**SOP 1.1 Training**

**Training Requirements**

1. Online Training
   1. Biosafety 101: Risk Assessment Learn@UW
   2. Biosafety 102: Bloodborne Pathogens for Lab Research Learn@UW
   3. Biosafety 104: Safe Use of Sharps Learn@UW
   4. Biosafety 201: NIH Guidelines Learn@UW
   5. UW HIPAA Training www.hipaa.wisc.edu
   6. UWHC Safety and Infection Control Training elearning.uwhealth.org
   7. CITI Human Subjects Training my.gradsch.wisc.edu/citi
      1. Human Subject Training Course: Human Subjects Research for
         1. Biomedical Researchers
         2. Social & Behavioral Science Researchers
      2. Good Clinical Practice Course
2. Laboratory Hands-On Training for Handling and Pre-Processing Human Blood Samples
   1. SOP training
   2. Good Laboratory Practice, Exposure and Emergency response Training
   3. Laboratory Safety Equipment Use and Maintenance Training

**I. ONLINE TRAINING COURSES**

Prior to hands-on laboratory training, all lab personnel must enroll in the following online training courses and certify their passing scores. Trained laboratory personnel are responsible to keep their training records up-to-date in compliance with institutional regulations.

1. **ONLINE TRAINING**

**Biosafety Training by UW Office of Biological Safety**

The UW OBS offers biological safety training courses designed to inform and prepare research personnel for work in campus biological research laboratories in compliance with standards set forth by the NIH and CDC. Courses are offered online through Learn@UW. Courses 101, 104, and 201 are required training for any person working in a biological laboratory in accordance with a registered biosafety protocol. Course 102 is required for laboratory staff Bloodborne Pathogens compliance training.

1. **Biosafety 101: Risk Assessment** Learn@UW

Building Biosafety Into Your Research - Risk Assessment. The goal of this training is to provide an introduction to the Office of Biological Safety and the Institutional Biosafety Office; to familiarize researchers with conducting risk assessments, including risk groups and biosafety levels; to present information on safety basics in biological research; and to discuss biosafety planning and exposure response.

Renewal: every 5 years.

1. **Biosafety 102: Bloodborne Pathogens for Lab Research** Learn@UW

This training has been developed specifically for researchers working with potentially infectious human materials and meets the requirements for annual training in the Bloodborne Pathogens Program. This course relates the OSHA Bloodborne Pathogens Standard to biological research settings for those working with human blood, cells, tissue, and other potentially infectious material. This course is both the initial bloodborne pathogen training and the annual refresher.

Renewal: annually.

1. **Biosafety 104: Safe Use of Sharps** Learn@UW

The goals of this training module are to present information about hazards related to the safe use of sharps. By the end of this module, trainees should be able to identify and differentiate laboratory and medical sharps; identify and mitigate risky procedures involving sharps; and develop awareness of safe handling techniques, proper disposal methods, and exposure response basics. This information, when put together, should allow laboratories to develop a sharps safety plan for their own work area.

Renewal: every 5 years.

1. **Biosafety 201: NIH Guidelines** Learn@UW

The aim of this training is to provide a good understanding of the underlying principles and intent of the NIH Guidelines concerning research activities involving the use of recombinant or synthetic DNA. Researchers should understand the responsibilities of all parties involved, including NIH, the University, PIs, and laboratory workers.

You will learn about the practices required to assure that your research is and remains in compliance with the NIH Guidelines. You will also learn about UW-Madison’s reporting procedures for accidental exposures to infectious material, releases of genetically modified organisms, violations, and any other problems relating to the NIH Guidelines.

Renewal: every 5 years.

1. **UW HIPAA** **Training** www.hipaa.wisc.edu

The [HIPAA Privacy Rule](http://hipaa.wisc.edu/ResearchGuide/documents/combinedregtext.pdf) (the Privacy Rule) is a new set of federal regulations providing protections for the confidentiality of health information used in clinical practice, research, and the operations of health care facilities. The intended purpose of the Privacy Rule is to ensure that health information confidentiality risks are minimized. The Privacy Rule gives patients new federal rights, and protects those rights by requiring new procedures of health care providers and human subjects researchers. In addition, the Privacy Rule requires the training of employees, including researchers, in the protection of confidential health information.

1. **UWHC Safety and Infection Control ‘Non-Clinical’ Training**

elearning.uwhealth.org

The Safety and Infection Control Course (Non-Clinical Version) is required for all UW Hospital and Clinics employees who do not provide direct, hands-on patient care, but have patient contact. The aim of the training program is to provide a solid base to understand institutional guidelines for management plans for environment of care and safety including management for life safety, utility systems, hazardous materials & waste, emergency, safety, security and medical equipment. Additional chapters of this training course focuses on institutional guidelines for infection control and patient safety.

Renewal: annually.

1. **CITI Human Subjects Training** my.gradsch.wisc.edu/citi
   * 1. Human Subject Training Course

The aim of this training program is to familiarize researchers with principals of human subjects protection for biomedical, education, social & behavioral science.

Renewal: every 3 years.

* + 1. Good Clinical Practice Course

Training modules address FDA-regulated clinical research and the responsibilities of investigators, IRBs, and sponsors when they participate in a study of an FDA-regulated product. Additionally, basic principals of Clinical Trial conduct and management are discussed.

1. **LABORATORY HANDS-ON TRAINING**
2. **SOP training**

Upon completion of all required online training sessions, new lab personnel complete a 3-months training period led by an experienced senior lab member to familiarize with all aspects of the SOP’s, standard laboratory practices including safe use and maintenance of laboratory workspace and equipment and record keeping. The hands-on training period is to ensure procedures are conducted safely and reproducibly before lab personnel start working independently.

Group meetings and group training sessions are held to familiarize all members when new SOP’s are introduced or procedures or equipment use need any updating.

Training records are collected and maintained up-to-date.

1. **Good Laboratory Practice, Exposure and Emergency response Training**

In conjunction to the SOP’s training new lab personnel are familiarized with good laboratory practices to mitigate risk of exposure to hazardous material. This training also introduces institutional guidelines for emergency responses and reporting in case of exposure to biologically or chemically hazardous material.

Preventive measures are discussed including Hepatitis B vaccination and titer tests.

Waste management, disposal, appropriate handling of any tools or equipment contaminated with human specimen and spill management is discussed.

See SOP for Waste Management, Disposal and Decontamination of Equipment, SOP Personal Protective Equipment (PPE) and Handling of Blood Specimen, SOP Blood Contaminated Material Spill Management for detailed protocols.

Note: large spills of potentially infectious material outside of containment or any incidents associated with the risk of aerosol exposure to infectious material are managed exclusively by a designated and respirator fit-tested lab member.

Copies of the following protocols are posted in a designated location accessible to any lab members at any time for quick reference for description of appropriate procedures:

* + - 1. Current version of Biological Safety Protocol
      2. Spill Management Protocols for both Inside or Outside Containment
      3. Bloodborne Pathogen Exposure Control Plan published by UW Environmental Health and Safety at

<http://www.ehs.wisc.edu/occ/BloodbornePathogenExposureProgram.pdf>

* + - 1. Bloodborne Pathogens Reference and Training Manual published by UW Occupational

Health Program and Safety Department

* + - 1. Chemical Hygiene Plan
      2. Emergency Responses manual with contact information
      3. Exposure and Accident reporting forms

1. **Laboratory Safety Equipment Use and Maintenance Training**

Biological Safety Cabinets (BSC) are maintained and certified by the UW OHS. Training for the proper use, decontamination and maintenance of BSC and appropriate choice and use of Personnel Protective Equipment (PPE) is provided to enrolling lab personnel at the start of their hands-on training period.

Please refer to SOP Personal Protective Equipment (PPE) for handling of blood specimen for detailed protocol.

**TRAINING:**

1. All protocols involving handling of blood specimens are first observed by trainee. An established trainer will perform the protocol(s).
2. After observation of trainer, the trainee will be observed once to make sure proper PPE and laboratory practice are utilized.
3. Trainee should be observed no later than 2 weeks after initial observation of trainer.

**OBSERVATION OF TRAINER BY TRAINEE**

Trainee Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Trainer Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Trainee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Trainer Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OBSERVATION OF TRAINEE BY TRAINER**

Trainee Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Trainer Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Trainee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Trainer Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Approvals:

The undersigned acknowledge they have reviewed the Standard Operating Procedure Preparation and Maintenance and agree with the approach it presents. Changes to this the Standard Operating Procedure Preparation and Maintenance will be coordinated with and approved by the undersigned or their designated representatives

Author:

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Title Assistant Scientist

Reviewer:

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Name Dona Alberti Date

Title Project Administrator

Authorizer:

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Name Joshua Lang Date

**Title** Principal Investigator