

Institutional Biosafety Committee

STUDY AMENDMENT

Principal Investigator:	
Department:	
Email:	
IBC Study #:	
Approved Biosafety Level:	
Project Title:	
Funding Agency(s)	
IBC Amendment #:	
IRB #	
IACUC #	

Perform a risk assessment per Section II-A-3 of the [NIH Guidelines](#) in order to determine the appropriate level of review by the IBC. Factors to consider include: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Any strain more hazardous than the parent (wild-type) strain should be considered for handling at a higher Biosafety level. Also consult OSHA requirements for guidance. If the proposed change **is considered a major amendment a new research application must be completed along with this form.** If this amendment involves BL2 or above studies, or the addition of new laboratory locations a laboratory inspection by the Biosafety Officer will be necessary. Submit all materials to IBC@downstate.edu

MINOR AMENDMENT*:

- Adding/removing co-investigators (new personnel should email ibc@downstate.edu that they “have read, understood and agreed to participate in the protocol”)
 - Adding/changing/removing cell lines
 - Adding/changing/removing transgenic animals
 - IACUC study #:
 - IACUC amendment #:
 - Adding/changing/removing laboratory room numbers:
 - Current room number(s): _____
 - Proposed room number(s): _____
 - Other
- *Submit amendment form and any supporting documents. The amendment will be considered by an IBC member for expedited review.

MAJOR AMENDMENT**:

- Adding/changing organism
 - Adding/changing transgene
 - Adding/changing infectious agents
 - Upgrade in containment level:
 - Current Biosafety Level: _____
 - Proposed Biosafety Level: _____
 - Other
- **Submit signed amendment form, AND a signed revised IBC Protocol Submission Form, and any supporting documents. The amendment will be considered in a convened meeting of the Biosafety Committee.

Describe the proposed change(s) and rationale for the change(s):

NOTE TO INVESTIGATORS: Study amendments may not be instituted until approval from the Institutional Biosafety Committee is given. Retain this form for your records.

Investigator: _____ Date: _____

The amendment of this project has been reviewed and approved by the Institutional Biosafety Committee.

Authorized IBC Member: _____ Date: _____

Rev. 2/19