



Regulated Biological Materials Permits

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Requirements

Various government bodies¹ regulate importation and interstate transportation of certain biological materials. No regulated materials may be received at Harvard University or by Harvard personnel until all relevant permit approvals are issued, and permit approvals must be issued prior to material shipments. Learn more about [shipping and transporting research materials at Harvard](#).

The Principal Investigator (PI) or comparable authorized person receiving the material is responsible for:

- Determining if a biological permit is necessary

¹ Including the Centers for Disease Control and Prevention (CDC), US Department of Agriculture (USDA), and Fish and Wildlife Services (FWS).



- Completing required permit applications and renewals
- Adhering to all applicable permitting requirements
- Training research staff on permitting requirements

Only PIs or persons responsible for material, space, and personnel oversight may apply for and maintain permits.

Harvard EHS Biosafety can help you prepare for the application process through documentation review.

Contact biosafety@harvard.edu:

- To help figure out if you need a permit
- When you begin a permit application
- If you have any questions during the application process
- If a permitting agency requests an inspection of the facility
- After your application is approved and you receive your permit(s)

Creating a Permit Account

You can submit permit applications to most permitting agencies online, including the CDC, USDA, and FWS. PIs must create their own accounts to request permits, renewals, amendments, and closures. **Federal regulations prohibit sharing login information between users.** Online accounts are digital forms of identification that are nontransferable and must not be shared between persons.

Lab members can help PIs prepare permit application information but are not permitted to act on behalf of these parties.



Before Applying for a Permit

No material may be received at Harvard University or by Harvard personnel until all relevant approvals are issued. Complete any permit-related COMS, IACUC, or IRB protocol(s) before or during your application submission.

Collect all the following information and documentation before beginning your permit application:

- Permittee name (PI) and their physical Harvard location (address where the material will be received and listed on the permit)
- Name of your department's [Biosafety Officer](#)
- Names of persons who will work with the materials (reference the [COMS protocol list](#) if applicable)
- Who you will be receiving materials from (names and physical addresses of the IATA-certified shippers or PI²)

If you do not know the receiving specifics you may generalize or leave this information out of your application (when possible)

- Approximate number of shipments you plan to receive and the type of transport (via courier, FedEx, etc.)
- List of rooms where the materials will be used and stored (freezer farms, core facilities, microscopy areas, animal facilities, etc.)
- Comprehensive summary of your research plans (reference your [COMS protocol](#) if applicable), including:

² On the shipping documents, the person listed as the provider of the material on the permit must also be the shipper. If the listed provider is not IATA-certified then they must be listed after the name of the shipper as being shipped “on behalf of (*insert provider’s name*)”.



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- Any plans to propagate, culture, or introduce into other animals or arthropods
- Agent information like biosafety level, source of materials, transgenes, and expected phenotype
- Your laboratory space's security and facility attributes:
 - How you will secure the material and who will have access to it
 - Laboratory ventilation system information (if applicable)
- Biosafety and containment measures that you currently or plan to follow, including:
 - Biosafety cabinet type(s) used
 - Specialty containment equipment for arthropod, plant, or animal research (air curtains, door sweeps, caging, etc.)
 - Personal protective equipment (may differ for greenhouse, animal, or arthropod facilities)
 - Types of personnel training (verify with your [Biosafety Officer](#))
 - Biowaste destruction method

Typical methods:

- Chemical destruction for liquid waste (10% bleach solution)
- Contracted medical waste vendor for solid waste (heat - autoclave or incineration)
- If or how you will perform material transfers outside of areas listed
- [COMS](#), IACUC, and IRB approval letters (if applicable)
- Lab standard operating procedures pertaining to lab safety



After Application Submission

Permit approval timelines range from several days to over a year. Some agencies or permit types may require an inspection of the facility or request more documentation. **Immediately notify biosafety@harvard.edu if an agency requests an inspection.** EHS can help you during preparation and the inspection.

After Permit Approval

Read your permit carefully after it is approved. Permit holders must meet all permit conditions, including shipping, facility, and safety requirements prior to and after receipt. Permit copies must be included in all shipments received by the lab (send a copy to the shipper) and shipping documentation kept upon receipt.

Email copies of approved permits to biosafety@harvard.edu.

Permits are usually only valid for a year. You must renew your permit before it expires if the permittee will continue to receive shipments.

Permit conditions typically stay in effect for the duration of material possession, including their applicability in the event of material transfer or shipments to other parties.

USDA PPQ Permits

You must renew USDA Plant Protection and Quarantine (PPQ) permits for the duration of material possession, even if you don't receive new materials.

References

CDC. (2021, October 1). *SAMS Identity Verification Overview*. Retrieved from Import Permit Program (IPP):
<https://auth.cdc.gov/sams/IdentityVerificationOverview.pdf?disp=true>

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USDA. (2023, January 9). *APHIS eFile Training*. Retrieved from Animal and Plant Health Inspection Service: <https://www.aphis.usda.gov/aphis/banner/help/efile/efile-training>

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