

Bio Basics Fact Sheet: Writing Standard Operating Procedures (SOP)

Purpose:

SOPs should be viewed as valuable research tools that are worth the time and effort required to prepare them. Written SOPs document that a risk assessment has been performed and provide a written means to inform and advise workers about hazards in their work place.

A well-written SOP satisfies several requirements:

- Attach it to the SOP section of an Institutional Biosafety Committee (IBC) application.
- Use it as a lab-specific training tool and documentation that workers have been informed of the biological hazards in their work place and have been trained how to prevent accidental exposure to those hazards.
- Use as a component of a laboratory-specific biosafety manual as required by CDC/NIH guidelines in the Biosafety Level 2 Special Practices section of [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 5th Edition](#):

“A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.”

SOPs should be written for all procedures that pose an identified potential risk to the health and safety of the worker and of others present in the lab. A separate SOP does not need to be written for each individual experiment, just for the handling of each organism. Organisms that pose the same risks and are handled in the same way may be included in one SOP. Be sure to include exposure controls and safety precautions for all identified potential risks of exposure associated with the types of procedures the organisms may be used for, i.e. centrifugation, contaminated sharps, homogenization, etc.

The process of writing SOPs requires an individual to think through all steps of a procedure and perform a risk assessment before work is begun. This process allows for standardization of materials and methods, resulting in quality research as well as identifying any safety issues associated with the procedure.

General Guidelines:

Every SOP should include:

- date written, dates of revisions, name of person that wrote the SOP
- procedural methods/materials (detailed enough to allow someone to complete the procedure)
- risk identification
- exposure controls
- waste disposal
- spill procedures

- accident procedures
- any pertinent references
- any required record keeping

SOPs must be lab specific. They should not consist of copies of manufacturer's inserts, manuals from other sources, or another lab's SOPs (unless work is collaborative and carried out in the same research space). You may, however, wish to refer to other documents.

See [sample SOP template](#). Expand each section as needed. The template is for guidance only and is not meant to be all-inclusive or a required format.

Steps to Write a SOP:

	Task	Examples	Resource
Step 1	Review laboratory protocols and identify the potential hazards associated with the procedures performed in the protocols - Risk Assessment.	Using Risk Group 2 microorganisms Using biological toxins Using rDNA (e.g. insertion of oncogene, potential for generation of replication competent virus, etc)	Risk Group Classifications (basis for biosafety level evaluation) Biosafety Levels & Risk Assessment MSDS for Biological Materials
Step 2	Determine the types of exposure risk to the identified hazards that each step could present.	Aerosol production Use of sharps Exposure to infected animals	Aerosol Production and Exposure Control Sharps Safety Sharps Safety Update Research Animal Resources
Step 3	Develop an exposure control plan that workers must adhere to that will minimize the risk of personal exposure and prevent the release of infectious agents. The exposure control plan must include each exposure risk identified in Step 2. Include personal protective equipment and work practices in accordance with the Biosafety Level determined by completing the Risk Assessment process in Step 1.	Secondary containment in centrifuges Working in a certified biological safety cabinet Frequency and method used to clean work surfaces Personal protective equipment required; gloves, face shields, lab coat, etc. Immunizations, if needed	Institutional Biosafety Committee (IBC) CDC/NIH publication Primary Containment for Biohazards - 3rd Edition Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 5th Edition NIH Guidelines for Research Involving Recombinant DNA Molecules
Step 4	Identify the types of wastes that will be generated and plan for how they will be treated/disposed of.	Sharps Culture media	Infectious Waste Disposal Chart

		Contaminated disposables Chemical waste Toxin waste rDNA waste including transgenic animal waste	Autoclaving Waste Biological Waste Disposal Plan Hazardous Chemical Waste Management Toxin Inactivation
Step 5	Develop a lab specific plan for how spills and accidental exposures will be handled. List emergency procedures including location of emergency equipment, emergency contact information with phone numbers, spill clean- up/decontamination methods, and when and how to seek emergency medical care. Include who the worker should notify in case of an accident and how to file an accident report. Include routine clean-up procedures and materials in plan.	Broken tubes in centrifuge Face/eye splash Needle stick, cut or contact with broken skin Contaminated liquid spill	Needle Sticks and Other Infectious Exposures General Emergency Procedure Reporting Workers' Compensation Related Injuries Biohazards and Toxin Decontamination & Spill Fact Sheet Biological Decontamination Plan Template

Completed SOPs should be:

- brief, succinct, and usable.
- used to train all new employees (remember to document training).
- reviewed with employees as part of their annual laboratory-specific safety update training (document training).
- reviewed annually for accuracy and completeness by supervisor and workers.
- available in the laboratory for worker reference.
- submitted with all IBC applications.
- used as a lab specific supplement to the department's Lab Safety Plan.
- signed by supervisor if written by someone other than P.I. or lab director.