**Biologically hazardous materials are defined as pathogenic organisms or materials that have the potential to transmit pathogenic organisms or biotoxins to humans, animals or the environment.** **These include among other things, primary human or wild animal specimens, wastewater samples, soil, pest plants, infectious cell lines and wild-type Risk Group 2 microorganisms.**

**A completed application form should be reviewed by the IBC before commencing work with Risk Group 2 or above biologically hazardous material, potential or actual, in UniSA premises.**

For your reference a copy of the Australian and New Zealand Standard for Safety in Laboratories 2243.3 can be located in the [SAI Global Online Database](http://search.library.unisa.edu.au/record/UNISA_ALMA6184616600001831), accessing via the [UniSA Library](http://www.library.unisa.edu.au/Default.aspx). Hint: search for “SAI Global”

Completed forms should be submitted to: biosafety@unisa.edu.au

|  |  |  |
| --- | --- | --- |
| **IBC use only** | **IBC Reference Number** |  |
|  | **Assessment Date** |  |
|  | **Review Due Date** |  |
|  | **Risk Category** | Risk Group 2 |

|  |  |
| --- | --- |
| **1** | **Project Title** |
|  |

|  |  |
| --- | --- |
| **2** | **Preliminary Information** |
| **Does this application replace another assessed project?** | [ ]  Yes [ ]  No |
| **If yes, what is/are the UniSA IBC reference number/s?** | IBC-B- |

|  |  |
| --- | --- |
| **3** | **Individuals who will be handling the biologically hazardous material(s)** |
| **3A** | **Project Leader** |
| **Project Leader’s Name** |  |
| **Email Address** |  |
| **Telephone Number** |  |
| **UniSA Academic Unit/Institute** |  |
| **Affiliations Other Than UniSA** |  |
| **Funds Source (including Grant ID, if applicable)** |  |
| **Has the Chief Investigator previously applied to this IBC?** | [x]  Yes [ ]  No |
| **If no, please provide as an attachment a brief one-page resume outlining relevant experience, biosafety training and qualifications in relation to working with the microorganisms, plants, invertebrates or animals listed in this application.** |

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| --- | --- |
| **3B** | **Preferred Contact Person** |
| **Same as above** | [ ]  Yes [ ]  No |
| **Preferred Contact Person Name** | **­­** |
| **Email Address** |  |
| **Telephone Number** |  |
| **UniSA Academic Unit/Institute** |  |
| **Affiliations Other Than UniSA** |  |

|  |  |
| --- | --- |
| **3C** | **Other Personnel****Note: Please notify biosafety@unisa.edu.au if there is a change of personnel.** |
| **Senior Research Staff****Name and Institution Affiliation** | **Post-Doctoral Research Staff****Name and Institution Affiliation**  |  **Research and Senior Research Assistants** |
|  |  |  |
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|  |  |  |
| **Postgraduate Students****Name and Student ID** | **Hons/Undergraduate Students****Name and Student ID** |  **Proposed or Actual, Overseas-based Collaborators or Affiliates Associated With This Project** |
|  |  |  |
|  |  |  |
|  |  | **Other Persons****e.g., UniSA Facility Personnel** |
|  |  |  |
|  |  |  |
|  |  |  |

| **4** | **Protocol** |
| --- | --- |
| **Brief Description of the Work in Simple Terms** |
|  |
| **Protocol Details***Note:* If more than one type of dealing is included on this application, please ensure that the work associated with each dealing type is clearly identified and outlined. |
|  |

| **5** | **Hazard Details** |
| --- | --- |
| **Please include the details for all biologically hazardous material for which the Chief Investigator is seeking approval for use** |
| **Material Identification *Including Primary Human or Animal Tissue/Bodily Fluids*** | **Manufacturer / Source** | **Listed as****Risk Group 2 In** **AS/NZS 2243.3 or Other Reference**  | **Listed as** **Risk Group 2 by Manufacturer** | **Transmission Route**  |
|  |  | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Yes[ ]  No[ ]  N/A | [ ]  Aerosol[ ]  Ingestion[ ]  Inoculation |
|  |  | [ ]  Yes[ ]  No [ ]  N/A | [ ]  Yes[ ]  No[ ]  N/A | [ ]  Aerosol[ ]  Ingestion [ ]  Inoculation |
|  |  | [ ]  Yes[ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Aerosol [ ]  Ingestion[ ]  Inoculation |
| **5A** | **Available Risk Management Resources** |
| [ ]  PC2 or Above Laboratory | [ ]  Sharps precautions | [ ]  Sealable Transport Containers  | [ ]  Pipette Aid | [ ]  Safety Glasses | [ ]  BSCII |
| [ ]  Waste Management  | [ ]  Decontamination | [ ]  Sealable Centrifuge Buckets or Rotors | [ ]  Spills Kit | [ ]  Closed-in Shoes | [ ]  Gloves |
| [ ]  Disposable Gown | [ ]  Surgical Mask | [ ]  Certified P2/N95 Respirator Mask | [ ]  Cloth Gown |  |  |

| **6** | **Security Sensitive Biological Agents** |
| --- | --- |
| **Is the biological hazard listed as a SSBA under Part 3 of the National Health Security Act 2007 (**[**http://www.health.gov.au/ssba#list**](http://www.health.gov.au/ssba#list)**)?**  |
| [ ]  Yes [ ]  No  | **If yes, please contact University Biosafety Officer (****biosafety@unisa.edu.au****) prior to submitting this form.** |

| **7** | **Risk Assessment and Management** |
| --- | --- |
| **Human Health****What are the possible hazard(s) to human health?** |
|  |
| **Human Health****How will the risks to human health be minimised and managed?** (Please include any vaccinations required or undertaken by staff and HDR students) |
|  |
| **Human Health****What is the likelihood of harm after risk minimisation strategies have been applied?** **(See** [**Appendix 1**](#_Appendix_1) **for definition of likelihood)** |
|  |
| **Spills****What spills procedures will be enacted in the event of a spill?** |
|  |
| **First Aid Treatment and Incident Reporting****What first aid treatment and incident reporting will be enacted?** |
|  |
| **Vaccination - If there is a hazard to human health, please list any vaccines available for the Risk Group 2 microorganisms used or likely to be contained within the samples.** |
|  |
| **If there is no vaccine available against one or more microorganisms used in this project, will immunocompromised persons be permitted to work with the microorganism?** |  [ ]  Yes [ ]  No If yes, will their work practices be changed to reduce the risk of infection? (Please describe) |
|  |

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| **7** | **Risk Assessment and Management** |
| **Will conducting this dealing pose a safety risk to other staff, students, animals or insects but are not directly associated with the project but who occupy the same facilities or share equipment?****If yes, what are:****a) the possible hazard(s) to other personnel or animals within the facilities,****b) the safety precautions that will be taken to protect them, and****c) how will staff and HDR students be notified of the risk****d) the likelihood of harm (See** [**Appendix 1**](#_Appendix_1) **for definition of likelihood)** |
|  |
| **Environmental Risks** *Note:* The environment includes water, soil, plants, air, insects and animals outside the laboratory. Risks can come from amongst other things: ova, embryos, sperm and seeds.  | Is there any likelihood of release into the environment?[ ]  Yes [ ]  No  |
| If Yes, would the inadvertent release of the material outside of the certified facility, pose a risk above that which already exists in the environment?  [ ]  Yes [ ]  No  If Yes, please list: a) possible hazard(s) to the environment, and b) likelihood of harm |
|  |
| **Training****What biosafety and biosecurity training will be conducted?***Note:* It is the responsibility of the project leader to ensure that staff, visiting scientists and students wishing to conduct the dealing, have been trained appropriately. Personnel must indicate to the licence holder that they have read and understood their training by signing a record of their training. This record of training may be reviewed during the IBC annual facility inspection |
|  |
| **Transport****Do you propose to transport the material outside an approved or certified facility?** [ ]  **Yes** [ ]  **No****If Yes, how will the material be transported?**Please include details of:* type of facilities and likely location of origin or destination
* packaging and labelling,
* transportation method,
* who will package and transport,
* decontamination of packaging before and after transport
* accounting processes

*Note:* “Transport” includes importing and exporting to or from UniSA or the Australian boarder, and between facilities within the same building. This applies to all life stages of the microorganism/s. |
|  |
| [ ]  **Import** the biological material into UniSAIf selected, complete the following details.Is the import subject to quarantine approval?[ ]  Yes Import Permit ID [ ]  No From where do you wish to import the biological material?Country: Institution or Company:  |
| [ ]  Transport the biological material**Within Australia, inside or from UniSA facilities**To which IBC certified facility will it be transported? (If specific details are unknown then please list the likely location and type of facility to which the biological material will be transported.)What is the Physical Containment level of this facility? **Export Outside of Australia**Country: Facility and Institution or Company: Physical Containment level of the facility and Regulator/IBC Certification:  |
| **Storage - Describe the storage method and storage facilities.** |
|  |
| **Disposal - How will the biologically hazardous material and their products be disposed of?**  |
|  |
| **References relevant to the dangers or safe use of the material to be used.**  |
|  |

| **8** | **Facilities** |
| --- | --- |
| Clearly identify the laboratories (including room numbers) where the biologically hazardous material(s) will be used and where stored |
|  | **Facility 1** | **Facility 2** | **Facility 3** |
| **Room Number(s)** |  |  |  |
| **Building** |  |  |  |
| **Type of Facility**  |  |  |  |
| **Facility Manager** |  |  |  |
| **Aspects of protocol to be performed in this facility** |  |  |  |
|  | **Facility 4** | **Facility 5** | **Facility 6** |
| **Room Number(s)** |  |  |  |
| **Building** |  |  |  |
| **Type of Facility** |  |  |  |
| **Facility Manager** |  |  |  |
| **Aspects of protocol to be performed in this facility** |  |  |  |
| **Will the dealing involve storage of the Biological Hazard outside of a facility listed above?** | [ ]  Yes [ ]  No |
| **If yes, where?** |  |

|  |  |
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| **9** | **Compliance Declaration** |
| I certify that I am aware of and have access to the Australian/New Zealand Standard 2243.3 (Safety in laboratories – Microbiological safety and containment); that I will take responsible care with the use of biologically hazardous material(s) specified in this application, and that all staff and students involved will be properly instructed in the safe use and disposal of such material(s). |
| **Project Leader Name** | **Project Leader Signature** | **Date**  / /  |

|  |  |
| --- | --- |
| **10** | **Facility Manager Declaration** |
| As Facility Manager I have been informed of the nature of and risks involved with this biological hazard(s) and after consideration of them, I hereby consent to the work being performed in the listed facility.I declare that:Appropriate safety equipment is available for this project.I will establish, review and monitor microbiological facility safety procedures. I will ensure that an Academic Unit/Central Unit/Institute biosafety manual is written and reviewed.Before granting facility access to personnel, I will induct personnel into relevant microbiological facility safety procedures, including the reading of the biosafety manual.I will ensure that if respiratory or mucosal infectious pathogens are used within these facilities, that a spills clean-up team is established, and trained in cleaning up spills outside of a Biosafety Cabinet or Cytotoxic Cabinet. In the event of an incident or accident I am aware that I must put into place the appropriate responses, and I will inform the IBC as soon as practicable of any incidents or accidents. |
| **Manager: Technical Services** **Name** | **Manager: Technical Services** **Signature** | **Date** |
| **Facility 1** | **Facility 1** |  / /  |
| **Facility 2** | **Facility 2** |  **/ /**  |
| **Facility 3** | **Facility 3** |  **/ /**  |
| **Facility 4** | **Facility 4** |  **/ /**  |

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| **11** | **Head of Academic Unit/Institute Declaration** |
| As the Senior Manager responsible for the research activities of the Chief Investigator, I have been informed of the nature of and risks involved with this biologically hazardous material(s). I certify that appropriate facilities and procedures are in place for the safe use of the material(s) specified and I hereby consent to the work. |
| **Dean of Research or Dean of Programs or Director** **Name** | **Dean of Research or Dean of Programs or Director****Signature** | **Date** |
|  |  |  / /  |

|  |  |
| --- | --- |
| **Office Use Only** | **Foreign Arrangement Approval** |
| Approval has been granted to conduct this dealing with the foreign entity listed below. |
| **Name of Overseas-based Collaborators/Affiliates or Contract/Arrangement, potential or actual** |  |
| **Name of Manager: Research Integrity** | **Signature of Manager: Research Integrity** | **Date** / /  |

# Appendix 1

|  |  |
| --- | --- |
| **LIKELIHOOD** | **DEFINITIONS OF LIKELIHOOD** **(Based on the WHO Laboratory Biosafety Manual 2020)** |
| **Very Likely** | Frequent exposure to or release outside the laboratory of pathogen, allergen, toxin or biosecurity hazard:* through the route of transmission
* at high concentrations or volume, such as culturing, above infectious dose
* infectious at a low infectious dose
* infectious by airborne route, used in laboratory activities associated with aerosolization (for example, sonication, homogenisation, centrifugation and pipetting) outside of a Biosafety Cabinet Level II or sealed container
* personnel entering area within 48 hours of aerosol contamination with respiratory infectious biological agent, without wearing a respirator
* infectious by contact and handled without PPE
* infectious by inoculation without sharps controls
* infectious by ingestion without procedural controls
* transmitted by fomite without protection
* which is communicable amongst other laboratory workers or external community contacts without procedural controls
* pathogen highly stable in the environment, with no denaturing or decontamination protocols
* academic or research staff, cleaning staff and students have low proficiency, experience, understanding or failure to comply with biosafety and biosecurity risk mitigation processes
* no vaccination available or undertaken, and no endemicity against an exotic disease
* staff or students are immunocompromised
* inadequate or poor availability of electrical power, dilapidated laboratory facilities, malfunctioning or damaged equipment. Facilities susceptible to boundary breaches from severe weather and access of insects and rodents to the laboratory.
* insect, animal, fish and their ova and sperm, seeds, plants and other organisms transportable or able to escape through a breach of biocontainment.
* Large susceptible population within the laboratory
 |
| **Likely** | Infrequent exposure to pathogen, allergen, toxin of biosecurity hazard, as above, and infrequent or inadequate use of risk mitigation proceduresFrequent exposure to pathogen, allergen, toxin or biosecurity hazard at low concentrations, and infrequent or inadequate use of risk mitigation procedures |
| **Unlikely** | Rare exposure to pathogen, allergen, toxin of biosecurity hazard, as above, and frequent and proper use of all risk mitigation proceduresFrequent exposure to pathogen, allergen, toxin or biosecurity hazard at low concentrations and frequent and proper use of all risk mitigation procedures |
| **Very unlikely** | Exposure to pathogen, allergen, toxin of biosecurity hazard, as above, can happen but probably never willPathogen, allergen, toxin of biosecurity hazard has been inactivated |