Dental Research Safety Committee Meeting

THURSDAY, SEPTEMBER 26, 2019 | REB 302 | 11:30AM-12:30PM

Please grab your lab’s safety binder and food!
Operations Updates

- Jim McBride
Longwood Updates
As of July 1st our hazardous waste vendor will now be Triumvirate Environmental.

Triumvirate will also be picking up and checking on your reusable biological sharps containers and removing/replacing them.

If you have any issues with hazardous waste or reusable sharps pickup, please contact the following:

1. HarvardMedPickups@triumvirate.com for Hazardous Waste
2. HarvardMedSharps@triumvirate.com for Reusable Sharps
3. Please cc lance_schumacher@harvard.edu
Past safety committee slides available

• Helpful for new and old LSOs to reference
• Can also view presentations from other Harvard safety committees!

https://www.ehs.harvard.edu/secure/programs/harvard-school-dental-medicine-safety-committee
LAB MOVES…
TELL EH&S!

- Move out/renovation to-do list
- Move in to-do list
- Other points to consider:
  - Changes/submission of COMS/IACUC protocols
  - Import/export permits
  - Shipping requirements
  - Inventory of materials
  - Document decontamination of equipment and destruction of any inventory prior to move
WHAT’S UP WITH ALL THE WESCODYNE AND VESPHENE?

A number of labs are using Wescodyne and Vesphene instead of bleach for their disinfectants.

Things to keep in mind if you choose to do this:

I. It might not be safe to drain-dispose. Check your SDS and labels and compare to our cut-sheet for sink disposal.

II. They might not be appropriate for the agents you are using. Bleach does work—you just need to use it properly.

III. They might be more hazardous to you and your equipment than bleach—make sure the reason you are avoiding bleach is appropriate.

i. Talk to your BSO to make sure it’s right for you.
COLLABORATION IS GREAT!
BUT KEEP THE FOLLOWING IN MIND…

- If doing work with a collaborator (internal/external), make sure your work is registered with COMS/IACUC, when required.
  - Internal collaboration requires work to be registered under at least one PI with COMS/IACUC.
  - External collaboration is trickier. Talk to your Biosafety Officer about options.
    - Cede review
    - Registration under a Harvard PI
New Lab Safety Officer Binders!

Lab Safety Officers will now be responsible for:

- Training and documenting their portion of the orientation checklist
  - (Jim will train and document his portion)
- Maintaining Exposure Control Plan and Hepatitis B vaccination records
  - Only if they are working with potentially infectious human materials
- Maintaining Chemical Hygiene Plan, Chemical Guidelines & SOPs specific to the lab.
- Annual Longwood CHP & ECP Review by PI
HSDM - Laboratory Safety Orientation Checklist

Laboratory Safety Training Review by Lab Safety Officer / PI

NOTE: The PI may authorize another person to operationally fulfill the role, but it remains the Principal Investigator’s responsibility to ensure that all personnel in the lab have the necessary skills (through training and experience), maturity and supervision to work safely in a lab with hazardous processes or substances. Consider the varying maturity and experience levels when orientating a person to the lab and when determining the appropriate assignments and supervision and training required. When considering personnel under the age of 18, see the University’s Criteria on Campus Policy [http://vostprotection.harvard.edu/minors-lab-policy]

- Review laboratory specific safety training/SOPs
  For highly hazardous materials, equipment, or processes that pertain to the individual's research program (may include COMIS protocols, radiation registration, etc. in addition to internal lab documents on carcinogens, etc.)

Laboratory Orientation

Review the following safety features:
- Lab Emergency Response Guide and location of Emergency Numbers
- Location of Safety Data Sheets in lab or online [ehs.harvard.edu/safety-data-sheets-sgs]
- Location of Chemical Hygiene Plan in lab or online [EH&S Safe Chemical Work Practices web page]
- PPE policy, lab’s PPE assessment report and location of required PPE (gloves, safety glasses, lab coats, etc.)

Yes / N/A

- Location and review of Exposure Control Plan [EH&S Bloodborne Pathogens web page]
  If yes, complete Hepatitis B Vaccination Offer form
- Waste management (see ehs.harvard.edu/programs/lab-waste-management) (check all that apply):
  - Hazardous Waste
  - Biological Waste
  - Radioactive Waste
  - Sharps Waste
- Location and proper use of highly hazardous materials, equipment, or processes
- Location and proper use of chemical fume hoods or biosafety cabinets or both

Trainee Information & Signatures

- Undergraduate
- Post Doctoral Fellow
- Intern
- Graduate Student
- Staff
- Core Customer
- Visitor
- Vendor

Trainee Name: ___________________________ Signature: ___________________________

Orientation given by (LSO/PI):________________________ Signature: ___________________________

HSDM - Laboratory Safety Orientation Checklist

Laboratory Safety Training Review by Director of Core Laboratories

NOTE: The PI may authorize another person to operationally fulfill the role, but it remains the Principal Investigator’s responsibility to ensure that all personnel in the lab have the necessary skills (through training and experience), maturity and supervision to work safely in a lab with hazardous processes or substances. Consider the varying maturity and experience levels when orientating a person to the lab and when determining the appropriate assignments and supervision and training required. When considering personnel under the age of 18, see the University’s Criteria on Campus Policy [http://vostprotection.harvard.edu/minors-lab-policy]

- Add researcher to lab roster in PeopleSoft [https://hrapps.capec.harvard.edu/pstprl/signon.html]
  Review the individual’s research program, identify core and specialized training requirements. Show researcher how to access training in the Harvard Training Portal [https://trainingportal.harvard.edu]

- Exception: Those who will work in a lab for less than a week under direct supervision or others who will not be working with or adjacent to hazardous materials, processes or equipment.

Laboratory Orientation

Review the following safety features:
- Lab Emergency Response Guide and location of Emergency Numbers
- Emergency evacuation route and meeting area
- Location of fire extinguishers and closest fire alarm pull station
- Location and proper use of safety showers and eyewash stations
- Location of accident report filing process [ehs.harvard.edu/programs/accident-reporting-investigation]

Yes / N/A

- Waste management (see ehs.harvard.edu/programs/lab-waste-management) (check all that apply):
  - Hazardous Waste
  - Biological Waste
  - Radioactive Waste
  - Sharps Waste
- Location and proper use of chemical fume hoods or biosafety cabinets or both
- Location and use of building spill cabinets or lab spill kits or both

Trainee Information & Signatures

- Undergraduate
- Post Doctoral Fellow
- Intern
- Graduate Student
- Staff
- Core Customer
- Visitor
- Vendor

Trainee Name: ___________________________ Signature: ___________________________

Orientation given by (Director of Core Labs): ___________________________ Signature: ___________________________

Laboratory/Core Name: ___________________________ Date: ___________________________

*Chris T will send out LSO Orientation Checklist & Hep. B Vaccination forms after meeting*
HSDM - Laboratory Safety Orientation Checklist

Laboratory Safety Training Review by Lab Safety Officer / PI

NOTE: The PI may authorize another person to operationally fulfill the role, but it remains the Principal Investigator’s responsibility to ensure that all personnel in the lab have the necessary skills (through training and experience), maturity and supervision to work safely in a lab with hazardous processes or substances. Consider the varying maturity and experience levels when orientating a person to the lab and when determining the appropriate assignments and supervision and training required. When considering personnel under the age of 18, see the University’s Minors on Campus Policy http://youthprotection.harvard.edu/minors-labs-policy.

☐ Review laboratory-specific safety training/SOPs
For highly hazardous materials, equipment, or processes that pertain to the individual’s research program (may include COMS protocols, radiation registration, etc. in addition to internal lab documents on carcinogens, etc.)

Laboratory Orientation

Review the following safety features:

☐ Lab Emergency Response Guide and location of Emergency Numbers
☐ Location of Safety Data Sheets in lab or online (ehs.harvard.edu/safety-data-sheets-sds)
☐ Location of Chemical Hygiene Plan in lab or online (EH&S Safe Chemical Work Practices web page)
☐ PPE policy, lab’s PPE assessment report and location of required PPE (gloves, safety glasses, lab coats, etc.)

Yes □ N/A

☐ □ Location and review of Exposure Control Plan (EH&S Bloodborne Pathogens web page)
   If yes, complete Hepatitis B Vaccination Offer form

☐ □ Waste management (see ehs.harvard.edu/programs/lab-waste-management) (check all that apply):

☐ □ Location and proper use of highly hazardous materials, equipment, or processes

☐ □ Location and proper use of chemical fume hoods or biosafety cabinets or both

Trainee Information & Signatures

☐ Undergraduate □ Post Doctoral Fellow □ Intern □ Visitor
☐ Graduate Student □ Staff □ Core Customer □ Vendor

Trainee Name: ____________________________________________ Signature: ____________________________

Orientation given by (LSO/PI): ____________________________________________ Signature: ____________________________

Laboratory/Core Name: ____________________________________________ Date: ____________________________

cc: Principal Investigator: A copy of this form must be kept on file by the laboratory.
cc: Laboratory Director/Executive Director/Research Operations Manager: A copy of this form must be kept on file by the Department.
1. Employees may accept or decline, you just need documentation that it was offered.

2. Offered at no cost (contact Jim for HMS billing code).

3. Please give Hep. B form to Jim when an employee leaves (must be kept for 30 years).
Harvard University Hepatitis B Vaccination Offer

Harvard University Occupational Exposure to Bloodborne Pathogens

Please complete the Harvard University Hepatitis B Vaccination Offer Form on page 2 if you may come in contact with human blood or other potentially infectious human materials or cultures of HIV or hepatitis B virus in the normal course of your job duties. As required by the OSHA Bloodborne Pathogen Standard (BBP), Harvard will make available at no charge the hepatitis B virus vaccine series to all Harvard employees who have potential occupational exposure to human blood and other potentially infectious material as defined in the OSHA BBP Standard unless the employee has (a) previously received the complete hepatitis B vaccination series, or (b) antibody testing has revealed that the employee is immune, or (c) the vaccine is contraindicated for medical reasons. Employees have the right to accept or decline the vaccine.

After reading the following Training Points for Employees Offered the Hepatitis B Vaccine, and the attached CDC Hepatitis B Vaccine Information Statement, please fill out and check the appropriate boxes on page 2, Harvard University Hepatitis B Vaccination Offer Form.

Training Points for Employees Offered the Hepatitis B Vaccine

1. Offered to the employee at no cost, the employee may initially turn down the offer to be vaccinated, but can request vaccination at a later date, without cost, if s/he is still at risk from an occupational exposure. Employees who do not wish to be vaccinated must read and sign the Vaccine Declination Statement included on this form.

2. Vaccine Efficacy, Safety, Benefits (Source: WHO Fact sheet N°204 Revised August 2008 Hepatitis B)
   - The complete vaccine series induces protective antibody levels in more than 95% of infants, children and young adults. After age 40, protection following the primary vaccination series drops below 90%. At 60 years old, protective antibody levels are achieved in only 65 to 75% of those vaccinated. Protection lasts at least 20 years and should be lifelong.
   - The vaccine has an outstanding record of safety and effectiveness. Since 1982, over one billion doses of hepatitis B vaccine have been used worldwide. In many countries where 8% to 15% of children used to become chronically infected with HBV, vaccination has reduced the rate of chronic infection to less than 1% among immunized children.
   - A vaccine against hepatitis B has been available since 1982. Hepatitis B vaccine is 95% effective in preventing HBV infection and its chronic consequences, and is the first vaccine against a major human cancer.

3. Please read the attached CDC Hepatitis B Vaccine Information Statement “HEPATITIS B VACCINE: WHAT YOU NEED TO KNOW”
Harvard University Hepatitis B Vaccination Offer Form

“I state that I have read the Hepatitis B vaccine information attached. I acknowledge that I am required to complete Bloodborne Pathogens Training. Please check any of these boxes that apply and complete the blank:

☐ On or about _____________ (date), I received the complete hepatitis B virus vaccination series;

☐ On or about _____________ (date), I received information that antibody testing has revealed that I am already immune to hepatitis B virus;

☐ On or about _____________ (date), I received information that the hepatitis B virus vaccine is contraindicated for medical reasons.

If none of the above boxes were checked, Harvard University will offer me the Hepatitis B vaccine at no cost. I choose the following:

1. ☐ “I accept the offer to be vaccinated and agree to complete the vaccination series. I will schedule an appointment with Harvard University Health Services (UHS) by calling 617-432-1370 (Longwood) or 617-495-5182 (Cambridge).”

   NOTE: Bring a copy of this completed page to the appointment with UHS.

2. ☐ “I decline to accept vaccination at this time. I understand that due to my occupational exposure to blood or other potentially infectious materials, I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B vaccine, at no charge to myself. However, I decline Hepatitis vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with Hepatitis B vaccine, I can receive the vaccination series at no charge to me.” (OSHA Bloodborne Pathogen Standard, CFR 1910.1030)

Employee Signature: ___________________________ Date: ___________________________

Employee Name: ___________________________ Harvard ID Number: ___________________________

Job Title: ___________________________ School/Dept: ___________________________

Supervisor’s or Principal Investigator’s Name: ___________________________

33-digit billing code for UHS: ___________________________

Please provide a copy of this form to your Supervisor, Laboratory Manager, or Safety Coordinator.
1 | What is hepatitis B?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus (HBV). HBV can cause:

**Acute (short-term) illness.** This can lead to:
- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

Acute illness is more common among adults. Children who become infected usually do not have acute illness.

**Chronic (long-term) infection.** Some people go on to develop chronic HBV infection. This can be very serious, and often leads to:
- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are infected can spread HBV to others, even if they don’t appear sick.

- In 2005, about 51,000 people became infected with hepatitis B.
- About 1.25 million people in the United States have chronic HBV infection.
- Each year about 3,000 to 5,000 people die from cirrhosis or liver cancer caused by HBV.

Hepatitis B virus is spread through contact with the blood or other body fluids of an infected person. A person can become infected by:
- contact with a mother’s blood and body fluids at the time of birth;
- contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
- contact with objects that could have blood or body fluids on them such as toothbrushes or razors;
- having unprotected sex with an infected person;
- sharing needles when injecting drugs;
- being stuck with a used needle on the job.

2 | Hepatitis B vaccine: Why get vaccinated?

**Hepatitis B vaccine can prevent hepatitis B,** and the serious consequences of HBV infection, including liver cancer and cirrhosis.

Routine hepatitis B vaccination of U.S. children began in 1991. Since then, the reported incidence of acute hepatitis B among children and adolescents has dropped by more than 95%—and by 75% in all age groups.

Hepatitis B vaccine is made from a part of the hepatitis B virus. It cannot cause HBV infection.

Hepatitis B vaccine is usually given as a series of 3 or 4 shots. This vaccine series gives long-term protection from HBV infection, possibly lifelong.

3 | Who should get hepatitis B vaccine and when?

**Children and Adolescents**

- All children should get their first dose of hepatitis B vaccine at birth and should have completed the vaccine series by 6-18 months of age.
- Children and adolescents through 18 years of age who did not get the vaccine when they were younger should also be vaccinated.

**Adults**

- All unvaccinated adults at risk for HBV infection should be vaccinated. This includes:
  - sex partners of people infected with HBV,
  - men who have sex with men,
  - people who inject street drugs,
  - people with more than one sex partner,
  - people with chronic liver or kidney disease,
  - people with jobs that expose them to human blood,
  - household contacts of people infected with HBV,
  - residents and staff in institutions for the developmentally disabled,
  - kidney dialysis patients,
- people who travel to countries where hepatitis B is common,
- people with HIV infection.

• Anyone else who wants to be protected from HBV infection may be vaccinated.

4 Who should NOT get hepatitis B vaccine?

• Anyone with a life-threatening allergy to baker’s yeast, or to any other component of the vaccine, should not get hepatitis B vaccine. Tell your provider if you have any severe allergies.

• Anyone who has had a life-threatening allergic reaction to a previous dose of hepatitis B vaccine should not get another dose.

• Anyone who is moderately or severely ill when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your provider can give you more information about these precautions.

Pregnant women who need protection from HBV infection may be vaccinated.

5 Hepatitis B vaccine risks

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

The following mild problems have been reported:
• Soreness where the shot was given (up to about 1 person in 4).
• Temperature of 99.9°F or higher (up to about 1 person in 15).

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people have gotten hepatitis B vaccine in the United States.

6 What if there is a moderate or severe reaction?

What should I look for?
• Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?
• Call a doctor, or get the person to a doctor right away.
• Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
• Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

• Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
• Call your local or state health department.
• Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO)
  - Visit CDC websites at:
    www.cdc.gov/ncidod/diseases/hepatitis
    www.cdc.gov/vaccines
    www.cdc.gov/travel
COLD & WARM ROOM SAFETY

CAUTION! Environmental rooms typically continuously recirculate air - there is usually no mechanically supplied air or exhausted ventilation.

NO DRY ICE, LIQUID NITROGEN OR COMPRESSED GAS
These may displace oxygen and cause a suffocation hazard. If compressed gas (other than breathing air or oxygen) is essential, contact EHS (Environmental Health and Safety) about identifying the correct oxygen or gas sensor and local alarm. Post the alarm procedure and train all room users to it.

NO FLAMMABLE LIQUIDS (e.g., solvents, alcohols)
Their vapors can accumulate, creating an explosive atmosphere, which can be ignited by electrical switches or other ignition sources.

NO HAZARDOUS OR VOLATILE CHEMICALS (e.g., chloroform, carcinogens, reproductive toxins, acutely toxic chemicals)

NO VOLATILE ACIDS (which can corrode metal)

NO FOOD OR BEVERAGE (which may become contaminated)

NO CARDBOARD, WOOD, CLOTH OR PAPER (e.g., boxes, pallets, shelves)
These cellulose materials support mold growth that can contaminate research materials or be carried and spread to other areas.

FURTHER MINIMIZE MOLD GROWTH:
- Promptly clean spilled media, buffers, and other liquids and thoroughly dry surfaces after cleaning.
- Report water leaks or condensation on surfaces to Facilities.
- Latch the door to minimize condensation from air leakage.
- If minimal mold is present, use wet cleaning methods with a detergent or disinfectant (including Wescodyne, but excluding concentrated bleach that can damage metal), and thoroughly dry surfaces after cleaning. Dry sweeping may disturb and distribute mold spores. If extensive mold is present, contact Facilities, which may hire a mold remediation firm.
Quarterly Cold Room Inspections

- No Cardboard! Please work with your lab to remove all cardboard and porous material. Reach out to Jim or Chris to obtain a plastic container replacement.
Suspicious Packages
Suspicious Packages

How to recognize a suspicious package and what to do

Fall 2019
Incident Review: June 2019

Research laboratory received a package

- At first glance, the package appeared to be a normal FedEx package
- There was nothing obviously wrong with the package
- The lab routinely receives shipments of research equipment, materials, and samples from collaborators and was expecting an incoming package at the time

Lab members initiate opening of the package

- The contents were not immediately recognizable and seemed unusual in comparison to what the lab normally receives
- The sender’s address was unknown to the lab
- Package placed within a laboratory fume hood
- Personal protective equipment was donned in order to further inspect the package

Lab members decided to seek assistance and not proceed further

- Material remained unrecognizable
- HUPD called
Lab members and PI did not recognize sender or the material found in the package.

Once material deemed suspicious, it was placed in a fume hood.

Called HUPD for help.
HUPD reached out to Cambridge Fire Hazmat team for help assessing the material

Cambridge Fire Hazmat entered the lab and ran field tests for various materials (radioactivity, chemical compounds, etc.)

The field test was positive for a controlled substance

The material was secured by the hazmat team and turned over to police for investigation

Because the package was not fully opened and secured in a fume hood, the lab prevented contamination of the laboratory and exposure of people in the area.
What to look out for

- Unexpected packages
- No return address, a nonsensical return address, or an unverifiable one
- Addressee's name or title may be inaccurate
- Incorrect or non-existent departments or position titles
- Excessive postage or no postage at all
- Powders, oily stains, discolorations or strange odors
- Mail that is inconsistent with the types of mail normally received
- Any letters or packages arriving before or after a phone call from an unknown person asking if the item was received
What to do if you come across a suspicious package

- Do not open or disturb, taste or smell
- If you are already handling the package, place in a safe location (e.g. fume hood) if nearby
- Leave the area and post a do-not-enter sign
- Wash your hands
- Call HUPD
- Remain in the area
Suspicious Packages Resources

- HUPD: Suspicious Mail & Packages
  - [https://www.hupd.harvard.edu/suspicious-mail-and-package](https://www.hupd.harvard.edu/suspicious-mail-and-package)

- Lab Emergency Response Guide
  - [https://www.ehs.harvard.edu/sites/ehs.harvard.edu/files/lab_emergency_response_guide_.pdf](https://www.ehs.harvard.edu/sites/ehs.harvard.edu/files/lab_emergency_response_guide_.pdf)

- USPS Suspicious Mail or Packages Poster
  - [https://about.usps.com/posters/pos84.pdf](https://about.usps.com/posters/pos84.pdf)
UNOFFICIAL GUIDE TO ECOMS

- Angela Reid, Biosafety Officer
Creating a New COMS Protocol

The following are subject to COMs oversight:

- Recombinant or synthetic nucleic acids as defined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
- Human or non-human primate blood, cells, tissues, fluids, and secretions
- Biological toxins subject to the National Select Agent Registry
- Bacteria, virus, fungi, yeast, parasites, and prions

PIs and their designees can create a new COMS protocol by logging into eCOMS at: https://esupport.hms.harvard.edu/COMSIACUC
Once on the homepage, on the left-hand side, there will be a button to create a "New COMS Study."

Enter all the information required in each field. On the last page, clicking "Finish" will bring you back to the main page for the study.

Once you are ready to submit the study for review, click "Submit New Study."

**NOTE:** Only the PI can submit new protocols and amendments.
PI Designees

- Only PIs or their designees can edit COMS protocols
- Who can do what?

<table>
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<th>PI</th>
<th>PI Designee</th>
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<td>Create a protocol/amendment</td>
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<td>Edit protocols</td>
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<td>Withdraw protocols</td>
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Activities

- Submit New Study
- Request Inactivation
- Edit PI Designees
- Log Public Comment
- Add Supporting Documents
- Copy Protocol
- Withdraw
Creating an Amendment

- Used to make changes to an approved, active COMS protocol
- Two types:
  - Administrative (changes to personnel ONLY)
  - Scientific (anything else—changes to facilities, biological agents, etc.)
- How to create an amendment:
  1. Under the study, in the left-hand navigation bar, click the button to create an amendment to the study.
  2. A new study page should pop up, that looks like the original, with the exception of the protocol number, which is the parent protocol number with a "-AXX" for the amendment number.
  3. Click "Edit Project"

***All information from the parent protocol will be copied into the amendment. DO NOT DELETE anything in the amendment—it's linked directly to the parent and you will delete information in the original study***
Whenever a study is about to expire or is up for its five-year renewal, you can copy the data from the current COMS into a new protocol, if you wish to continue the study.

All the information should transfer if the protocol was originally written in the new COMS system.

*TIP: If you download and save a PDF copy of an old approval letter, you can right-click on the saved document in the file and select to "Open with" Microsoft Office Word. This might convert the text to an editable Word document, making it easier to transfer the information.
Withdrawing a Protocol (Pre-approval)

- Sometimes a PI will decide not to go through with a study or a BSO will determine the contents of the application do not fall under COMS purview.
- In these and other scenarios where a protocol has not been approved by COMS, but is no longer necessary or desired, it should be withdrawn.
Requesting COMS Protocol Inactivation

- Whenever a study has expired, has been replaced with a new protocol, or is otherwise no longer active, it should be inactivated in the eCOMS system.
- This process is NOT automatic—even if a protocol expired. The PI must request inactivation.
What are your COMS questions?