



Biological Safety Regulatory Compliance References

Introduction

All activities involving biological materials must comply with the applicable federal, state and local regulations, laws and statutes, and all university policies. This information is provided as a reference tool for the Institutional Biosafety Committee and the university community as large.

The list is subject to change. Questions should be directed to the EHS Biological Safety division. University review and approval of proposed research activities may be required.

Mandatory Federal Regulations & Guidelines

- [NIH Grants Policy Statement](#), especially Public Policy Requirements and Objectives, Health and Safety Regulations and Guidelines (Part II, 4)
- NIH Grants Policy Statement, [4.1.23 Public Health Security and Bioterrorism Preparedness and Response Act \(Select Agents\)](#)
- CDC Federal Select Agent Program, [Select Agents Regulations](#)
- CDC [Biosafety in Microbiological and Biomedical Laboratories](#), when Select Agents are used
- [USA Patriot Act](#)
- [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)
- OSHA Standards
 - [29 CFR 1910.1030, Bloodborne Pathogens](#)
 - [29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories](#)
 - [29 CFR 1910.1200, Hazard Communication](#)
 - [29 CFR 1910.132, Personal Protective Equipment](#)
 - [29 CFR 1910.133, Eye and Face Protection](#)
 - [29 CFR 1910.134, Respiratory Protection](#)
- [National Institutes of Health Guidelines for Human Stem Cell Research](#)
- USDOT [Hazardous Materials Regulations](#), 49 CFR, for air and ground transportation of biological materials
- EPA Pesticide Registration, [Selected EPA-registered Disinfectants](#), products used to disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms on inanimate objects and surfaces

- [USDA Animal and Plant Health Inspection Service](#)
 - [Animal Health / Import into the US](#)
 - [Animal Health / Export from the US](#)
 - [Biotechnology / Permits](#)

State of Colorado Regulations

- [CDPHE Solid waste regulations](#)
- [CDPHE Epidemic and Communicable Disease Control, 6CCR 1009-0](#)
- [Colorado Department of Agriculture Livestock Health](#)
- [Colorado Department of Agriculture Import Requirements](#)

Recommended Federal Guidelines

- CDC [Biosafety in Microbiological and Biomedical Laboratories](#), when Select Agents are not in use
- FDA [Cellular & Gene Therapy Guidances](#)
 - [Guidance for Industry: Potency Tests for Cellular and Gene Therapy Products \(PDF\)](#)
 - [Guidance for FDA Reviews and Sponsors: Content and Review of Chemistry, Manufacturing, and Control \(CMC\) Information for Human Gene Therapy Investigational New Drug Applications \(INDs\) \(PDF\)](#)
 - [Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy \(PDF\)](#)

Other Best Practices References

- National Research Council, [Prudent Practices in the Laboratories](#), National Academies Press
- WHO [Laboratory Biosafety Manual](#)
- American Society for Microbiology, [Biological Safety: Principles and Practices](#)