



**Santa Clara  
University**

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# Biosafety Program

**Santa Clara University (SCU)  
500 El Camino Real  
Santa Clara, CA 95053**

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## Program Approval Record

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<b>Name</b>	<b>Title</b>	<b>Department</b>
Jeff Charles	Director	Facilities
Daryn Baker	Manager	Biology
Esther Pham	Director	Research Compliance and Integrity
Angel Islas	Chair	Biosafety Committee
Prepared/ updated by Carol Robinson	Biosafety Officer	EHS
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Sean Collins	Director	EHS

## Program Approval

<b>Approving Body</b>	<b>Revision</b>	<b>Date</b>
Biosafety Committee	0	5/14/10
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# Biosafety Program

## 1. Purpose

This Biosafety Program describes policies, procedures, equipment, personal protective equipment, and work practices that are capable of:

- Protecting Santa Clara University (SCU) employees from health hazards due to exposure to infectious agents;
- Preventing environmental contamination from biohazardous materials; and
- Ensuring compliance with National Institutes of Health (NIH) recombinant DNA (rDNA) and Centers for Disease Control and Prevention (CDC) and NIH Biosafety in Microbiological and Biomedical laboratories guidelines as well as applicable federal, state and local requirements.

## 2. Applicability

This program applies to all uses of and exposures to biologically hazardous materials at SCU. Biohazardous materials are infectious agents or biologically derived infectious materials that present a risk or a potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment.

Biohazardous materials include the following:

- Human, animal, and plant pathogens
- All human blood, blood products, tissues and body fluids (aka Bloodborne Pathogens)
- Potentially infected animals, animal tissue, blood, blood products, and other body fluids
- Cultured cells (all human and non-human primates) and potentially infectious agents these cells may contain
- Toxins (bacterial, fungal, plant, etc.)
- Certain types of recombinant DNA molecules and hosts (e.g., bacterial, viral, mammalian) based on NIH risk group classifications (RG1 to RG4)
- Diagnostic specimens
- Materials on the list of Select Biological Agents and Toxins published by US Department of Health and Human Services (HHS) and the US Department of Agriculture (USDA)

## 3. Definitions

NOTE: The most pertinent definitions for all users are contained in [Attachment 1](#). Review and use as necessary.

## 4. Roles and Responsibilities

The following are the SCU Roles and Responsibilities in regards to Biosafety:

Group	Responsibilities
Associate Provost for Research Initiatives	<ul style="list-style-type: none"> <li>▪ Appoint the members of the Biosafety Committee</li> </ul>
Biosafety Committee	<ul style="list-style-type: none"> <li>▪ Assist in the development of appropriate procedures as required by NIH, CDC and/or Select Agents and Select Agent Toxins regulations to oversee the possession and/or use of biohazardous materials.</li> <li>▪ Review and approve with the Biosafety Officer applications for the possession and/or use of biohazardous materials.</li> <li>▪ Recommend the suspension or termination of the possession or use of biohazardous materials, including research, where the Committee finds noncompliance or that such use or possession poses a threat to the health and safety of the community.</li> <li>▪ Review routinely the policies and procedures for working with biohazardous materials and recommend modifications as necessary to ensure appropriate biosafety measures and compliance with federal and state requirements.</li> <li>▪ Assist with a periodic review of the possession and/or use of biohazardous materials to ensure compliance with federal and state requirements.</li> <li>▪ Work with the University's Biosafety Officer in developing and adopting emergency plans covering accidental spill and personnel contamination resulting from use or possession of biohazardous materials.</li> </ul>
Biosafety Officer (Environment, Health and Safety)	<ul style="list-style-type: none"> <li>▪ Provide technical support in regard to biosafety hazards, controls and procedures to the Biosafety Committee, Faculty, staff and others as needed.</li> <li>▪ Review and approve with the Biosafety Committee applications for the possession and/or use of biohazardous materials.</li> <li>▪ Manage a program for conducting periodic audits of biosafety facilities, controls and procedures.</li> <li>▪ Manage a program for investigating biosafety related incidents, such as spills or exposures to biohazardous materials.</li> <li>▪ Report findings and recommendations from audits and incident investigations to the Biosafety Committee and, where appropriate, to the relevant academic department chair.</li> <li>▪ Ensure that each participating laboratory has emergency plans for dealing with accidental spills and personnel contamination.</li> <li>▪ Conduct or otherwise support biosafety training.</li> <li>▪ Provide guidance on proper waste disposal methods based on applicable regulatory requirements and</li> </ul>

	<p>University practices.</p> <ul style="list-style-type: none"> <li>▪ Ensure that this biosafety program is kept up-to-date with regulatory requirements and applicable best practices.</li> <li>▪ Serve as the Responsible Official for the CDC/USDA Select Agent Program as needed.</li> </ul>
Office of Research Compliance and Integrity	<ul style="list-style-type: none"> <li>▪ Receive applications for research or teaching projects involving Recombinant DNA or Biologically Hazardous Materials and notify the requestor of the Biosafety's decision regarding the application.</li> </ul>
Laboratory Supervisor	<ul style="list-style-type: none"> <li>▪ Identify the biohazards associated with proposed research or teaching exercise, the appropriate level of containment, the laboratory practices and techniques required to perform the experiments safely and emergency procedures.</li> <li>▪ Submit an application for the possession and/or use of biohazardous materials to the Biosafety Committee.</li> <li>▪ Implement the approved level of containment, laboratory practices and techniques and emergency procedures.</li> <li>▪ Comply with applicable regulatory requirements and all requirements approved through the University application process.</li> <li>▪ Ensure that staff and students receive training in and know and follow the specific biosafety laboratory practices applicable to their work.</li> <li>▪ Notify the committee in writing and in advance if there any changes in laboratory practice or emergency procedures are planned.</li> </ul>
Laboratory Manager/Technicians	<ul style="list-style-type: none"> <li>▪ Ensure that appropriate materials and equipment are identified and available for the safe handling of biohazardous materials.</li> <li>▪ Provide equipment and facilities in support of waste disposal in the Biology Department.</li> <li>▪ Oversee the use of the autoclave and maintain associated records.</li> <li>▪ Ensure that lab hoods and biosafety cabinets are in working order and arrange prompt repair and recertification as necessary.</li> <li>▪ Monitor laboratory work practices and waste disposal in teaching labs and other department areas.</li> </ul>

## 5. Requirements

### Program Administration

The Biosafety Program will be managed by the SCU Biosafety Committee and the Biosafety Officer in accordance with the responsibilities listed in Section 4 of this program. The charter of the Biosafety Committee is found in [Attachment 2](#).

### Pre-Use Review and Approval Process

Prior to purchasing, creating, or using biohazardous materials, the Laboratory Supervisor must complete following steps:

- Submit a completed *APPLICATION FOR RESEARCH OR TEACHING PROJECT INVOLVING RECOMBINANT DNA OR BIOLOGICALLY HAZARDOUS MATERIALS* to the Office of Research Compliance and Integrity..
- Respond to requests for additional information or modifications.
- Receive written approval of the application.

The process for submittal and review of the application is described in the [Office of Research Compliance and Integrity website](#).

### Other Reviews

Laboratory personnel must also comply with the application processes associated with the following programs if applicable to the work described in the *APPLICATION FOR RESEARCH OR TEACHING PROJECT INVOLVING RECOMBINANT DNA OR BIOLOGICALLY HAZARDOUS MATERIALS*.

- Work with radioactive sources or radiation producing devices is subject to the requirements of the **Ionizing Radiation Safety Program**.
- Work with animals is subject to the requirements of the University's **Animal Care and Use Program**.

Further information on each is available on the Office of Research Compliance and Integrity and Environment, Health and Safety (EHS) websites.

### Annual Review

#### ***Project Review***

Each year, the Biosafety Officer will distribute review forms to the responsible Laboratory Supervisor. The responsible Laboratory Supervisor will review the form, confirm whether there have been any changes and return the form to the Biosafety Officer. Review forms may be automatically approved by the Biosafety Officer and Biosafety Committee Chair if there have not been any changes. Alternatively the same review and approval process as used for new applications will be followed for annual project reviews requiring a more extensive review.

## Program Review

The Biosafety Officer will conduct a review of the Biosafety program and compliance with its requirements every three years. The results of this review will be communicated to the Biosafety Committee for review and corrective action as required.

## Qualification

Santa Clara faculty, students and staff must complete the training described in Section 6 of this program prior to working with biohazardous materials.

## Risk Group Classification System

NIH has established guidelines on research involving recombinant DNA molecules (rDNA) in which biohazardous materials are classified into four risk groups based upon their relative pathogenicity for healthy adult humans: Risk Group 1 (RG1) pose the lowest risk and those in Risk Group 4 (RG4) the highest. Grouping biohazardous materials with similar levels of risk into risk groups is a useful technique for identifying general controls.

Risk groups are not absolute, however, which is why organisms must undergo a review prior to their use at Santa Clara University. The following tables describe the risk groups and abbreviated control guidelines.

Table 1: Risk Groups

Risk Group	RG1	RG2	RG3	RG4
Definition	An agent that is unlikely to cause human or animal disease.	An agent that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventative measures are available and the risk of spread of infection is limited.	An agent that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and prevention measures are available.	An agent that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.
Example	E-coli, Bacillus subtilis,; animal tissues infected with Risk Group 1 (RG1) agents.	<i>Salmonella</i> spp., adenoviruses, Hepatitis viruses; human or primate blood or body fluids, unfixed tissues or cell cultures of human origin; introducing rDNA into RG2 agents	Mycobacterium tuberculosis, retroviruses (HIV, SIV), herpesvirus 1 (B virus), prions; introducing rDNA into RG3 agents	Ebola, Lassa, and Marburg viruses; specimens from individuals infected with RG4 agents; introducing rDNA into RG4 agents

## Biosafety Levels

CDC and NIH has established four levels of biosafety, based on the degree of hazard associated with an organism, to describe the combination of laboratory practices and techniques, safety equipment, and facilities needed to protect against exposure. These four biosafety levels (BSL) require successively more restrictive practices and facilities as work moves from the least restrictive BSL1 to work with the highest hazard level of BSL4. No work at the BSL3 or BSL4 is currently being performed at Santa Clara



University. Santa Clara University is not equipped with facilities that meet BSL3 or BSL4 requirements.

**Table 2: Control Categories**

Control Category	BSL1	BSL2	BSL-3	BSL4
	Suitable for work involving well-characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.	Suitable for work involving agents of moderate potential hazard to personnel and the environment.	Applicable to work is done with agents which may cause serious or potentially lethal disease as a result of an inhalation exposure.	Required for work with agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.
Engineering Controls	Standard lab with open bench and sink. Lab constructed so as to be easy to clean and decontaminate.	Same as BSL 1 plus: Class II Biosafety Cabinets, autoclaves and aerosol containing centrifuge caps available as needed.	To be instituted only if approved by the Biosafety Committee.	Not available at SCU
Other Controls	Standard microbiological practices	Restricted access when work is in progress, biosafety hazard signs, sharps precautions, safety procedures such as waste decontamination and medical surveillance.	To be instituted only if approved by the Biosafety Committee.	Not available at SCU
Personal Protective Equipment	Appropriate shoes (no sandals, open-toed or slip on footwear).	Lab coats. Safety goggles if there is a splash or spray hazard present.	To be instituted only if approved by the Biosafety Committee.	Not available at SCU

## Engineering Controls

Certified biological safety cabinets will be used for control of potential exposure to droplets, splashes, spills or aerosols in BSL2 labs. The biological safety cabinets at Santa Clara must meet Class II specifications and must be certified to meet manufacturers' specifications when installed, moved and at least annually in accordance with the [SCU Hoods, Spray Booth and Ventilation Program](#).

## Decontamination

Decontamination is a process or treatment that renders equipment, environmental surfaces, or biohazardous waste safe to handle. Levels of decontamination include:

- Sterilization (high-level decontamination) uses a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.
- Disinfection (intermediate-level decontamination) uses a liquid chemical to eliminate virtually all pathogenic microorganisms, with the exception of bacterial spores, on work surfaces and equipment.

- Cleaning (low-level decontamination) uses water, detergent, and some mechanical action such as scrubbing with a gloved hand or brush. Cleaning is often a required step before sterilization or disinfection, because it removes all material such as soil or organic material and reduces the number of microorganisms on an object.

Sterilization takes place at SCU in autoclaves. Autoclaves are located Alumni Science 355. Autoclave operators must be qualified and follow the SCU autoclave procedures.

The following are disinfectants approved for use at Santa Clara University. Use an appropriate disinfectant per the following table. Prepare fresh solutions of bleach or Lysol daily. Contact the EHS Director to add disinfectants to the approved disinfectant table.

**Table 3: Approved Disinfectants**

Name	Description	Concentration, ppm	Minimum Contact Time
Lysol or equivalent	Lysol contains quaternary ammonium compounds. Quaternary ammonium compounds are cationic detergents with strong surface activity.	5 oz. in 1 of gallon water (1:256)	10 minutes
70% Alcohol	Ethyl and isopropyl alcohol in concentration of 70% to 90% are good general-use disinfectants. However, they evaporate fast and therefore have limited exposure time.	70% alcohol is used in spray bottles and in wipes.	Until the liquid evaporates
Bleach	Chlorine-containing solutions have broad spectrum activity. Regular bleach contains 5.25% sodium hypochlorite.	Bleach is diluted 1:10 resulting in a final concentration of 0.525%.	10 minutes
Nolvasan	Chlorhexidine diacetate	1 ounce (2 tablespoons) per gallon water	10 minutes

All materials and equipment contaminated with or containing biohazardous materials must be decontaminated with an approved disinfectant that is effective against the type of biohazardous material as follows:

- upon completion of procedures involving the use of biohazardous materials
- in the event of spills of such materials
- before being washed, stored, or discarded

Disinfectants must be used in accordance with the Table 3 above and the manufacturers' instructions. Longer exposure times, i.e., 20 to 30 minutes, may be necessary. This is especially true when high-level disinfection is to be achieved.

Decontaminate:

- Work surfaces. Decontaminate at least once a day after use and after any spill of viable material. This is generally done by spraying with 70% alcohol and allowing to air dry.
- All cultures, stocks and other regulated liquid wastes. This is generally done by adding a disinfectant and allowing at least 10 minutes contact time. Then dispose of the non-alcohol-containing liquids generated by this decontamination process down the drain and rinse with water for 1–2 minutes.

- Other contaminated materials (or dispose of as biohazardous waste).
- Plasticware and other non-disposable items: Wipe down with 10% bleach solution and then spray all with 70% ethanol. Allow to air dry.
- Biological safety cabinets, centrifuges and other equipment potentially contaminated with biohazardous materials: Decontaminate prior to servicing, maintenance and/or removal from the laboratory.

Dispose of any wipes or other supplies used in cleanup and disinfection as medical waste in accordance with the guidance in Table 4.

## **Biosafety Level 1 Controls and Practices (BSL1)**

### ***BSL1 Containment***

A standard laboratory will generally meet BSL1 criteria. The lab must be separated from public areas by a door. Laboratory surfaces must be able to be cleaned and disinfected. Handwashing facilities must be provided, preferably near the point of exit to public areas. Separate hanging areas should be provided for street clothing and laboratory coats. A biological safety cabinet is not required.

### ***Good Laboratory Practices***

- Limit access to lab areas while working with biohazardous materials.
- Wear appropriate shoes (no sandals, open-toed or slip on footwear).
- Wash hands:
  - After handling viable materials
  - After removing gloves
  - Before leaving the laboratory
- Do not eat, drink, smoke, handle contact lenses, apply cosmetics or store food for human use in work areas.
- Mouth pipetting is prohibited; use mechanical pipetting devices instead.
- Follow procedures for the safe handling of sharps. Use a high degree of caution when handling any contaminated sharps. Handle broken glassware with brush and dustpan, tongs, or forceps, not directly with hands. Do not bend, break, recap or remove used needles from disposable syringes before disposal. Dispose of sharps in a puncture resistant sharps container.
- Perform all procedures carefully to minimize the creation of splashes or aerosols.

### ***BSL1 Waste Procedures***

Place medical waste including tissues, cell cultures, microbiology specimens, inoculated plates, and media as well as contaminated gloves and wipes in a red biohazardous waste bin lined with a red biohazard bag. Do not overfill and keep the lid shut when not adding waste. When the bag is 3/4 full, tie shut and place in the designated storage area.

## **Biosafety Level 2 Controls and Practices (BSL2)**

### ***Containment***

For routine procedures, a biological safety cabinet is not necessary. A Class 2 Biological Safety Cabinet (BSC) must be used whenever there is the potential to produce droplets or aerosols of biohazardous materials. When appropriate, line the BSC with absorbent pads to absorb any spills or splatters (e.g., when sterility is not required, when handling blood or other potentially infectious materials). Do not block the front grill.

Do not store materials in the BSC. Take only what is needed to perform the procedure and place in the BSC upon initiation of the procedure. Upon concluding the procedure, follow decontamination procedures and then remove everything from the BSC, including all equipment.

Other containment requirements include the following:

- Place RG2 biohazardous materials into well-constructed containers with a secure leak proof lid for transport. Label the container with a biohazard symbol, the name of the agent, the amount, and the user's name and telephone number.
- Use centrifuge safety cups while performing centrifugation procedures
- Protect vacuum lines and systems with disinfectant traps and filters.
- Replace glassware with plasticware, where feasible.
- Restrict the use of sharps to applications where alternative equipment is not available.

### ***Warning Signs and Labels***

All BSL2 labs must have a sign displayed on each entry door that includes the Biohazard symbol. Refrigerators and freezers that contain biohazardous materials in BSL2 labs must also be labeled with the biohazard symbol.



### ***Administrative Practices***

Restrict access to lab areas while work with biohazardous materials is in progress.

Wash hands after removing gloves and when leaving the laboratory. Remove lab coat and contaminated personal protective equipment and clothing before leaving lab.

### ***Personal Protective Equipment***

Safety glasses, gloves, lab coat and closed toe shoes is the minimum personal protective equipment required. A face shield must also be worn when there is a risk of aerosol formation or splashes.

### ***BSL2 Decontamination Procedures***

In addition to the general decontamination procedures described above, the following are additional decontamination procedures for work involving organisms in BSL2 labs:

- Spray the BSC and work surfaces with Lysol or bleach and then spray with 70% alcohol. Allow the surface to air dry.

- Decontaminate serological pipettes, pipette tips and other similar solid plasticware by soaking in a beaker containing a disinfectant for at least 15 minutes prior to discarding as solid biohazard waste. Then dispose of non-alcohol-containing liquids generated by this decontamination process down the drain and rinse for 1–2 minutes. If pipettes, pipette tips are to be re-used following decontamination, rinse with water.
- If aspirated liquid waste is 2/3 full, aspirate a disinfectant through the suction tube so that the final concentration is appropriate, allow it to soak for at least 15 minutes and then empty entire contents down the drain. Rinse with water for 1–2 minutes.
- Decontaminate the centrifuge and any associated equipment after centrifuging with an effective disinfectant. Record decontamination information in a log maintained at the centrifuge.

### ***BSL2 Waste Procedures***

- The following BSL2 waste procedures are required in addition to the BSL1 waste procedures listed in the BSL1 section above. Also see Table 4 for a summary of waste procedures.
- A rigid plastic container labeled as containing biohazardous waste should be lined with a red biohazard bag and be equipped with a closing lid. This should be kept next to the experiment and always closed when not in-use. When the bag is approximately  $\frac{3}{4}$  full the the container should be transported to the appropriate waste collection or treatment (e.g. autoclave room) area and the bag removed for disposal/treatment.
- Contaminated sharps should be collected in a sharps container labeled as containing biohazardous waste. Once  $\frac{3}{4}$  full, take the sharps container to the appropriate waste disposal storage location. All other solid waste contaminated by blood or other RG2 biohazardous materials should be disinfected in the waste container before leaving the lab. Upon completion of disinfection, contact the Laboratory Manager or EHS for disposal.

### **Use of human blood or other potentially infection materials**

In addition to following BLS2 level precautions, the use of human blood or other potentially infectious materials must also comply with the requirements of the [SCU Bloodborne Pathogens Program](#), including medical requirements such as the Hepatitis B vaccination program.

### ***Medical Waste Disposal***

All waste biological materials that meet the definition of medical waste must be rendered sterile before disposal or transferred to a licensed contractor for disposal. The following table outlines the Medical Waste treatment and disposal options.

Table 4: Medical Waste Disposal Table

Waste Category	Examples	Treatment and Disposal
<p><b>Liquid human and animal waste</b></p> <p>Blood, blood products, body fluids</p> <p>DOES NOT INCLUDE urine or materials stained with dried blood.</p>	<p>Student blood</p> <p>Animal blood</p>	<p>Not autoclavable</p> <p>Collect in an approved biowaste container lined with a red biohazard bag. Store and package in place</p> <p>Waste transportation and disposal by licensed contractor</p>
<p><b>Medical Sharps</b></p> <p><b>Potentially pathogenic or infectious</b></p> <p>DOES NOT INCLUDE: Non-contaminated sharps (see Standard Sharps below)</p>	<p>Needles</p> <p>Syringes with or without needles attached</p> <p>Scalpels</p>	<p>Not autoclavable</p> <p>Collect in approved red sharps container. When the sharps container is <math>\frac{3}{4}</math> full, close it, double bag in red biohazard bags and seal the bags. Disinfect the outside of the biohazard bag using an approved disinfectant and then place bag completely inside the biological waste bins in the designated storage area.</p>
<p><b>Standard Sharps</b></p> <p>Not contaminated</p> <p>Contaminated with biological materials that are not pathogenic</p> <p>DOES NOT INCLUDE: Medical Sharps (see above)</p>	<p>Pasteur pipettes</p> <p>Slides</p> <p>Broken glassware</p>	<p>Not autoclavable</p> <p>Collect uncontaminated broken glassware, etc. in a Glass Waste cardboard box.</p> <p>Note: Do not dispose of in regular trash</p>
<p><b>Solid Waste (non-sharp)</b></p> <p>Solid objects, no liquids</p> <p>Contaminated with biological materials that are not pathogenic</p>	<p>Gloves</p> <p>Paper towels</p> <p>Culture or blood tubes</p> <p>Plasticware i.e., culture plates, specimen vials, pipette tips</p>	<p>Autoclavable</p> <p>Soak reusable equipment in a disinfectant.</p> <p>Collect in an autoclavable biohazard bag. Sterilize with autoclave as directed. Once properly packaged, may be disposed of in municipal trash.</p>
<p><b>“Mixed” Biological Waste</b></p> <p>Material with one or more hazardous components other than biohazards.</p>	<p>Alcohol/biological mixtures</p> <p>Formalin/tissue mixtures</p> <p>Radioisotope marked cell cultures or microbes</p>	<p>Not autoclavable</p> <p>Contact EHS staff for assistance in handling mixed hazard wastes.</p> <p>(1) Organic solvents, like ethanol or formalin solutions, are not autoclavable and must be drained off for disposal as hazardous waste</p> <p>(2) Biological waste contaminated with radioactive materials requires special handling. Contact Radiation Safety Officer (RSO) for disposal or questions about radioactive waste</p>

## ***Emergencies and Exposures***

Spills of biohazardous materials will be cleaned up by person who responsible for the spill as follows:

- Spills Involving RG 1 Organisms
  - Don gloves and lab coat.
  - Soak up gross spill with paper towels. Place towels in a medical waste container.
  - Soak more paper towels in an approved disinfectant and place over the spill area or create a berm with paper towels and pour disinfectant over the spill area.
  - Allow disinfectant to remain in contact with spill area for a minimum of 20 minutes.
  - Soak up disinfectant with clean paper towels and place in a medical waste container.
- Spills Involving RG 2 Organisms
  - Don gloves, lab coat and eye protection (safety glasses for small spills with minimal risk of splashing, and goggles and face shield for spills with a risk of splashing). Also wear disposable shoe covers if there a risk of contaminating shoes.
  - Prepare a fresh solution of 10% household chlorine bleach (1 part bleach and 9 parts water or add a scant ½ cup bleach to 1 quart of water)
  - Spread towels over the spill from the outside toward the middle. After the towels soak up the spill, place them in a medical waste container.
  - Create a berm with paper towels and pour the 10% bleach solution over the spill area.
  - Allow disinfectant to remain in contact with spill area for a minimum of 20 minutes.
  - Soak up disinfectant with clean paper towels and place in a medical waste container.

The Laboratory Supervisor must always be notified of spills. If assistance is needed, warn others in the area, evacuate the area, travel to a safe location, and call Campus Safety Services x4444.

## ***Accident Investigation and Reporting***

Accidents involving injury or illness must be reported on the Incident Review Form (available from Human Resources) and distributed as indicated.

All accidents and near misses/accidents (injuries, fires, spills, explosions, ect) must be reported to the EHS Director as soon as possible after the occurrence. The EHS Director analyzes accidents and “near misses” and provides recommendations to proper authorities.

## 6. Training

Before working with biohazardous materials, SCU faculty, staff and students are required to receive training in biohazards and safe handling procedures. Required training includes the following:

- Biosafety course designed for users of biohazardous materials.
- Those who work with human blood or other potentially infectious materials are also required to read the [SCU Bloodborne Pathogen Program](#).
- Hands-on training provided by the Laboratory Supervisor regarding the specific hazards of biohazardous materials used in the lab and applicable controls.

## 7. Reporting

The Biosafety Officer will review the Biosafety Program for compliance every three years and refer any issues to the Chair of the Biosafety Committee. If the program is found to be non-compliant, the Biosafety Committee will take appropriate actions, including root cause analysis, to ensure that the issues are corrected going forward.

## 8. Document Retention

The following documents are retained at these locations for three years, unless otherwise indicated:

<b>Record</b>	<b>Location</b>	<b>Duration</b>	<b>Responsible Party</b>
Submitted Application for Research Project Involving Recombinant DNA or Biologically Hazardous Materials	Office of Research Compliance and Integrity	3 Years	Director, Office of Research Compliance and Integrity
Requestor's Application for Research Project Involving Recombinant DNA or Biologically Hazardous Materials	Laboratory Supervisor's Records	3 Years	Laboratory Supervisor
Annual Biosafety Program Review	EHS Files	3 Years	Biosafety Officer
Vaccination Forms, reports from the Occupational Health Clinic and other medical records	Department of Human Resources	30 Years after termination of employment	Department of Human Resources
Incident Review Record	EHS Files	3 Years after termination of employment	EHS Director



Sharps Injury Log	Department of Human Resources	5 Years after incident	Department of Human Resources
Personnel Training	EHS Files	3 Years after termination of employment	EHS Director
Medical Waste Bill of Lading	EHS Files	3 years	EHS Director

## 9. Key References and Resources

The following is a brief summary of the regulatory authorities that either regulate or provide guidelines for research which involves the use of potentially hazardous biological materials (infectious agents, recombinant DNA molecules, etc.) at SCU. Copies of these documents are available from EHS or can be downloaded from the Internet.

- [SCU Bloodborne Pathogen Program](#)
- [SCU Injury Illness Prevention Program](#)
- [Santa Clara University Research Compliance & Integrity](#) website for biosafety and animal care & use programs
- [National Institute of Health \(NIH\): Guidelines for Research Involving Recombinant DNA Molecules](#)
- [Centers for Disease Control and Prevention \(CDC\) and the National Institute of Health \(NIH\) Guidelines on: Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#)
- [Occupational Safety and Health Administration: Bloodborne Pathogens Standard](#)
- [Department of Health and Human Services \(HHS\): Requirements for Facilities Transferring or Receiving Select Agents](#)
- [California Medical Waste Management Program](#)
- [Centers for Disease Control and Prevention: Guide for Shipping Infectious Substance](#)
- [Department of Agriculture \(USDA\) Animal and Plant Health Inspection Service \(APHIS\) requirements for Import and Export](#)

## **Attachment 1 - Definitions**

**Biohazardous Waste** – A waste that is one of the following:

(A)

(i) Regulated medical waste, clinical waste, or biomedical waste that is a waste or reusable material derived from the medical treatment of a human or from an animal that is suspected by the attending veterinarian of being infected with a pathogen that is also infectious to humans, which includes diagnosis and immunization; or from biomedical research, which includes the production and testing of biological products.

(ii) Regulated medical waste or clinical waste or biomedical waste suspected of containing a highly communicable disease.

(B)

Laboratory waste such as human specimen cultures or animal specimen cultures that are infected with pathogens that are also infectious to humans; cultures and stocks of infectious agents from research; wastes from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research, discarded animal vaccines, including Brucellosis and Contagious Ecthyma, as defined by the department; culture dishes, devices used to transfer, inoculate, and mix cultures; and wastes identified by Section 173.134 of Title 49 of the Code of Federal Regulations as Category B “once wasted” for laboratory wastes.

(C)

Waste that, at the point of transport from the generator’s site or at the point of disposal contains recognizable fluid human blood, fluid human blood products, containers, or equipment containing human blood that is fluid, or blood from animals suspected by the attending veterinarian of being contaminated with infectious agents known to be contagious to humans.

(D) Waste containing discarded materials contaminated with excretion, exudate, or secretions from humans or animals that are required to be isolated by the infection control staff, the attending physician and surgeon, the attending veterinarian, or the local health officer, to protect others from highly communicable diseases or diseases of animals that are communicable to humans.

**Biological safety cabinet** - A ventilated cabinet that serves as a primary containment device for operations involving biohazard agents or biohazardous materials.

**Diagnostic Specimens** - any human or animal materials that is being transported for diagnostic or investigational purposes. This included clinical laboratory or research specimens.

**Medical Waste:** any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste not regulated by the federal hazardous waste law; sharps and trace chemotherapy wastes generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; waste generated in autopsy or necropsy; waste generated during preparation of a body for final disposition such as cremation or interment; waste generated in research pertaining to the production or testing of microbiologicals; waste generated in research using human or animal pathogens; sharps and laboratory waste

that poses a potential risk of infection to humans generated in the inoculation of animals in commercial farming operations; waste generated from the consolidation of home-generated sharps; and waste generated in the cleanup of trauma scenes.

**Biologicals:** medicinal preparations made from living organisms and their products, including, but not limited to, serums, vaccines, antigens, and anti-toxins.

**Laboratory Supervisor-** The SCU employee bearing primary responsibility for all essential aspects of the work being carried out, including technical, budgetary and administrative compliance.

**Recombinant DNA** are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

**Sharps** - Objects that can be reasonably anticipated to penetrate the skin or any other part of the body and result in an exposure incident, such as needles and syringes, slides, pipettes, capillary tubes and scalpels.

## **Attachment 2 – BioSafety Committee Charter**

The Biosafety Committee will strive to ensure that all biohazardous materials used in teaching and research are obtained, used, stored, transferred, and destroyed properly and safely. The Committee will work with the Biological Safety Officer to minimize risks associated with biological hazards and to ensure compliance with relevant laws and regulations pertaining to biohazardous materials. The Biosafety Committee is responsible for:

- assisting in the development of appropriate procedures as required by NIH<sup>1</sup>, CDC<sup>2</sup> and/or Select Agents and Select Agent Toxins regulations<sup>3</sup> to oversee the possession and/or use of biohazardous materials;
- recommending the suspension or termination of the possession or use of biohazardous materials, including research, where the Committee finds noncompliance or that such use or possession poses a threat to the health and safety of the community;
- routinely reviewing the policies and procedures for working with biohazards and recommending modifications as necessary to ensure appropriate biosafety measures and compliance with federal and state requirements;
- assisting with a periodic review of the possession and/or use of biohazardous materials to ensure compliance with federal and state requirements;
- working with the University's Environmental Health and Safety Officer in developing and adopting emergency plans covering accidental spill and personnel contamination resulting from use or possession of biohazardous materials.

The Committee will meet 2-3 times a year. The Chair will be elected from the group annually. Operational recommendations of the Committee will be made to the Associate Provost for Research Initiatives and/or the Assistant Vice President for University Operations. Policy recommendations will be made to the appropriate University Policy Committees.

The Biosafety Committee will be composed of at least five members who are appointed by the Associate Provost for Research Initiatives. The members will collectively have experience and expertise in potential biohazards, particularly recombinant DNA, and the capability to assess the safety of research involving recombinant DNA and infectious agents and identify any potential risk to public health, animal and plant health or products, or the environment posed by such research.

1 [http://osp.od.nih.gov/sites/default/files/resources/NIH\\_Guidelines.pdf](http://osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines.pdf)

2 <http://www.cdc.gov/biosafety/publications/bmb15/index.html>

3 <http://www.selectagents.gov/SelectAgentsandToxinsList.html>