



INSTITUTIONAL BIOSAFETY COMMITTEE

**Review of GMP Project Risk Assessment:
Specific Project Amendment**

1. Individual submitting risk assessment:

Name: Position:
Office Phone: Mobile Phone:
Email:

2. Supervisor of project (if different from above):

Name: Position:
Office Phone: Mobile Phone:
Email:

3. Personnel directly involved in this project:

Name:	Employee ID:	Email:

4. Is this for an external client?

Yes (Complete below) No (Skip question #4)

Name: Email:
Office Phone: Mobile Phone:

5. Is this for a University of Colorado Principal Investigator (PI)?

Yes (Complete below) No (Skip question #5)

PI Name: Email:
Office Phone: Mobile Phone:
Contact Name (if different from PI):
Email:
Office Phone: Mobile Phone:

6. The project is considered: Research Manufacturing

7. Select the relevant biohazardous materials involved and describe the specific hazards of each:

Human tissue/cell cultures/fluids:

Animal tissue/cell cultures/fluids:

Non-human primate (NHP) tissue/cell cultures/fluids (i.e., New World NHP or Old World NHP):

Infectious agents/human pathogens/zoonotic agents:

 Attenuated:

Viral vectors; replication defective:

Recombinant nucleic acids:

 Oncogenes:

 Toxins:

Proteins expressed:

8. Describe the procedures specific to this project amendment below. In bulleted points, detail the general steps with volumes/materials and any potential hazards not covered by the general facility's standard operating procedures (e.g., large volumes, aerosol-producing manipulations such as homogenization, protein purification type employed, specific agents such as EBV) along with mitigation strategies to minimize risks.