

Permits and Documentation

Description

State and Federal Permits that May be Required For Shipping and Transport of Biological Materials

[su_spoiler style="fancy" icon="chevron" title=" Permit Information "] Permits are issued in the name of the PI who is required to keep them updated and current as necessary; the Biosafety Office does not hold any "centralized" permits.

Most biological materials require an import permit for entry into the US. Many also require permits for inter-state movement in the US. AND Some biological materials require permits for possession.

- A [CDC Import Permit](#) is required for the importation of etiological agents causing disease in humans, non-sterilized human or animal tissues/fluids known or suspected to contain disease agents, hosts/vectors known or suspected to contain disease agents.
- A [USDA/APHIS Veterinary Permits](#) required for import and interstate movement of livestock disease agents (naturally occurring or engineered), derivatives of livestock disease agents, material known or reasonably expected to contain livestock disease agents, vectors of livestock diseases, animal products, materials containing animal products: USDA AHIS Veterinary Services (VS) Permit Interstate movement of microorganisms infectious to livestock/poultry including bacteria, viruses, protozoa, and fungi, arthropod vectors of livestock/poultry diseases, and tissues, blood, serum, or cells from known infected livestock/poultry.
- A [USDA/APHIS Plant, organism and Soil Permit](#) is needed for import or interstate movement of plant pests, plant pathogens, biological control agents, bees, plant pest diagnostic laboratories, soil microbe isolation laboratories, federal noxious weeds and parasitic plants.
- A [USDA APHIS Plant Protection and Quarantine \(PPQ\)](#) permit is required for the importation interstate transport and possession of regulated plants and plant products for consumption or propagation including: plants for planting such as nursery stock, small lots of seed, and post entry; plant products such as fruits and vegetable, timber, cotton and cut flowers; protected plants and plant products such as orchids, and threatened and endangered plant species; transit permits to ship regulated articles into, through, and out of the U.S.; and controlled import permits to import prohibited plant materials for research.
- A [Biotechnology Regulatory Services \(BRS\)](#) import permit is required for the importation, interstate movement, or environmental release of certain organisms developed using genetic engineering that may pose a plant pest risk.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" Biological Materials with additional regulatory oversight "]

- The transfer of **Select Infectious Agents and Toxins** is also regulated by the USDA/CDC. Each shipment of listed agents must be registered with the USDA/CDC through a responsible facility official at both the shipping and receiving entities. Please contact EH&S Biosafety before sending or requesting any Select Agents. The current list of Select Agents and Toxins can be [found here](#).
- A Florida Department of Agriculture and Consumer Services (FDACS) permit is required for the intra-state movement of any organism which may pose a risk to Florida agriculture

, become a nuisance, threaten native Florida wildlife, or pose a serious medical hazard to humans or livestock.

Note: A courtesy letter to the Florida Department of Agriculture and Consumer Services [Division of Animal Industry](#) is required for possession or use of any of the State of Florida [reportable animal diseases](#).

- **Export of Etiologic Agents of Humans, Animals, Plants and Related Materials** is regulated by the US Department of Commerce, Dept. of State, and Dept. of the Treasury. Export to certain countries is prohibited. A wide variety of etiologic agents of human, plant and animal diseases, including genetic material, and products which might be used for culture or production biological agents, will require an export license. Check the [BioAgent Export Control List](#). Additional information may be obtained by calling the Biosafety Office at 352-392-1591.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" Responsibilities "] The **PI is responsible for obtaining and maintaining any permit**. Inspections by the regulatory body may be required. If you have a permit or notification, you must Register the permit through the Biohazard Project Registration system in Gator TRACS.

[/su_spoiler] [su_spoiler style="fancy" icon="chevron" title=" Common misconceptions about permits "]

The fine print is not important.

- Not true. Permit conditions can be quite stringent; make sure you can meet the requirements.

The agent is endemic so there is no need for a permit.

- Not true. Examples include *Ralstonia solanacearum*, Citrus canker

It is non-pathogenic so there is no need for a permit.

- Not true. Examples that require a permit include *Liberibacter crescens*, GE *Agrobacterium*

State and Federal regulators copy EH&S Biosafety on all permits, so they are aware I have a permit.

- We are not copied on permits so please do not assume that we are aware of your permits. The mechanism for notifying the Biosafety Office is through a Biohazard Project Registration in Gator TRACS.

Federal or State approval trumps UF approval, so there is no need to inform Biosafety.

- Not true – additional “local” requirements may be in place (previous problems, proximity of susceptible hosts, shared research space – all factor into approval of research).

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Consult the **Biosafety Manual** or contact the Biosafety Office for more information and regulatory contacts.