, HOSTS, OR VECTORS OF HUMAN DISEASE

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Importation permits are issued by the Etiologic Agent Import Permit Program at the Centers for Disease Control and Prevention (CDC) following review of a completed application form. The regulation, application, and instructions can be found at the CDC website (http://www.cdc.gov/od/eaipp/). Completed application forms may be returned to the CDC, Etiologic Agent Import Permit Program by FAX (FAX: 404-718-2093) or by mail to: Centers for Disease Control and Prevention, Etiologic Agent Import Permit Program, 1600 Clifton Road, N.E., Mailstop A-46, Atlanta, GA 30333

Please note the following:

- Currently there is no fee for processing a U.S. Public Health Service import permit.
- *At least 15 working days* are required to process import permit applications, renewals and modifications. Please allow 15 working days before inquiring about the status of your permit.
- Import permit applications, renewals and modifications are processed in the order they are received. Requests for expediting permits will be handled on a case-by-case basis and only for documented emergencies.
- Requests for renewal of an existing permit and modifications will require the completion of a new application and current signature of the permittee. To prevent lapses in import permit status, please submit renewal applications at least 30 days prior to expiration date of current permit.
- Incomplete or illegible applications will result in significant delays or denial of a permit. Applications may be typed or handwritten. However, if handwritten, applications must be legible. Applications will be returned without action if incomplete or illegible.
- Attach additional sheet(s), noting the section number, if more space is needed.

Section A. The person requesting the permit (permittee or applicant) should be: (1) Knowledgeable and skilled in the handling of the infectious agent or biological material (in general, regulatory affairs officers or other administrative personnel are not acceptable as permittees), (2) Be directly responsible for work with the infectious material, and (3) Should be located at the address within the U.S. where work with the infectious material will be performed. Enter your complete name, address, telephone, and FAX number. Failure to include the telephone and FAX numbers where you can be reached during the day will result in prolonged delays. The name appearing in this section and in Section F should be the same. Permits are only issued to a single individual.

Section B. Enter complete name, address, telephone and FAX number of the sender. Multiple senders may be listed on an attached sheet as needed. Please provide a complete list of senders for each permit application submitted. List the corresponding infectious material that will be shipped for each source if applicable.

Section C. Describe the type of material and answer “yes” or “no” to the questions given. If the material being imported has been rendered sterile (e.g., radiation or chemical treatment) and is known not to contain infectious agents for humans, then a permit is not required for importation. If the material is suspected or known to contain an etiologic agent, then please indicate what the agent is and give a description of the material being imported (e.g., tissue and blood containing Hepatitis A virus). Indicate the natural host for the agent (e.g., human, mouse, insect, etc.). Note that incomplete information may result in significant delays or denial of your permit request.

Importers of select agents and toxins (as defined in 42 C.F.R. Part 73) must be registered with CDC in accordance with 42 C.F.R. Part 73 (*Possession, Use and Transfer of Select Agents and Toxins; Final Rule*). The regulation, 42 C.F.R. Part 73, and registration application forms are available through the CDC Select Agent Program website at: http://www.cdc.gov/od/sap. The transfer of select agents and toxins requires prior authorization by CDC or APHIS on APHIS/CDC Form 2 in accordance with § 73.16. Please note, identification of select agents or toxins in specimens presented for diagnosis, verification, or proficiency testing has additional reporting requirements under 42 C.F.R. 73.

Indicate if the material will be for laboratory use only or if it will be used in the production of biological products for subsequent human or animal use. When describing the objectives of the work, please state the intended use(s) (for example, infectious disease research or diagnosis, assay development, commercial production, etc.)

Section D. Importation into the U.S. refers to the package as it passes through the port of entry to the applicant's address. Moving imported material from one air carrier to another at the port of entry on the way to its domestic destination is not considered a transfer for the purposes of this permit. A transfer within the U.S. refers to shipping from one address within the U.S. to another address within the U.S. Permits for single importations are valid for six months. Permits for multiple importations are valid for one year. For multiple shipments, enter the number of shipments you expect to receive in the next 12 months and number of transfers you expect to make in the next 12 months.

Section E. Describe the physical containment devices and personal protective equipment utilized by personnel handling the material to be imported (e.g. biological safety cabinets, respirators, face shields). Indicate the biosafety level of the laboratory where the work will occur and any other information pertinent to available facilities. Definitions of biosafety levels should follow that published in "Biosafety in Microbiological and Biomedical Laboratories" (BMBL). The BMBL is available on the internet at http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm. Describe the qualifications, technical experience, and relevant safety training for personnel that will be handling this material. A *curriculum vitae* and/or list of publications may be requested.

Section F. Type or print your name legibly in the appropriate space and sign name in the indicated space. *The application must be signed by the same person listed in Section A, or the permit application will not be processed*. Type or print the title and degree of the applicant and the date that the application is signed.