# 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_