



## Biosafety Level Guide for Ascending Levels Agent Risk



### Introduction

BSL levels consider the combination of microbiological practices, safety equipment, and facility safeguards needed for the study agent(s) to be handled, to help protect the staff handling the study agent(s), non-study associated staff, the public and the environment.

Each level **builds upon the previous levels** (BSL-1 through BSL-4) and become more stringent.



### Standard Precautions

The primary strategy for prevention of transmission of infectious materials in the health care setting is how blood and body fluids are handled to protect health workers from unknown human pathogens.

See OSHA Bloodborne Pathogen Standard for additional details at <https://www.osha.gov/bloodborne-pathogens>

**Will be implemented during subject administration due to the potential for BBP exposure.**

**Suggested Minimal PPE:** Disposable gown (preferred) or launderable lab coat, nitrile gloves, eye protection, face mask.



# Biosafety Levels (BSL) Guide



## BSL-1



**Trained staff (microbiological, assigned duties, and emergencies)**



**Decontaminate work area after work or spill(s)**



**Limit access**



**Closable doors**



**Use hand hygiene**



**Windows do not open (if present)**



**Sink(s) for handwashing available**



**Effective insect/rodent control program**



**Current biosafety manual for work performed**



**Proper medical waste management**



**Biohazard signage**



**Use required PPE**



**No eating, drinking in work area(s)**



**Easily cleanable surfaces (non-porous)**



**Minimize aerosol creation**



**Suggested minimal PPE:** Disposable gown (preferred) or launderable lab coat, nitrile gloves, eye protection (agent/study dependent).

**E.g.**

**Examples:** adeno-associated virus (AAV), plasmids, mRNA.

# Biosafety Levels (BSL) Guide



## BSL-2



**Medical surveillance, and immunizations as needed**



**Extreme caution using sharps**



**Use of BSCs. In lieu of BSC use, additional PPE will be required**



**Extra caution to minimize aerosol creation**



Suggested minimal PPE: Disposable gown (preferred) or launderable lab coat, nitrile gloves, eye protection, face mask.

- This PPE may be reduced if a BSC is used for study agent(s) preparation.

**E.g.**

**Examples:** Adenovirus, autologous T-cells, Respiratory syncytial virus (RSV), Vaccinia virus

## BSL-3 & BSL-4



**Shield  
Consulting**

Have questions about BSL-3 or BSL-4?

Our experts at Shield Consulting can help!

Contact Shield Consulting, a subsidiary of Sabai Global:  
[info@consultingshield.com](mailto:info@consultingshield.com)

\*Please note that **CBS does not review studies that fall under BSL-3 or BSL-4 containment**. For more information on these containment levels please refer to the [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#)

\*Adapted from [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#) and [NIH Guidelines](#)