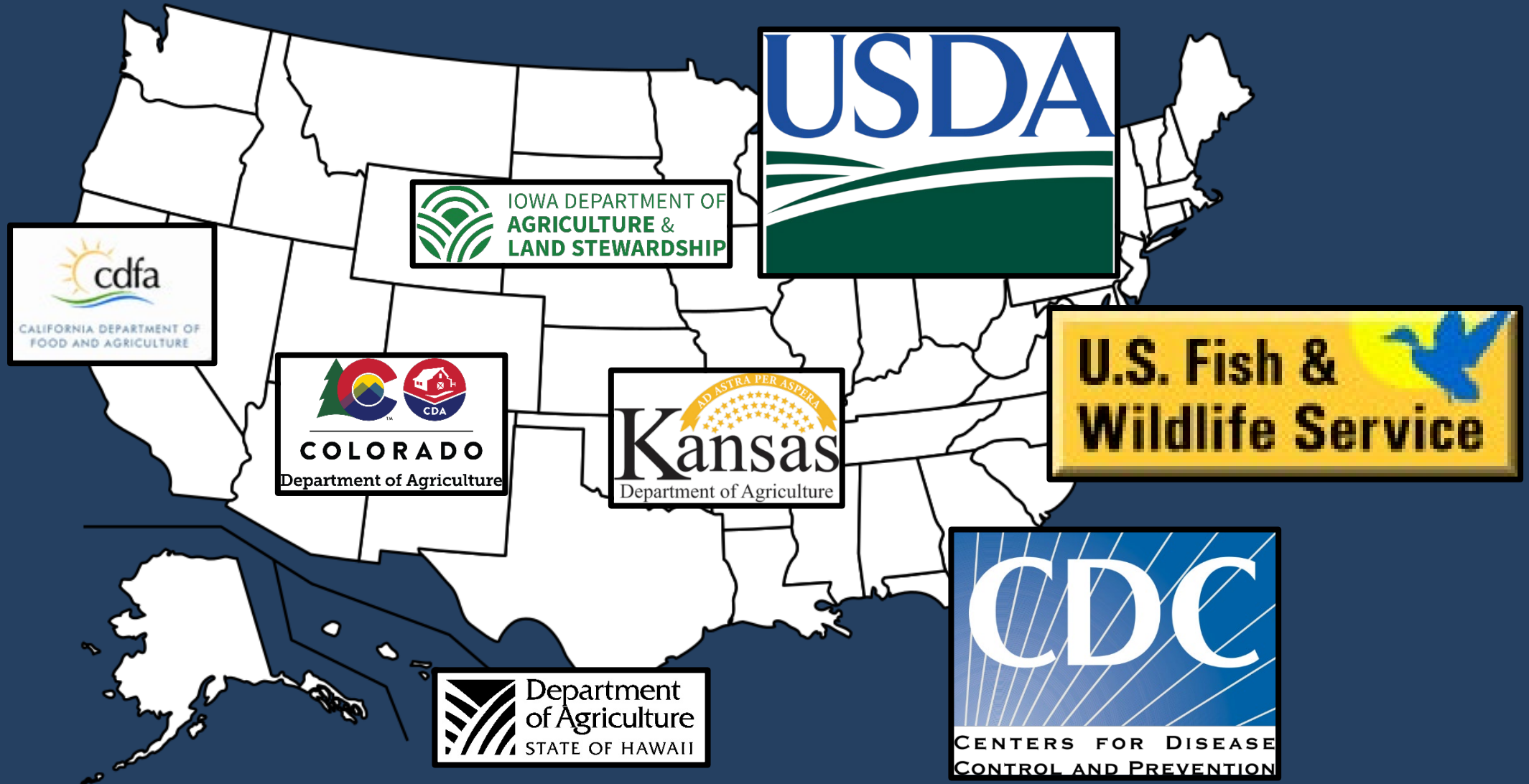


IMPLEMENTING A COMPREHENSIVE IMPORT PERMIT PROGRAM AT A LARGE UNIVERSITY

ARISTEA LUBAR
UNIVERSITY OF CALIFORNIA, SAN DIEGO

UC San Diego

The United States Has a Variety of Federal and State Entities Which May Require Permits

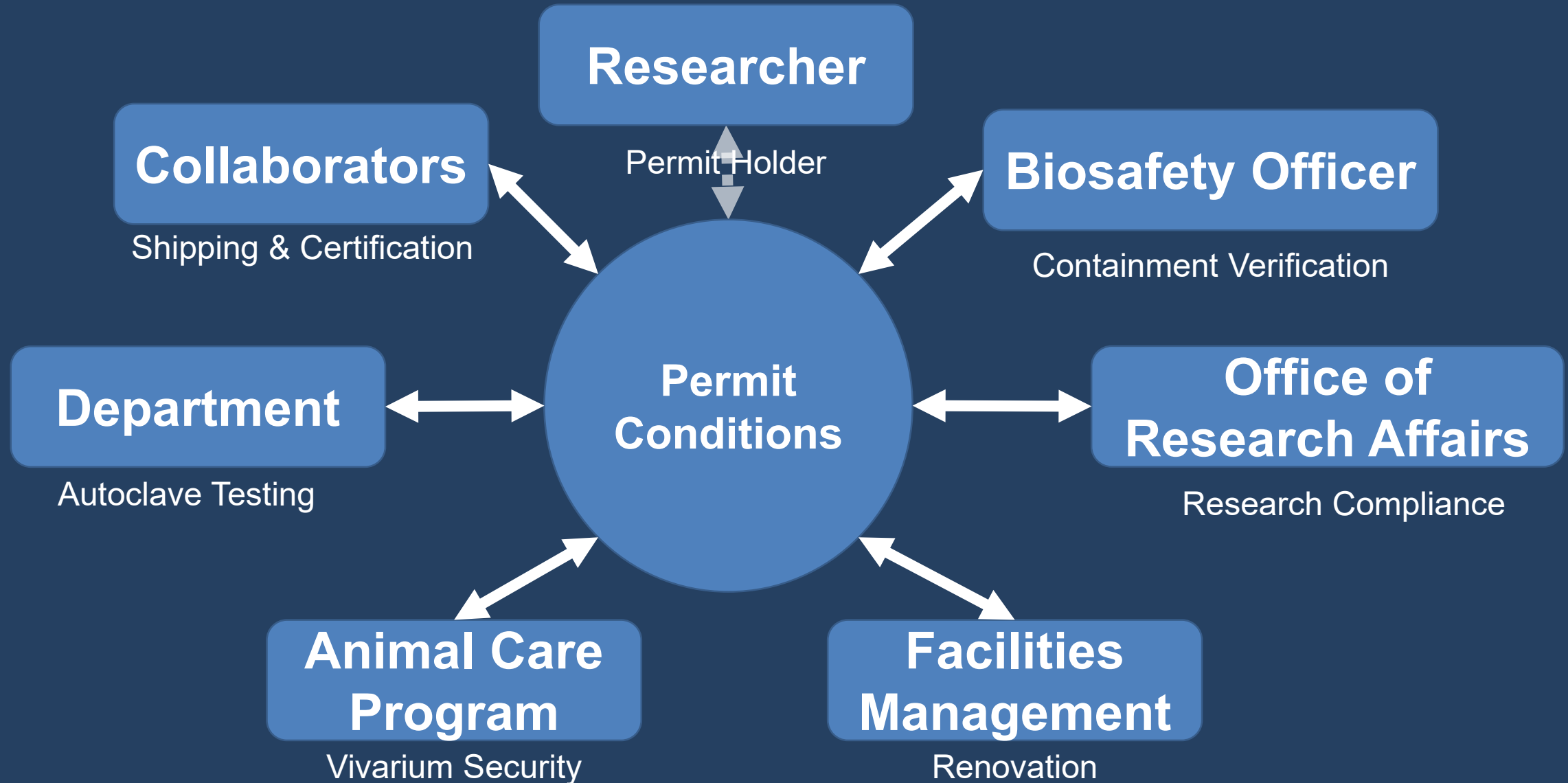


Large Institutions Frequently Engage in Global Partnerships

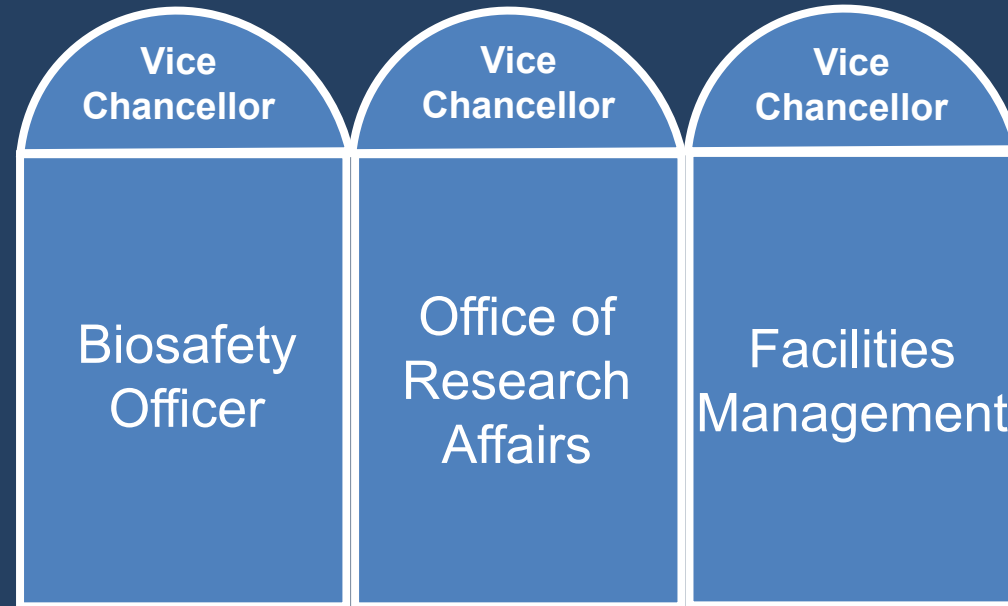


“UC San Diego has entered into over 300 memoranda of understanding (**MOUs**) and collaboration agreements, collectively called ‘international agreements,’ with universities and institutions worldwide.” – UCSD Office of International Affairs, SEP 2018

Numerous Stakeholders May Be Required for Approval and Permit Compliance



Large Institutions Present Unique Challenges for Obtaining Permits & Permit Compliance



- Stakeholders may be managed under separate leadership (“silos”).
- Infrastructure may be managed by multiple entities (autoclave spore testing, biosafety cabinet certification, security access, etc.).

Researchers may not understand which stakeholders to involve.

Researchers May Not Have Access to all the Information Requested by Permitting Agencies

How can I access
the floor plans for
my lab?

Is my autoclave
certified or
permitted?

Spore test records?



Who is in charge
of security access
controls?

How many air
changes/hr in my
lab?

Who is our waste
vendor?

**Researchers May Submit a Permit Application
at Any Time Without Official Notice to Their Institution**

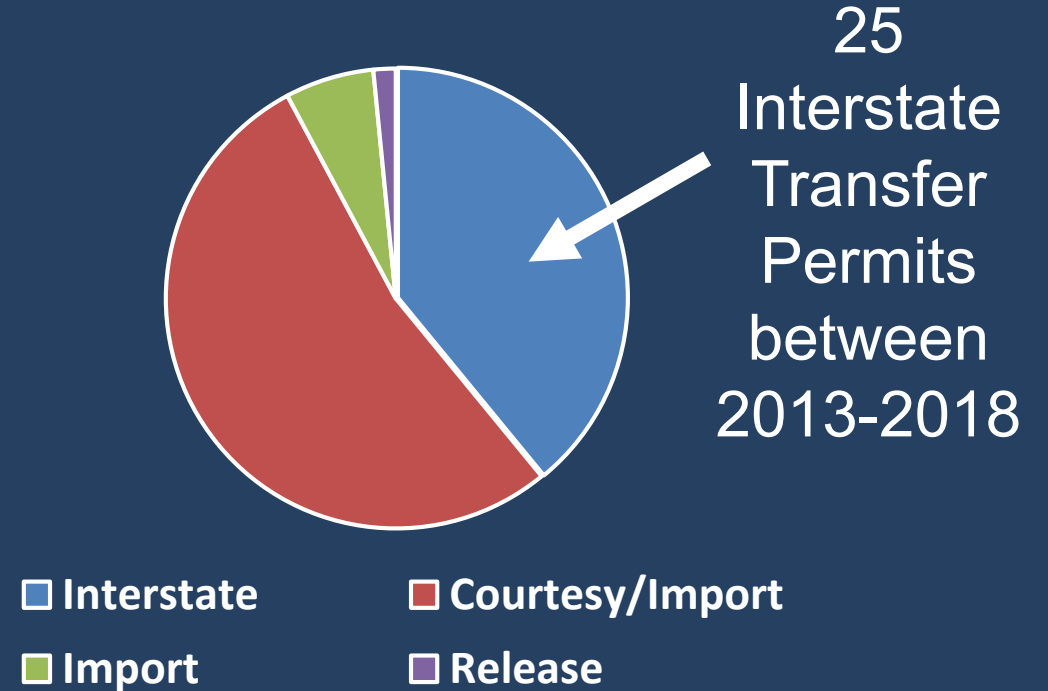
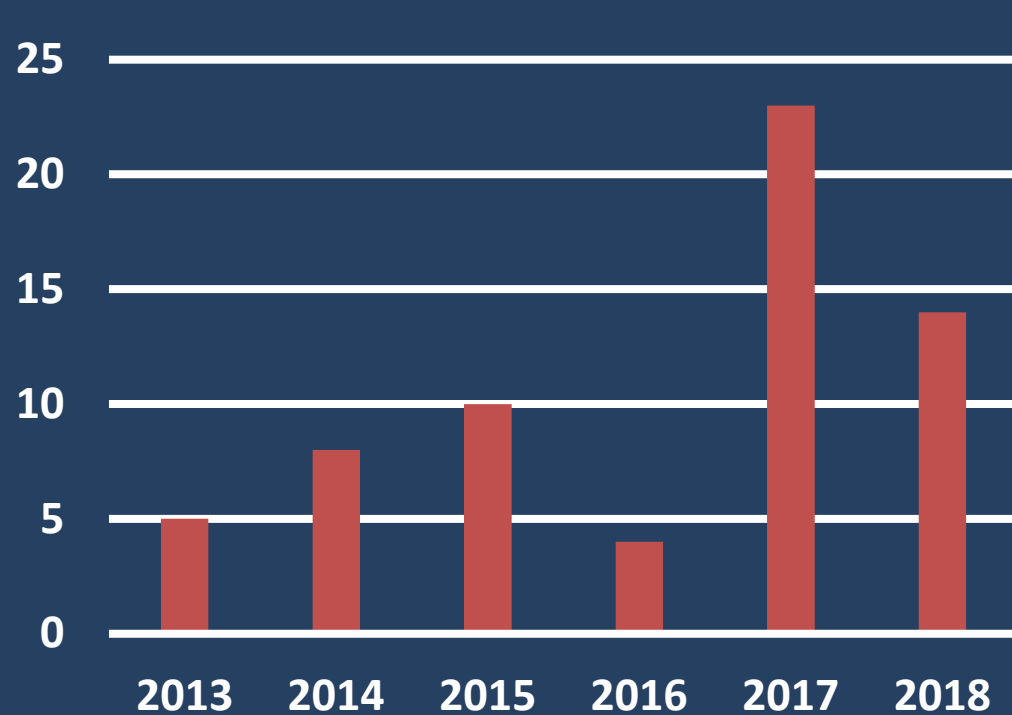


Untracked Permits? In *My* Institution?

It's more likely than you think.


Free Permit Check!

USDA Biotechnology Regulatory Services Permit Submissions from UC San Diego Over a 5 Year Period



From USDA/APHIS BRS Permit and Notification Database, September 2018

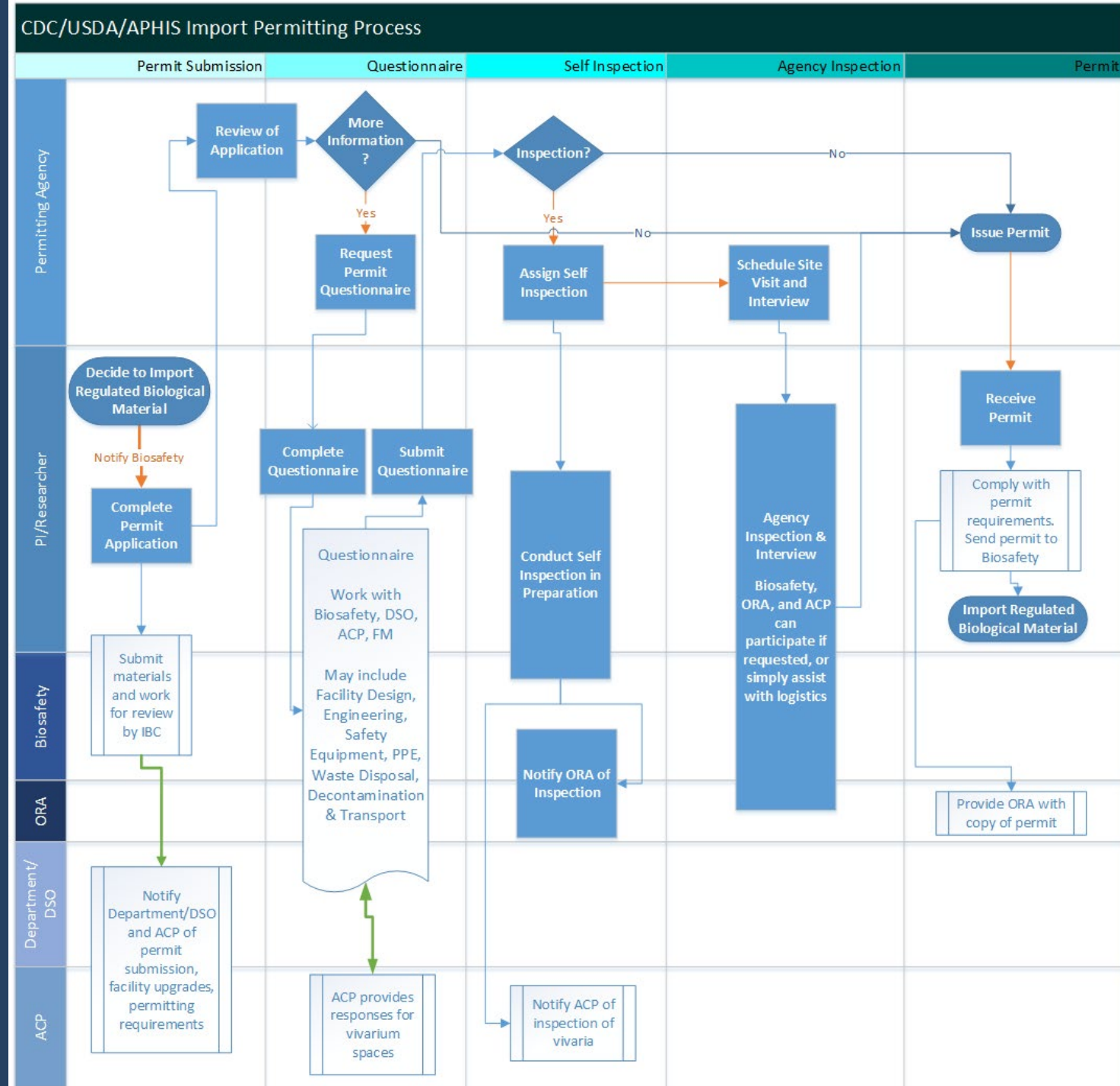
Some Permits May Be Tracked Through Existing Infrastructure, But Others May Fly Under The Radar.



If a marine archaeologist submits a USDA permit request to import soil, does it send up an institutional flag?

- No Recombinant DNA/RNA.
- No infectious material.
- Not commercial (No Material Transfer Agreement).
- Lab does not generate biohazardous waste.

How Do We Provide Guidance and Involve These Stakeholders?



Import Support Program Components



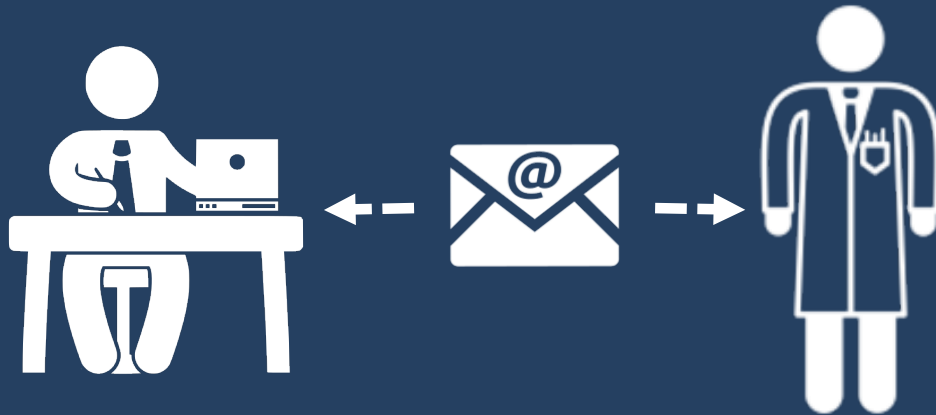
Outreach



Guidance Documents



Site Visits



Consultations



Stakeholder Communication

Institutional webpage:

- Provide guidance.
- Identify researcher responsibility.
- Offer resource links.
- Route researchers to contact BSO/Biosafety group for consultation.

Shipping: Biological Materials Permits

Last Updated: July 8, 2019 2:29:03 PM PDT

[Give feedback](#)

This page is intended to serve as guidance and overview regarding import permits for shipments of diagnostic specimens, biological materials, or recombinant or synthetic nucleic acids.

Definition: A shipment importing, domestic transfers, or exporting, of biological materials may require permits from [Center for Disease Control \(CDC\)](#), [United States Department of Agriculture \(USDA\)](#), [Animal and Plant Health Inspection Services \(APHIS\)](#), Department of Commerce (contact [Export Control](#)) and [U.S. Fish and Wildlife Service \(FWS\)](#). The State of California may require additional permits for the importation of biological materials, for example from the [California Department of Food and Agriculture](#) for plant pests, and from the [California Department of Public Health](#) or [California Department of Fish and Wildlife](#) for importation of wild animals.

Note: the [California Department of Fish and Wildlife](#) is a distinct entity from FWS, and is also responsible for issuing additional in-state permits, including those for plant sampling and scientific collection. If you are proposing field research and are unsure if you need a permit, please reach out to EHSBIO@UCSD.EDU or jacuc@ucsd.edu.

Importing or Domestic Transfer Responsibilities

With shipping biological materials comes the responsibility to:

- Identify if your material will require a federal permit for
 - Importation
 - Domestic transfer between states
- Work with EH&S and Shipping Department for permit application and permitting process
- Advise your collaborator/shipper of any needed permits
- Submit complete documentation to obtain a permit
- Arrange for any required on-site inspections
- Complete shipping training
- Receive the permit and follow all permit conditions
- Appropriately ship and package materials

To help navigate the various permitting requirements for applicable regulatory agencies, here are some available resources:

- [CDC Import Permit Program \(IPP\) tool](#)
- [USDA/APHIS guidelines for ePermits](#)
- [USDA/APHIS guidelines for Animal Products That Do Not Require An Import Permit](#)
- [U.S. Fish and Wildlife Service](#)

Even if you think your material may be exempt from permitting requirements, please contact [EHS Biosafety](#) for assistance. EHS Biosafety is here to help you make determinations about permitting, and otherwise assist and inform you about the permitting process.

INTERNATIONAL RESEARCH

- **Partnership with the Office of Research Affairs (ORA).**
- **Article in the ORA Monthly Newsletter.**
- **Lecture hosted by ORA as part of a presentation series on research compliance and integrity.**





ARISTEA LUBAR, B.S.

Laboratory of

LANCE SCOTT, PH.D.

RESEARCH SAFETY MANAGER

DIVISION OF RESEARCH SAFETY

DEPARTMENT OF ENVIRONMENT, HEALTH, & SAFETY, UCSD

9500 GILMAN DRIVE, MC 0090
CRSF, BUILDING, ROOM 241
LA JOLLA, CALIFORNIA 92093-009
TEL: (858) 534-6138; FAX: (858) 555-5555
E-mail: alubar@ucsd.edu

CDC Statement

February 21, 2019

This is to certify that the contents of this parcel are not known or suspected to contain an infectious biological agent, because [HOW THIS IS KNOWN NOT TO CONTAIN AN INFECTIOUS AGENT/WHY THERE IS NO REASON TO SUSPECT IT CONTAINS AN INFECTIOUS AGENT/DESCRIPTION OF HOW MATERIAL WAS RENDERED NON-INFECTIOUS].

This shipment contains the following biological materials:

1. Organism (genus, species, and strain if relevant), media/buffer, and quantity [e.g. *Escherichia coli* DH5a in LB broth, 2mL]

[SIGNATURE]

Aristea Lubar

Division of Research Safety

Department of Environment, Health, & Safety

9500 Gilman Drive, MC 0090

CRSF 241

La Jolla, CA 92093

Telephone: (858) 534-6138

alubar@ucsd.edu

Example CDC certification statement provided to assist a researcher importing exempt material from an international collaborator.

Biosafety Site Visits Can Be Conducted With an Eye to Permit-Required Infrastructure and SOPs

- Facilities and Containment
- Security Access/Restricted Movement
- Engineering Controls
- Delivery Documentation
- Waste Management/Decontamination



Consultations Are the Backbone of Permit Support



- Our institution has seen many researchers requesting permit consults.
- Many of these consults have been for exempt material, for which there is less agency guidance.
- Guidance documents provide a baseline; not all researchers require extensive support.

We can't provide all the answers, but we can help with direction.

Import Support Program Benefits: Why Do This?



**Researcher
Satisfaction**



**Liability
Reduction**



**Biorisk
Reduction**



**Institutional
Preparedness**



**Leadership
Engagement**

Research Safety Program Enhancement

- Since implementation, the number of permits tracked by our department has tripled.
- Researchers with materials outside IBC purview are being tracked.
- IBC is approving facilities and work practices in line with permit requirements.
- ORA-IBC communication has increased.
- Permitting agency engagement has increased.

Researchers Are Frequently Left to Navigate Complex Federal Agency Requirements Alone

Collection and International Shipping of Infectious Agents and Materials and Working with Regulatory Agencies on Permits



Douglas M. Watts Ph.D.
Department of Biological Sciences
University of Texas at El Paso



Import permit support represents an unfilled need for researchers, and a potential area of insufficient coverage for biosafety professionals in institutions which do not handle RG4 or FSAP materials.

From the Southern Biosafety Association (SBA) Spring Symposium 2019, May 31st, 2019

Biosafety Permitting References

- Centers for Disease Control (CDC) Import Permit Program (IPP) [<https://www.cdc.gov/cpr/ipp/index.htm>]
 - CDC Guidance Document Overview of IPP [<https://www.cdc.gov/cpr/ipp/docs/overview-of-cdc-ipp.pdf>]
- United States Department of Agriculture (USDA/APHIS) Permits and Certifications [<https://www.aphis.usda.gov/aphis/resources/permits>]
 - USDA/APHIS Guidelines: Animal Products That Do Not Require An Import Permit [<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/no-import-permit-req>]
- U.S. Fish & Wildlife Service (FWS) Permits [<https://www.fws.gov/permits/>]
 - FWS Laws, Treaties & Regulations [<https://www.fws.gov/permits/ltr/ltr.html>]
 - CITES Appendices [<https://www.cites.org/eng/app/appendices.php>]
- University of California San Diego Shipping: Biologicals Materials Permits [<https://blink.ucsd.edu/facilities/services/shipping/hazardous/bio-permit.html>]



Acknowledgements

Sheryl Major, BSO
Seth Mullen, HGT-BSO
Melissa Ly, ABSO
Susan Mayo, ABSO
Lance Scott, RSM

University of California San Diego
Division of Research Safety
Dept. of Environment, Health & Safety



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