

# Establishing Yale's Biosafety Stewardship Program

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# Outline

1. The problem we want to address
2. Objectives of the biosafety stewardship program
3. Resources available to us
4. The freezer inventory project: Initial tasks to establish our biosafety stewardship program
5. Ongoing work in this program
6. Key outcomes

# Cold Storage in Research Institutions

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Do you know?

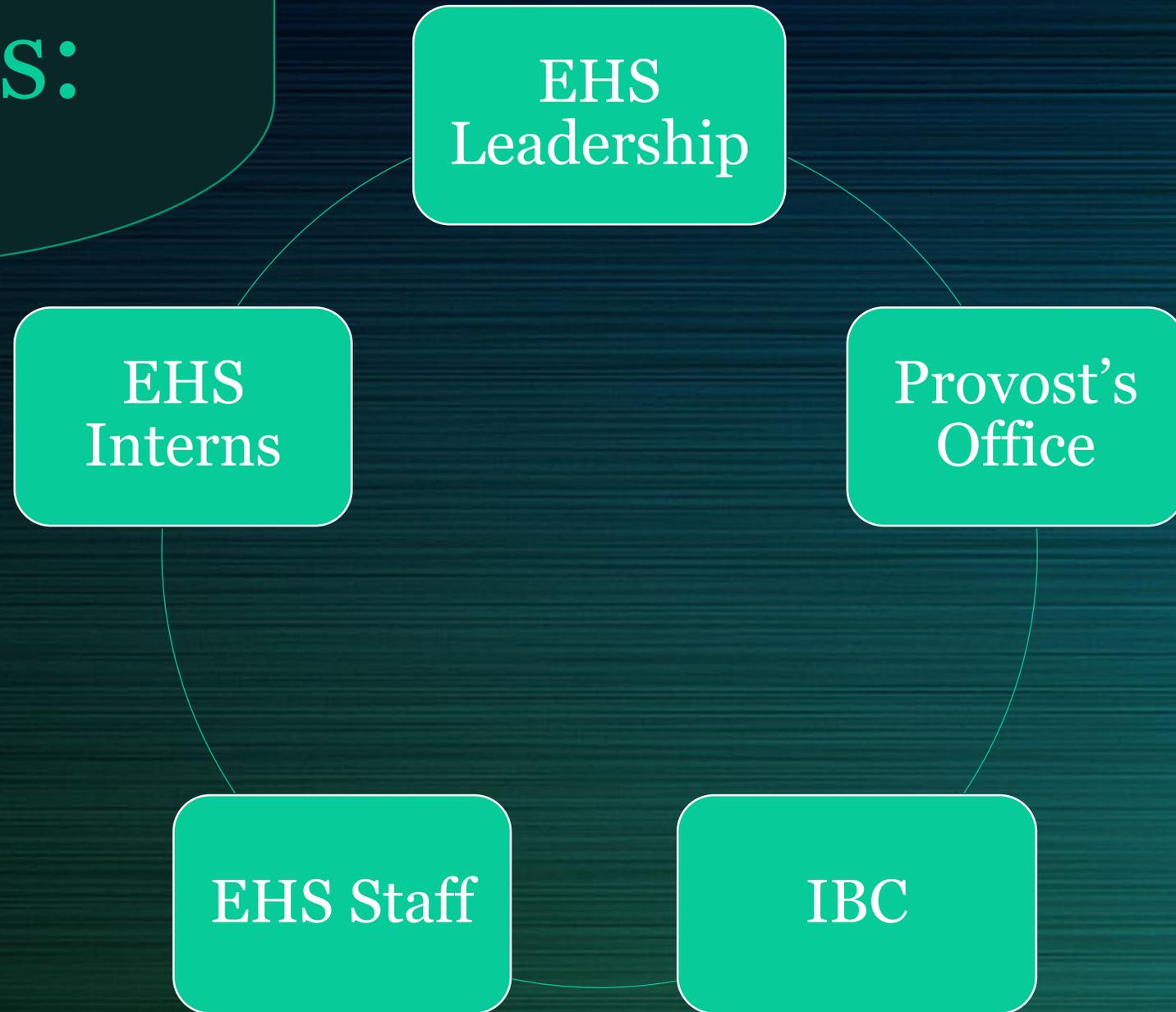
What's In Your Freezer?



# Objectives

1. **Establish a Yale policy** for high risk biomaterial management
2. Survey and Inspect all cold storage units to identify and address **unknown samples and freezers**
3. Verify that all labs with high risk biomaterials have **an actively updated inventory**.
4. Confirm an updated inventory in the Yale Environmental Health and Safety (EHS) **database** for all cold storage units on campus.

# Resources:



# The Freezer Inventory Project

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1. Develop a Yale policy on High Risk Biomaterial Management.
2. Learn from other institutions (Northwestern University)

**Yale University**  
**High Risk Biomaterial Management Policy**  
Approved by Yale University Biosafety Committee on July 16, 2015

**PURPOSE**  
Yale University is committed to providing a safe environment for research. We do this in part by ensuring that hazardous materials, such as Select Agents and toxins, stored at teaching institutions, Yale is home to many of biological agents are stored and managed in a way that pose serious health risks to humans. In a report published by universities on August 28, 2014<sup>1</sup>, a national survey of the management of all HRBs is needed. Yale University, as a steward of HRBs, to minimize the health and wellbeing of the public.

The purpose of this Policy is to set the standards for the management of HRBs at Yale, consistent with the requirements of this Policy, Yale University Biosafety programs (see Supplementary Guidance).

**APPLICABILITY**  
This Policy applies to all faculty, staff, students, and visitors in laboratories and clinics at Yale, or in other locations that do not preclude the addition of more HRBs.

**DEFINITIONS AND SCOPE**  
HRBs include:

- Select Agents and Toxin List

**ROLES AND RESPONSIBILITIES**

**Office of Environmental Health and Safety (EHS) Responsibilities**

- Develop and update HRB inventory
- Manage Yale's information on HRBs
- Assist Principle Investigators (PIs) in identifying and managing HRBs
- Assist PIs in identifying and managing HRBs
- Determine the disposition of HRBs
- Determine the disposition of HRBs working with the Yale's Biosafety Office
- Endeavor to find a proper location for HRBs
- Periodically survey labs and clinics for HRBs
- EHS has the authority to remove HRBs to ensure an accurate inventory

**Principal Investigator (PI), PI, managers, supervisors and staff, students, affiliates and visitors**  
These responsibilities include:

- Identify all HRBs present in their laboratories
- Laboratories should have a system so that HRBs are identified by labeling containers, by

**Yale University Biological Safety Committee**

- The Biological Safety Committee reviews Yale's inventory of HRBs and determines the appropriate location and use of a specific HRB. It will consider NIH policies regarding HRBs.
- The Biological Safety Committee has the authority to remove, relocate, or destroy HRBs.

**COMPLIANCE**  
EHS has the authority to take necessary actions to enforce compliance with this Policy, including addressing unsafe conditions, including stopping an activity or shutting down a facility if necessary. Issues related to the implementation of this policy should be referred to the Biological Safety Committee for their review and advice.

Policy Approval: This Yale Policy was approved by the Yale Biosafety Committee on July 16, 2015.

**SUPPLEMENTARY GUIDANCE AND REFERENCES**

1. For information on Select Agents:  
<http://www.selectagents.gov/regulations.html>
2. For Risk Group classification and NIH Guidelines:  
[http://osp.od.nih.gov/sites/default/files/NIH\\_Guidelines.html](http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html)



### 3. Preparations (cont.)

- Supplies to labs
- Inventory templates
- Unknown disposal procedure

## Review, Evaluation, and Disposition of **Unknown** Biological Materials

You found a container(s) with **Unidentified Biological Contents** (writing/label unrecognized)



Follow this protocol and make Yale a Safer Place!

start here

1. Gather information from your research group, former members, and collaborators



We deal with the Unknowns according to Likely Risk Priorities and Separate Waste Streams.

2. Is this Likely containing **Radioactive Material** (e.g. labeled)?



GM reading higher than background?

Yes

No

LSC sampling above background?

Yes

No

Find out historical info. Contact your **Safety Advisor** for proper disposal



3. Is this Likely containing ONE of the **High Risk Biological Materials (HRBs)**?

#### HRBs:

- A Select Agent
- A known risk group 2, 3, 4 human pathogen
- A Restricted Substance (animal or plant pathogen requiring a permit)

PI has a strong reason to keep the material in lab?

Yes

No

PI reasonably certain identification will be done with some additional effort?

Yes

No

Identify, inventory, and register with EHS all HRBs. Contact your **Safety Advisor** for assistance.

- Document the unknown with available details,
- Put the sample in a red bucket with enough pads at the

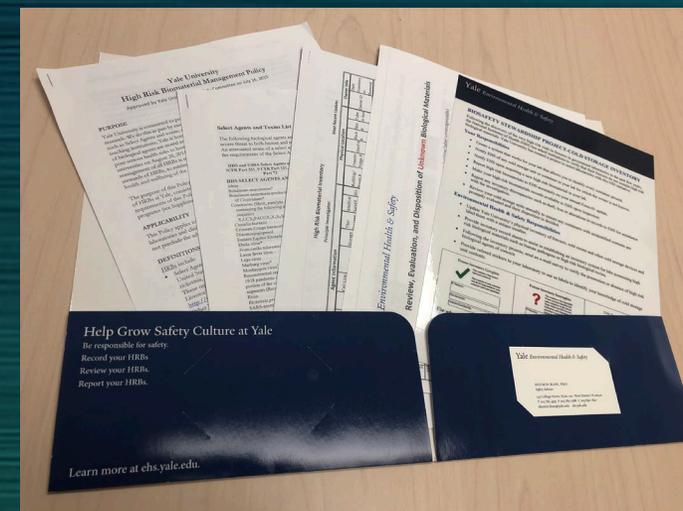
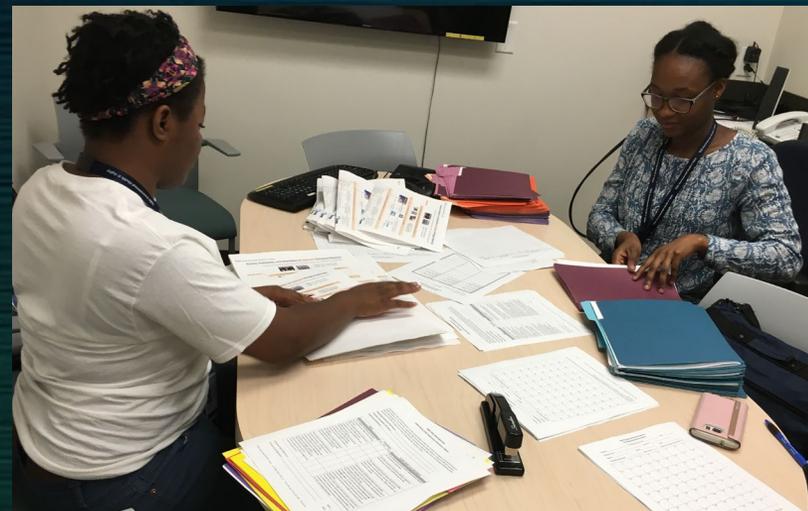
## 3. Preparations (cont.)

- Supplies to labs
- Inventory templates
- Unknown disposal procedure
- Compliance Status stickers

Freezer Inventory Complete	Freezer Inventory Incomplete	Unit Status Unknown
 <p>The contents of this freezer have been reviewed.</p> <p>The contents of each container and PI responsible for each container have been identified.</p>	 <p>The contents or responsible PI have not been identified for some containers in this freezer. Please follow the EHS Review, Evaluation, and Disposition procedure to complete inventory of this freezer.</p>	 <p>As of _____, this unit and/or its contents have not been identified as being assigned to a PI. If you have any information on this unit or its contents, please contact EHS at 203-785-3550.</p> <p><b>If a PI is not identified as being responsible for this unit and/or its contents by the date below, all contents will be removed and disposed of by EHS staff following approval from the Department Chair responsible for this lab.</b></p>
PI Name(s):	PI Name(s):	Deadline Date:
Date Reviewed:	Date Reviewed:	EHS Staff Name:
Contents Reviewed By:	Contents Reviewed By:	

## 4. Outreach:

- Seminars
- Flyers and announcements
- Information folder for safety advisors prep visits



## 5. Trial Run

Lab visits :





# How big is the task?

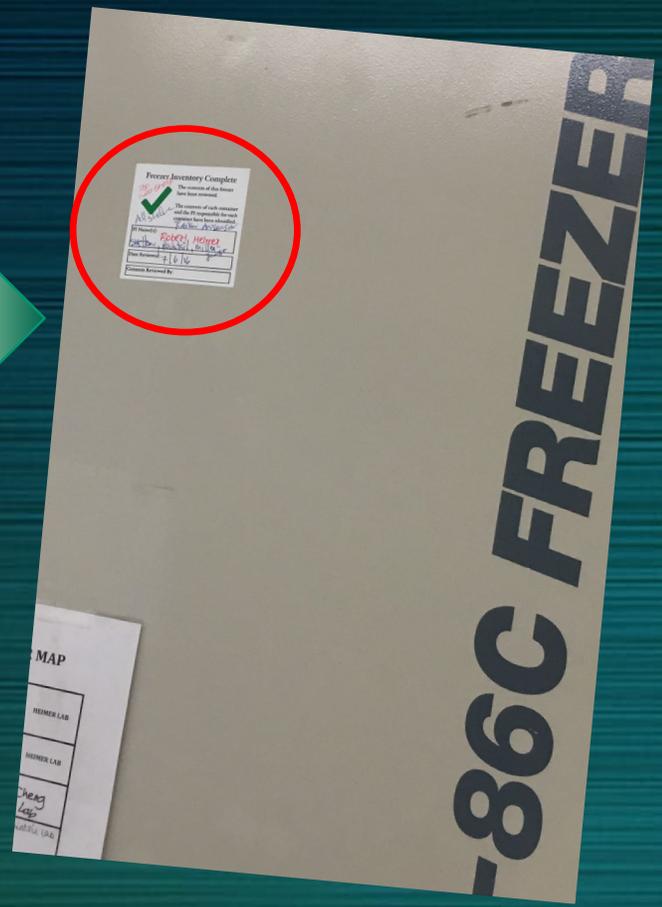
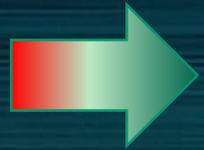
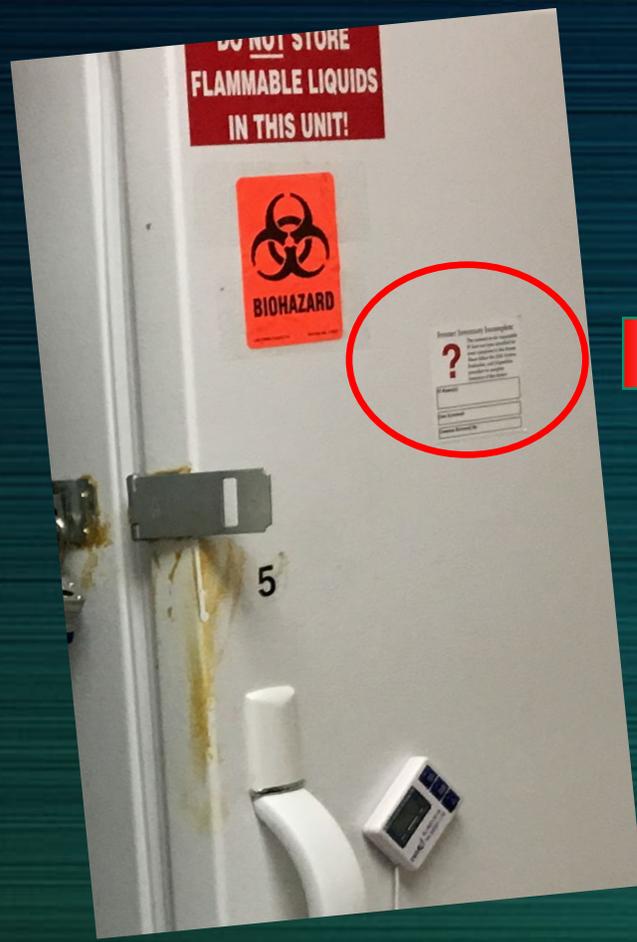
- > 50 research and clinical buildings
- > 500 principal investigators (PIs)
- > 5000 cold storage units in use



# 6. Yale-wide lab visits: Building-by-building, Floor-by-floor, Lab-by-lab.

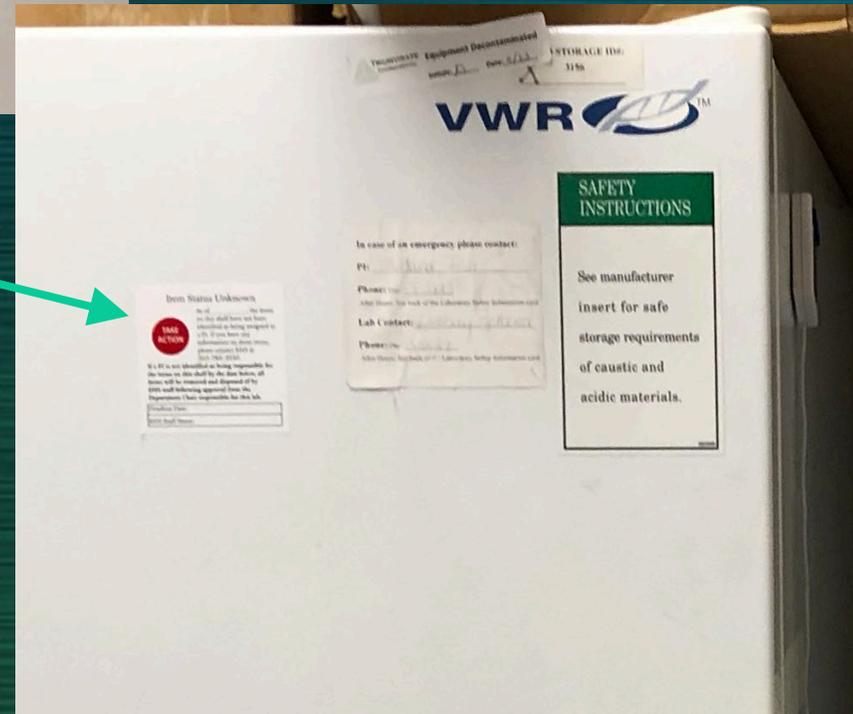
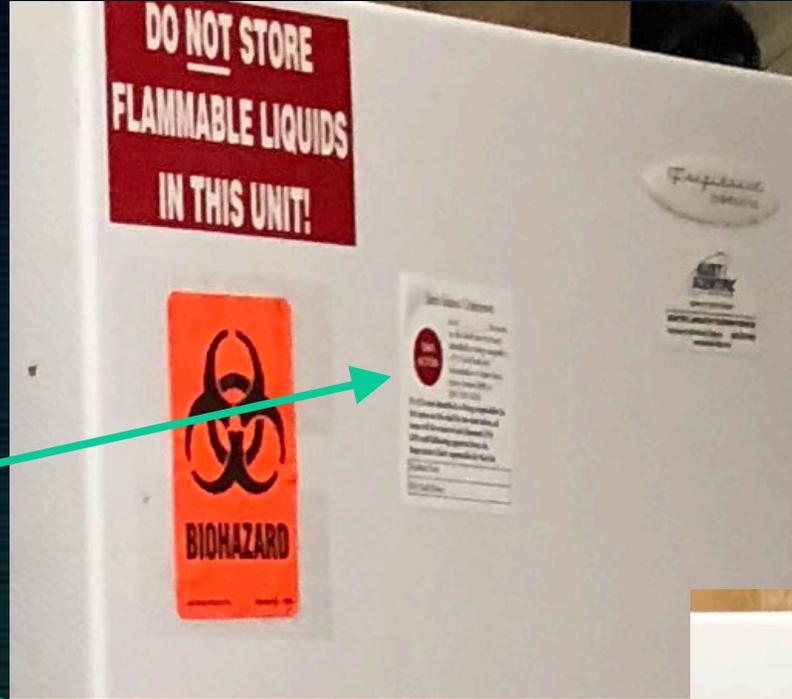


# 7. Return visits



8. Identify  
“Take  
Action”  
units:

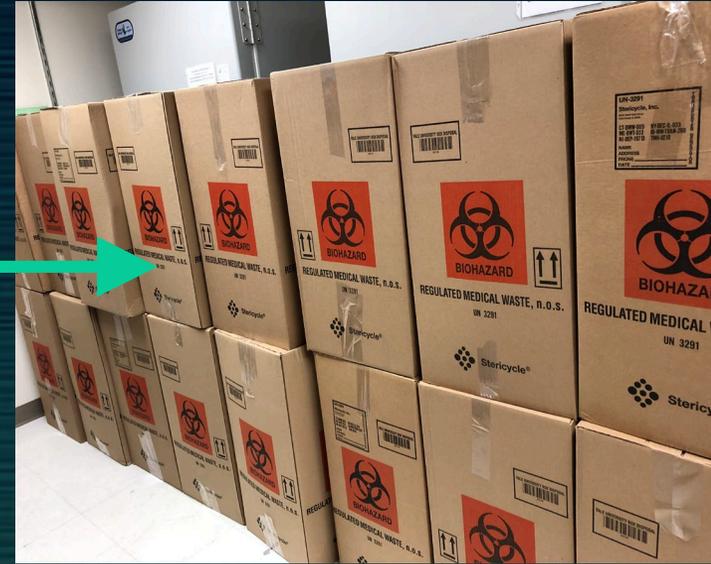
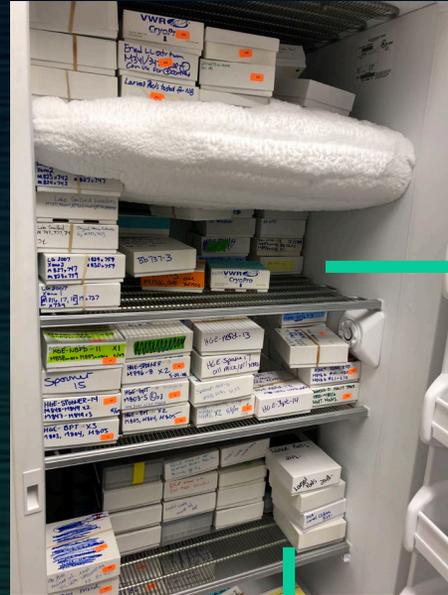
Orphan  
Abandoned  
Unknown



(Contracted with TEI)

9. Disposal of  
“Action  
Required”  
units:

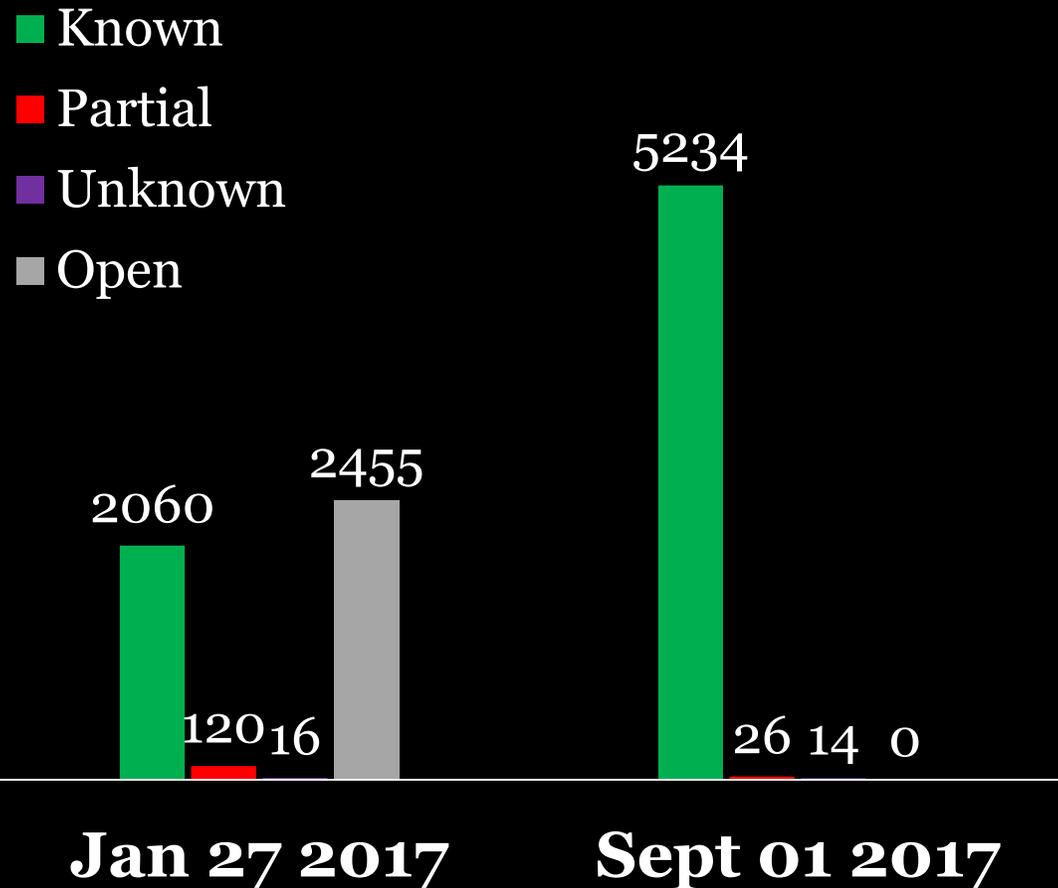
!!! Researchers  
DO NOT want  
to throw away  
THEIR  
samples!!!



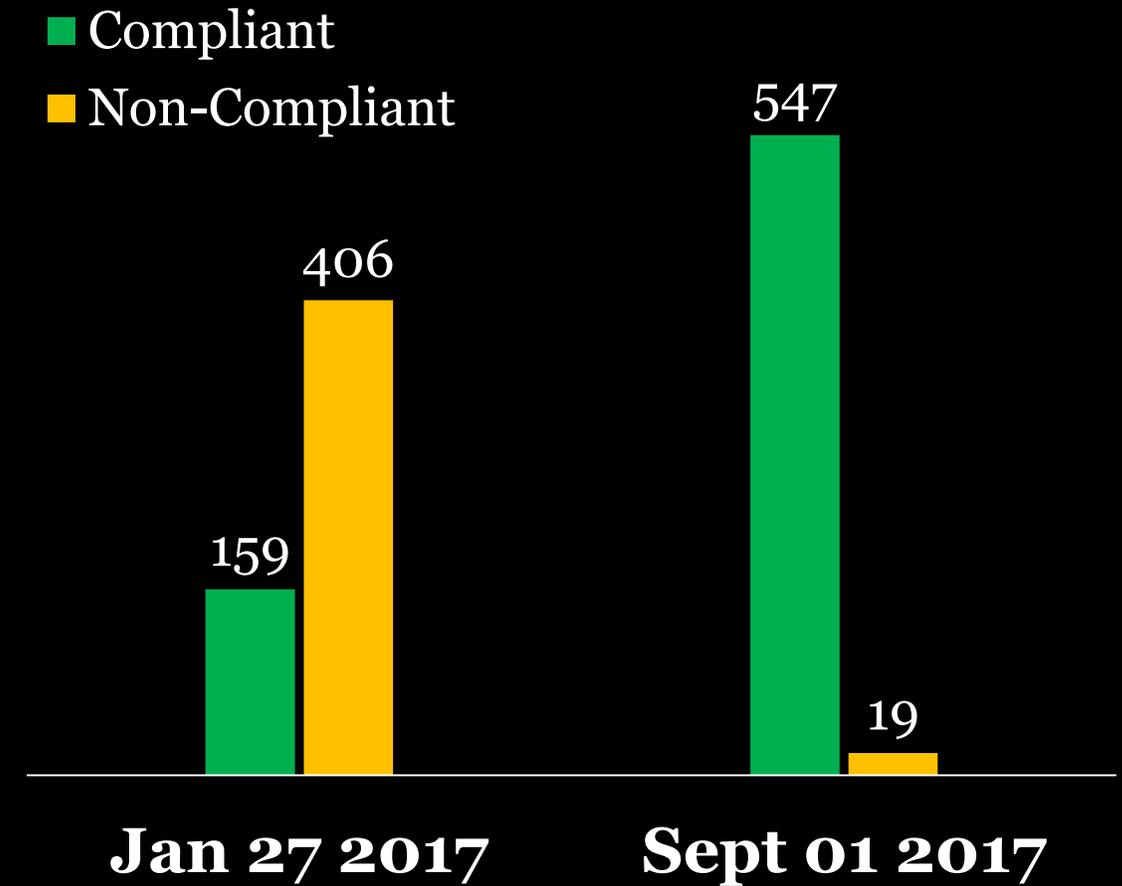
# Project progress monitoring

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## Cold Storage Inventory Status



## Principal Investigator Status



# Ongoing Work

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1. Cold storage inventory updates online
2. High risk biomaterial inventory updates online
3. Regular surveys by EHS

The screenshot shows the EHS Integrator Cold Storage Inventory web application. At the top, there is a navigation bar with buttons for Home, Principal Profile, Registration, Survey, and Inventory. Below the navigation bar, the page title is "Cold Storage". A welcome message reads "Welcome to EHS Cold Storage Inventory". A help section provides instructions: "For help with this web application: Refer to the Help menu at the top-right corner of every page. For additional assistance, please contact your Safety Advisor." Below the help section, there are two tabs: "My Cold Storage Inventory" and "All Other Cold Storage Inventory". A search bar contains fields for Unit ID, Serial Number, MEI Code, and Building/Area, with a Search button. Below the search bar, a summary bar shows "11 Draft Cold Storage Inventory Items" and a note: "Cold Storage Inventory items that have not been submitted." A table displays the inventory items with columns for Start Date, Unit ID, MEI Code, Type, Model, and Building/Area.

Start Date	Unit ID	MEI Code	Type	Model	Building/Area
2018-11-27	10606	n/a	Liquid Nitrogen Dewar	OTHER	MALONE ENGIN CEN
2018-11-27	10607		Liquid Nitrogen Dewar	OTHER	MALONE ENGIN CEN
2018-11-27	10608		Liquid Nitrogen Dewar	OTHER	MALONE ENGIN CEN

# Key Outcomes

1. We have a High Risk Biomaterial Management policy in place,
2. Identified and disposed unknown/unwanted biomaterials; identified and cleaned up orphan/abandoned freezers,
3. Ensured labs with high risk biomaterials have updated active inventory,
4. Set up online cold storage database that can be updated easily.
5. Freed up freezer spaces, streamlined cold storage in labs.

# Thank You!

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- Yale EHS Director Peter Reinhardt
- BSO Ben Fontes and Associate BSO Deb Ferry
- Deputy Director: Kevin Charbonneau
- EHS staff and interns: Rob Davis, Donique Haynes, Kole Sheriff, Julio Badillo, Ray Charles Capanzana, Taylor Gainey, Tamara Gray

