Inactivated Biological Agents: Use at Wayne State University

Introduction**:**

Wayne State University (WSU) does not currently have the required facilities for working with any high risk ([Risk Group 3 or 4](https://my.absa.org/tiki-index.php?page=Riskgroups)) pathogens. As such, the use of inactivated biological agents is of potential value to WSU researchers. Successful inactivation lowers the risk related to working with these organisms and as a consequence also reduces the resources required. Work with inactivated Risk Group 3 or 4 pathogens can be performed safely in an Office of Environmental Health and Safety (OEHS) approved [BSL-2 facility](http://research.wayne.edu/oehs/bio-safety/bsl-2_audit_wsu.pdf). The inactivation process must be completed by the supplier and the methods used evaluated and approved by the WSU Institutional Biosafety Committee (IBC) **prior** to this material being shipped onto campus.

Purpose:

Events during the past decade have raised awareness of the need to verify that the methods used to achieve inactivation are sufficient and conducted correctly1. The WSU IBC requires documentation regarding the use of inactivated high risk biological organisms for the following reasons:

1. To ensure that inactivation methods described are sufficient for inactivation of the specific biological samples being acquired
2. To maintain records regarding the type and location of inactivated, high risk biological agents on campus
3. To improve the ability of the OEHS to respond when alerts are received indicating that the inactivation process may have failed on the part of the lab of origin.

High Risk Agents:

High risk agents subject to this process include:

1. CDC/USDA Select Agents2
2. Risk Group 3 agents3
3. Risk Group 4 agents3
4. Any material (blood, tissues, etc.) that is either known or reasonably expected to harbor agents included in the groups above

N.B. For use of inactivated Risk Group 2 agents, please contact the WSU Biosafety Officer

IBC Biological Agent Inactivation Guidelines:

To help provide increased safety for the use of biological agents which are categorized as Select Agents and/or Risk Group 3 or 4 when viable, the WSU IBC has implemented the following guidelines:

Prior to Receiving Samples:

1. Please request the following from the lab of origin prior to confirming that you are able to receive such samples.
* Completed WSU Biological Agent Inactivation Form (see below)
* SOP detailing the inactivation procedure, including evidence that it is a validated method
* SOP detailing the procedure used to confirm inactivation along with viability results
1. Submit the complete package to the WSU IBC for review and approval
	* Submissions can be e-mailed to the WSU Biosafety Officer
2. The PI for the facility receiving the inactivated material will be responsible for identification and analysis of potential risks and hazards associated with the material to be used.

Points to be considered include:

* Risks that would be present if the material were not inactivated
* Use of BSL-2 Precautions (handle the material with the possibility that it might contain viable infectious agents, assess use of PPE and appropriate engineering controls)
1. Awareness Training: Information related to a viable and pathogenic isolate must be provided to all personnel that will be using the material.

Training must cover:

* + Symptoms (clinical, incubation period)
	+ Mode of transmission
	+ Completion of the WSU OEHS [Biosafety/BBP](http://research.wayne.edu/oehs/training/lab.php) training module

Pathogen Safety Data Sheets and Risk Assessment information can be found on the [Public Health Agency of Canada’s](http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php) website4.

Upon Receipt of Samples:

1. Retain all documentation while the material is on-site
* Future shipments of the same material from the same source must include details of the inactivation procedure and the viability testing results for that batch.
1. In the event that a PI is notified of a possible failure to inactivate a specific batch that has been received at WSU, the PI must take action to:
	* Secure materials in a manner that restricts access to all users in the lab
	* Notify the Biosafety Officer immediately and provide a summary of recent activities that have been performed using the agent in question
2. Transferring of materials to other PI’s at WSU is prohibited without prior approval of the WSU Biosafety Officer and IBC
3. Report Incidents & Seek Care:
* Medical care should be sought as soon as possible after exposure (see below).
* Research staff must notify PI of all accidents, injuries, or exposures involving inactivated agents
* Document incidents on WSU ‘Report of Injury Form’ <http://idrm.wayne.edu/risk/rofi.pdf>
1. Notify the Biosafety Officer if work with inactivated agent ceases and material is no longer stored on WSU campus

Exposure Response Contacts:

* **Principal Investigator (PI):**
* **WSU Public Safety:** 313-577-2222, emergency transportation
* **Occupational Health Services (Henry Ford Medical Center – Harbortown)** – 313-656-1618, M-F 8 AM – 4 PM
* **Emergencies or After Hours: Henry Ford Hospital (2799 W. Grand Blvd.) or Detroit Receiving Hospital (4201 St. Antoine)**
* **Office of Environment Health & Safety:** 313-577-1200, spills or clean-up
* **Institutional Biosafety Committee Contact:** Richard Pearson. PhD, 313-993-7597

References:

1. [High containment laboratories, Improved oversight of dangerous pathogens needed to mitigate risk.](http://www.gao.gov/assets/680/679392.pdf)  United States Government Accountability Office, August 2016
2. [Select agents and toxins list](https://www.selectagents.gov/SelectAgentsandToxinsList.html). Federal Select Agent Program, CDC
3. [Risk Group Database](https://my.absa.org/tiki-index.php?page=Riskgroups). American Biological Safety Association
4. [Pathogen Safety Data Sheets and Risk Assessment](http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php). Public Health Agency of Canada

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| To be completed by lab receiving samples |
| Name of Responsible Party: Click here to enter text. | Date: Click here to enter a date. |
| Contact Info: Tel: Click here to enter text. E-mail: Click here to enter text. |
| Name of agent being obtained: | Risk Group prior to inactivation:  | Proposed BSL Level for work at WSU: |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Intended Research Purpose: (Please provide a brief description of the work to be performed at WSU – further information may be requested) |
| Click here to enter text. |
| Intended Start Date: Click here to enter text. | Duration: Click here to enter text. |
| Research Location(s): |
| Building, Room#: | Type of Activity: (e.g., Storage, BSL-2 etc.) | Certification Date of BSC:(if applicable) |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |
| Click here to enter text. | Click here to enter text. | Click here to enter a date. |

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| To be completed by Institution sending samples |
| Name of Responsible Party: Click here to enter text. | Date: Click here to enter a date. |
| Name of Company/Institution: Click here to enter text. |
| Contact Address: Click here to enter text. |
| Contact Info: Tel: Click here to enter text. E-mail: Click here to enter text. |
| Name of Institutional Biosafety Officer: Click here to enter text. |
| Contact Info: Tel: Click here to enter text. E-mail: Click here to enter text. |
| Is Laboratory preparing inactivated samples certified by CLIA, CAP, or ISO? (Provide info. Below) |
| CLIA: Click here to enter text. | CAP: Click here to enter text. | ISO: Click here to enter text. |
| Name of validated inactivation method to be used (Please attach SOP): Click here to enter text.  |
| References to substantiate method:  |
| Click here to enter text. |
| Click here to enter text. |
| Viability assay to be used (Please attach SOP): Click here to enter text. |
| Results for sample being sent (Please attach details): Click here to enter text. |

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| To be completed by the WSU BSO |
| Date Received: Click here to enter a date. | Date Reviewed: Click here to enter a date. |
| Reviewed by: Click here to enter text. |
| Approval: WSU IBC | Signature: | Date: Click here to enter a date. |