# Appendix C – Risk Assessment

## PART A: Research/Investigation

Principal Investigator:

Department:

Location of Research:

Funding agency:

Agent Used:

Material Safety Data Sheet (MSDS) available:

Risk Group Level of Agent:

Biological Safety Level Used:

**Title & Brief Description of Research Activity:**

## PART B: Characterization of Agent

**1. Is the agent a living microorganism?** Yes  No  NA

***If no, go to question #2***

Is the agent pathogenic based on the wild type strain? Yes  No  NA

What is the host range of the agent?

Healthy humans,  Animals,  Immunocompromised humans,  Plants

Is the agent transmissible? Yes  No  NA

If yes, what is the route of transmission? Airborne, ingestion, broken skin, mucous membranes, vectors, other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is the agent attenuated? Yes  No  NA

Does the attenuation reduce the risk? Yes  No  NA

Lab strain? Yes  No  NA

Source\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is the organism well characterized? Yes  No  NA

Will the agent be genetically modified? Yes  No  NA

***If yes, answer question #2***

NIH Risk Group:  RG1,  RG2,  RG3,  RG4,  NA

Other/Comments:

**2. Are recombinant DNA constructs used or created?** Yes  No  NA

***If no go to question #3***

Is a viral vector being used? Yes  No  NA

***If yes, answer question #1***

What is the host range of the viral vector?

Healthy humans,  Immunocompromised humans,  Animals,  Bacteria (phage),  Plants

Is there a risk of the target cells becoming oncogenic? Yes  No  NA

Does the DNA code for production of a human toxin? Yes  No  NA

Where will the DNA construct be inserted?

Human, Animal, Plant, Bacterium, Tissue, Cells, Fungi/yeast, Other\_\_\_\_\_\_\_\_\_\_\_\_\_

**3. Are human or non-human primate materials involved?**  Yes  No  NA

***If no, answer question #4 in Part C on page #3***

Human blood cells or tissue? Yes  No  NA

Non-human primate (NHP) blood cells or tissue? Yes  No  NA

Other human bodily fluids? Yes  No  NA

* Other NHP fluids? Yes  No  NA
* Human derived cell lines or tissue? Yes  No  NA
* NHP cell lines or tissue? Yes  No  NA
* Are any of the materials fixed or preserved? Yes  No  NA

**If yes,** fixative used?\_\_\_\_\_\_\_\_\_\_\_\_

Other/Comments:

## PART C: Characterization of Staff/Protocols

4. Does the principal investigator have experience with this agent? Yes  No  NA

5. Do workers require special training to safely work with the agent? Yes  No  NA

6. Is the training documented? Yes  No  NA

7. Increased risk for exposure for certain workers or activities? Yes  No  NA

8. Are there risks to maintenance or custodial staff in the lab? Yes  No  NA

9. Are there procedures in place to minimize exposure? Yes  No  NA

10. Are there alternative activities that may reduce the risk? Yes  No  NA

11. Is there a vaccination available against the agent? Yes  No  NA

12. Is medical surveillance appropriate for monitoring exposure? Yes  No  NA

13. Does the research involve a large scale operation? (>10 Liters) Yes  No  NA

14. Are vertebrate animals used in the research? Yes  No  NA

***If no, skip to question #20 in PART D***

15. Are animals infected or exposed to the agent? Yes  No  NA

16. Is shedding of the agent possible? Yes  No  NA

17. Is the animal infectious to other animals or humans? Yes  No  NA

18. Will bites/scratches increase the risk of exposure to the agent? Yes  No  NA

19. Has the vertebrate animal protocol been approved by IACUC? Yes  No  NA

Other/Comments:

## PART D: Characterization of Facilities/Equipment

20. Are there sharps protocols? (plastic, safe-sharps, disposal, etc.) Yes  No  NA

21. Are there proper waste disposal arrangements in place? Yes  No  NA

22. Is there an autoclave available for biohazardous waste? Yes  No  NA

23. Is the waste autoclaved correctly to assure sterility? Yes  No  NA

24. Is the biohazardous labeling of the sterile waste concealed

before disposal in the dumpster? Yes  No  NA

25. Is the laboratory waste properly transported? Yes  No  NA

26. Is biohazardous waste properly segregated? Yes  No  NA

27. Is a Class II Biological Safety Cabinet (BSC) recommended? Yes  No  NA

28. Is an effective and appropriate disinfectant in use? Yes  No  NA

29. Is the disinfectant contact time sufficient? Yes  No  NA

30. What types of personal protective equipment are recommended?

gloves  eye protection  lab coats/aprons

face protection respiratory protection  Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

31. Are laundry and decontamination facilities or services available? Yes  No  NA

32. Is there a contingency plan in case of exposure/accident? Yes  No  NA

33. What Biosafety level is recommended for the work?

Laboratory work BSL1 BSL2 BSL3 BSL4

Animal Work: ABSL1 ABSL2 ABSL3 ABSL4

Other/Comments:

## PART E. Risk Assessment/Final Analysis/Approval

**(*To be completed by biosafety coordinator or appointee*)**

Date of risk assessment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Risk assessment conducted by:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IBC approval required for research based on risk assessment? Yes  No  NA

Submitted to IBC (date):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewed by IBC on (date):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Corrective action (s) required for approval of research?: Yes  No  NA

***If yes, describe below:***

Corrective actions completed? Yes  No  NA  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IBC approval granted: Yes  No  NA  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_