

University of Nebraska Medical Center
Biosafety Policies and Procedures

UNMC IBC
Biosafety Risk Assessment Summary

IBC34- Form 1

IBC# _____ (to be determined by the IBC Office)

Title of Project

Principal Investigator _____

Date _____

Risk Factor

Risk Group

Pathogenicity/virulence

Infectious Dose

Route of Spread

Communicability

Environmental stability

Host range

Economic impact

Availability of prophylactic/treatment

Vectors

Concentration/volume

Recombinant properties

Overall Risk Group _____

Recommended Containment Level _____

Notes: _____

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Risk Factor Assessment Outline

Pathogenicity/virulence

- RG1 Unlikely to cause disease, low individual and community risk.
- RG2 Mild or moderate disease with moderate individual risk and low community risk; any pathogen that can cause disease but under normal circumstances, is unlikely to be a serious hazard to a healthy worker, the community, livestock, or the environment.
- RG3 Serious livestock, poultry or wildlife disease with high individual risk and low community risk; any pathogen that usually causes serious disease or can result in serious economic consequences or does not ordinarily spread by causal contact from one individual to another.
- RG4 Severe livestock, poultry or wildlife disease with high individual risk and high community risk; any pathogen that usually produces very serious and often fatal disease, often untreatable and may be readily transmitted from one individual to another or from animal to human or vice-versa, directly or indirectly, or by casual contact.

Infectious dose

- RG1 Not applicable (rare cause of human disease)
- RG2 High (>1,000 organisms)
- RG3 Medium (10-1,000 organisms)
- RG4 Low (1-10 organisms)

Route of spread

- RG1 Not applicable (rare cause of human disease)
- RG2 Primary exposure hazards are through ingestion, inoculation, and mucous membrane route
- RG3 May be transmitted through airborne route; direct contact or via vectors
- RG4 Readily by aerosol transmission

Communicability

- RG1 Not applicable (rare cause of human disease)
- RG2 Geographical risk of spread if released from the laboratory is limited.
- RG3 Geographical risk of spread if released from the laboratory is moderate
- RG4 Geographical risk of spread if released from the laboratory is high.

Environmental stability

- RG1 Not applicable
- RG2 Short term survival (days), can survive under ideal conditions
- RG3 Moderately resistant (days to months)
- RG4 Highly resistant (months to years), e.g. spores.

Host range

- RG1 Not applicable
- RG2 Infects a limited number of species
- RG3 Infects multiple species
- RG4 Infects many species

Economic aspects

- RG1 Not applicable
- RG2 Limited economic impact
- RG3 Severe economic impact
- RG4 Extreme economic impact

Availability of prophylactic and therapeutic treatments

- RG1 Not applicable
- RG2 Effective treatment and preventative measures are available
- RG3 Prophylactic and/or treatments may or may not be readily available
- RG4 Prophylactic and/or treatments are not available

Vectors

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- RG1 Not applicable
- RG2 Do not depend on vectors or intermediate hosts for transmission
- RG-3 May depend on vectors or intermediate host for transmission
- RG4 May depend on vectors or intermediate host for transmission.

Concentration/volume

- RG1 Not applicable
- RG2 Low quantity of high titer
- RG3 High quantity (10 liters or more) of high titer as described by the BMBL
- RG4 Not applicable

Recombinant properties

- RG1 Recombinant is a RG1 organism and modifications have not changed the risk; low probability of RG2 replication-incompetent virus becoming competent
- RG2 Recombinant is a RG2 organism and modifications have not changed the risk, DNA from RG2 or RG3 organism is transferred into RG1 organism but not the whole genome, DNA from RG4 organism is transferred into RG1 organism, or the recombinant is a RG3 or RG4 organism and the modification has resulted in proven attenuation; moderate probability of RG2 replication-incompetent virus becoming competent
- RG3 Recombinant is a RG3 organism and modifications have not change the risk, the recombinant is based on a RG2 organism; however, the modifications have increased to RG3 organism.
- RG4 Recombinant is a RG4 organism and modifications have not changed the risk, DNA from RG4 organism is transferred into RG1organism in absence of demonstration of lack of virulence or pathogenicity.