

**BIOSAFETY SCHEDULE D: RESEARCH INVOLVING POTENTIALLY INFECTIOUS MICROBIAL AGENTS (Risk Group  $\geq 2$ ) OR SPECIMENS EXPOSED TO THESE INFECTIOUS MICROBIAL AGENTS (excluding any material previously described in either Schedule A or B)**

Names of Agents	Is this a Select Agent <sup>1</sup> ?	Is agent infectious to humans?	Is agent infectious to animals?	Is agent replication competent?	Risk Group <sup>2</sup>
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

<sup>1</sup>for a list of Select Agents, please see: <http://www.cdc.gov/od/sap/docs/salist.pdf>

<sup>2</sup>See the following links for assistance in Risk Group classification:

[http://www4.od.nih.gov/oba/rac/guidelines\\_02/APPENDIX\\_B.htm](http://www4.od.nih.gov/oba/rac/guidelines_02/APPENDIX_B.htm)

<http://www.absa.org/XriskgroupsX/index.html>

<http://www.phac-aspc.gc.ca/msds-ftss/>

1. List approximate maximum volume(s) of cultures of these agent(s) generated at any one time. Note: if any cultures are  $\geq 10$  liters, please include Schedule C in application.

2. Describe any procedures that will be performed with this material which may be associated with an increased potential risk of exposure of personnel (e.g. increased risk of exposure may be associated with generation of splashes, sprays or aerosols from centrifugation, sonication, homogenization, vortexing, FACS, use of sharps (needles or glass), cage cleaning of infected animals, etc. Management of these risks should be addressed in the PI's laboratory-specific SOPs)

3. Will you be introducing these biological agents into animals?  Yes  No

If "yes", you will also need to apply for IACUC approval **in addition to IBC approval** before beginning your research. You will also need to **include Biosafety Schedule E** with this application.

4. Will you be introducing these biological agents into humans?  Yes  No

If "yes":

(a) Please provide sufficient pertinent information to facilitate the risk assessment by the IBC, such as:

- i. *The nature of the potentially infectious material to be introduced into the patients.*
- ii. *Have these agents been passaged through animals or other cells or cell lines?*
- iii. *Method of delivery and health status of the patients*
- iv. *Frequency of administration*
- v. *The anticipated effect of the introduction of the agent upon the patient (if known)*
- vi. *The expected persistence of the infection after administration (if known)*
- vii. *How long after administration will you obtain specimens to be analyzed? What types of specimens will be obtained?*
- viii. *What types of analyses will be performed? (e.g behavioral analyses, in vivo instrumentation, blood tests, analyses of tissue biopsies?)*
- ix. *At what stage of your experiments will the infectious agent(s) be inactivated or lysed?*
- x. *What biosafety precautions will be taken to avoid inadvertent exposure to other patients, researchers, or health care providers.*

*\* If you are introducing agents into humans, you will also need to apply to IRB approval **in addition to IBC approval** before beginning your research. You may also need to include Biosafety Schedule B with this application.*

(b) Indicate any safety tests or pathogen screening which will be performed on these agents prior to delivery into humans:

5. Will these experiments result in acquisition of new characteristics of these infectious agents, such as altered virulence or infectivity, or changes in resistance/susceptibility to drug therapy or changes in host range? ?  Yes  No

If "yes", please describe: