Biological Risk Assessment Form

Permit Holder: Link to Personnel Google Sheet: Romeo File Number:	Date submitted: Location(s) for this work:

1.0 Hazardous Characteristics of a Biological Agent

List all organisms below that will be manipulated during the work at the same Risk Group Level in the same location. Organisms that form a collection and are not manipulated should be appended as a separate list. If you are not isolating/culturing pathogens from environmental, human or animal clinical samples, under organism, describe sample type.

Organism or Tissue Type/Animal Source	**# Organism required to initiate infection**	**Treatment available?**	**Splash Potential** **Concentration**	**Origin**
	Infectious Dose ☐ Healthy individuals susceptible ☐ Immunocompromised individuals susceptible ☐ Not applicable (cell lines/tissues) ☐ Documented Lab Acquired Infections (LAI)	☐ Vaccination ☐ Prophylaxis ☐ Other	☐ Liquid culture ☐ Culturing ☐ Stock ☐ Solid Culture ☐ Sampling only ☐ Volumes >1L Working concentration	☐ Pure culture ordered from supplier ☐ Exotic pathogen (not normally found in North America) ☐ Endemic pathogen (can be cultured from environment in N.A.) ☐ Human Clinical Sample ☐ Isolates ☐ Environmental Sample ☐ Isolates ☐ Animal Sample ☐ Isolates
	Infectious Dose ☐ Healthy individuals susceptible ☐ Immunocompromised individuals susceptible ☐ Not applicable (cell lines/tissues) ☐ Documented Lab Acquired Infections (LAI)	☐ Vaccination ☐ Prophylaxis ☐ Other	☐ Liquid culture ☐ Culturing ☐ Stock ☐ Solid Culture ☐ Sampling only ☐ Volumes >1L Working concentration	☐ Pure culture ordered from supplier ☐ Exotic pathogen (not normally found in North America) ☐ Endemic pathogen (can be cultured from environment in N.A.) ☐ Human Clinical Sample ☐ Isolates ☐ Environmental Sample ☐ Isolates ☐ Animal Sample ☐ Isolates

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Organism	ePathogen Confirmation of Risk Group (RG) and PSDS(Provide hyperlink if available)	Mode of Transmission or Route of Exposure	Vector Use?	Toxin Production under experimental conditions?	Viral Replication Competency
		☐ Inhalation ☐ Ingestion ☐ Injection ☐ Direct Skin, Eye or mucosal membrane exposure	☐None ☐ Yes, list vector(s)	☐None ☐ Yes, list toxin(s)	☐ Low ☐ Medium ☐ High ☐ N/A
		☐ Inhalation ☐ Ingestion ☐ Injection ☐ Direct Skin, Eye or mucosal membrane exposure	☐None ☐ Yes, list vector(s)	☐None ☐ Yes, list toxin(s)	☐ Low ☐ Medium ☐ High ☐ N/A
		☐ Inhalation ☐ Ingestion ☐ Injection ☐ Direct Skin, Eye or mucosal membrane exposure	☐None ☐ Yes, list vector(s)	☐None ☐ Yes, list toxin(s)	☐ Low ☐ Medium ☐ High ☐ N/A
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		☐ Inhalation ☐ Ingestion ☐ Injection ☐ Direct Skin, Eye or mucosal membrane exposure	☐None ☐ Yes, list vector(s)	☐None ☐ Yes, list toxin(s)	☐ Low ☐ Medium ☐ High ☐ N/A

3.0 Genetic modification ☐ **No** ☐ Yes **(provide details below)**

	List each organism and Corresponding Section of Biosafety Protocols that addresses safe work
☐ Primary Cell Line	
☐ Secondary Cell Line	
☐ Oncogenic	
☐ Plasmid or Cosmid Use	
☐ Recombinant techniques	
Describe the Genetic Modification to be used:	

4.0 Hazardous Characteristics of Laboratory Procedures (Check any that will be used with biohazardous agents listed above)

Laboratory Procedure	**Corresponding Section of Biosafety Protocols that discusses how to safely conduct the task (Cite which manual and section)**
☐ Working with Animals (potential for bites/scratches)	
☐ Sharps Use, Needles	
☐ Glass	
☐ Pipetting	
☐ Mixing	
☐ Pouring infectious materials	

☐ Lyophilizing	
☐ Cell sorting	
☐ Blenders	
☐ Centrifuge	
☐ Sonicator	
☐ Vortex	
☐ Grinding	
☐ Vigorous Shaking	
☐ Homogenizing	
☐ Flaming inoculating loops	
☐ Large volume of biohazardous material in use, greater than 1 L	
☐ Toxin production	
☐ Cryogenic techniques	
☐ Collection of Environmental Samples	
☐ Culturing Environmental Samples	
☐ Collection of Human tissues, bodily fluids	
☐ Manipulation of Human tissues, bodily fluids	
☐ Opening containers of infectious materials whose internal pressures may be different from ambient (e.g. heated samples)	
☐ Biohazardous materials in powdery form	
☐ Transport biohazardous materials outside of the lab	
☐ Ship/Receive/Transport biohazardous materials outside of the lab building	
☐ Vacuum filtration of biohazardous materials	
☐ Non-standard manipulation (not listed above)	

5.0 Dual Use Potential

Dual Use Research is biological research with legitimate scientific purpose, the results of which may be misused to pose a biologic threat to public health and/or national security.

Does this research (check all that apply):	Y	N
Allow for increased pathogencity?	☐	☐
Widens pathogen's host range?	☐	☐
Renders vaccination or standard treatment ineffective?	☐	☐
Allow for non-standard contamination or increased transmissibility?	☐	☐
Allow for increased ability of the pathogen to survive in conditions such as public food/water supply or animal feed supply?	☐	☐
Allow for concealment of a RG 2, 3 or 4 pathogen from detection	☐	☐
Allow for ease in obtaining RG 2, 3 or 4 pathogen? (e.g make it yourself kit, or isolate at home kit)	☐	☐

6.0 Hazards Associated with Work Practices, Safety Equipment and Facility Safeguards

☐PPE in Use

Gloves When?

Labcoats When?

Safety Glasses When?

Face Shields When?

Biosafety Spill Kit Locations?

- ☐ Two pairs of gloves
- ☐ Spill warning signs (minimum two signs)
- ☐ Tape
- ☐ Tongs
- ☐ Absorbent materials (can be paper toweling)
- ☐ Disinfectant, list
- ☐ Disposal bags or containers

☐ Biosafety cabinet f2Ŏl·ú\2yʔ

Biosafety Protocols for safe use of Biosafety Cabinet in Section of Biosafety Manual.

☐ Centrifuge Safety Cups

☐ Sealed Centrifuge Rotors

☐ O-rings inspected <12 months

тⱣл Medical Surveillance (Choose one)

☐ Users are advised of symptoms of infection, and reporting of all known exposures or potential Laboratory Acquired illnesses to Supervisor AND Biosafety Officer hw

☐ Additional measures of medical surveillance are suggested (supply details).

7.0 Post Exposure Protocols/ Emergency Proceduresʸ Cite section of manual

8.0 Waste handling and decontamination

Autoclave to be used Location?

Last Validation performed: Chemical Integrator Biological Indicator

Chemical Disinfection to be used

List disinfectants and concentrations?

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For Biosafety Committee Use Only - Local Risk Assessment

Section 1 - Risk Assessment:

1. Risk group of agent(s): 1 ☐ 2 ☐
2. Infectious to humans: Y ☐ N ☐
3. Is a vaccine available? Y ☐ N ☐ Not Required ☐
4. Is a standard treatment available? Y ☐ N ☐
5. Is there a splash potential? Y ☐ N ☐
6. Does the procedure generate aerosols? Y ☐ N ☐
7. Does the procedure involve high concentration? Y ☐ N ☐
8. Does the procedure involve high volume? Y ☐ N ☐
9. Animals subjected to biohazards? Y ☐ N ☐
10. Non-standard manipulations ("other" on Biological Risk Assessment form)? Y ☐ N ☐
11. Aerosol(inhalation) ☐ droplets/ingestion ☐ Direct contact ☐ Injection ☐ None ☐
12. Known laboratory acquired infections? Y ☐ N ☐
13. Number of organisms for infection (for each pathogen or group of pathogens): _____

Section 2 – Controls in Place:

1. Facility meets or exceeds CL applied for: Y ☐ N ☐
2. BSC available for aerosol generating procedures? Y ☐ N ☐ Not Applicable ☐
3. Procedures listed on BRAF are appropriate to control exposure? Y ☐ N ☐
4. PPE in use is adequate to prevent transmission of agent? Y ☐ N ☐
5. Facility users are trained and up to date? Y ☐ N ☐
6. Self-monitoring for LAI sufficient? Y ☐ N ☐
7. Medical surveillance recommended or required? Y ☐ N, Self-monitoring sufficient ☐ Traffic flow patterns from clean to dirty areas are established and followed? Y ☐ N ☐
8. Waste management plan is sufficient Y ☐ N ☐

Section 3 – Recommendations/Restrictions:

Committee has recommendations/restrictions (to be listed on permit): Y ☐ N ☐ (list)

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Date BSC Review: _____ BSO's Signature: _____ Chair's Signature: _____

yy/mm/dd