**Biological hazards are organic substances that pose a threat to the health of humans and other living organisms. Biological hazards include pathogenic micro-organisms, viruses, toxins (from biological sources), spores, fungi and bio-active substances. Examples include 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 hazardous biological material, potential or actual, in UniSA premises.**

The Australian and New Zealand Standard for Safety in Laboratories 2243.3 is available through the [UniSA Library](https://www.library.unisa.edu.au/). 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** |  |

|  |  |
| --- | --- |
| **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?** |  |

|  |  |
| --- | --- |
| **3** | **Key Contacts** |
| **3A** | **Project Leader** |
| **Project Leader’s Name** |  |
| **Email Address** |  |
| **Telephone Number** |  |
| **UniSA Academic Unit/Institute/Centre** |  |
| **Affiliations Other Than UniSA** |  |
| **Has the Chief Investigator previously applied to this IBC?** | [ ]  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.** |

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

| **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 hazardous biological 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[ ]  N/A |
|  |  | [ ]  Yes[ ]  No [ ]  N/A | [ ]  Yes[ ]  No[ ]  N/A | [ ]  Aerosol[ ]  Ingestion [ ]  Inoculation [ ]  N/A |
|  |  | [ ]  Yes[ ]  No[ ]  N/A | [ ]  Yes [ ]  No[ ]  N/A | [ ]  Aerosol [ ]  Ingestion[ ]  Inoculation[ ]  N/A |
| **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 Identification** |
| --- | --- |
| **Human Health** **What are the possible hazards to human health?** |
|  |
| **Human Error Risk****Will there be any situations which may increase the risk of human error above normal, such as working in cramped spaces, researcher fatigue when conducting long and complex experiments, boredom from performing repetitive tasks, researcher fatigue when working after normal daylight hours, inexperience of personnel when first starting a new PhD, job or project, or distraction caused by things like noise or co-workers?** [ ]  **Yes** [ ]  **No**If ‘Yes’, please describe. |
|  |
| **Volume and Concentration Risk****Will the hazardous biological material be cultured or propagated?** [ ]  **Yes** [ ]  **No**If ‘Yes’, **e**stimate the highest volume and concentration ofhazardous biological material that will be generated. |
|  |
| **Inoculation of Animals or Humans****Will humans or animals will be inoculated with infectious viruses which will cause viremia?**[ ]  **Yes** [ ]  **No**If yes, describe:* How long after inoculation the viremia will last. Please describe the assays used to determine the length of time of viremia.
* If tissue or blood from the inoculated human or animal will be collected after inoculation, how long after inoculation will tissue or blood collection be conducted.
* If the humans or animals will secrete, excrete pathogenic agents or microorganisms in their excrement, skin or fur, how long after inoculation will the humans or animals continue to secrete, excrete pathogenic agents or microorganisms in their excrement, skin or fur. Please describe the assays used to determine this time.
 |
|  |
| **Will conducting this dealing pose a safety risk to other staff, students, animals or insects that are not directly associated with the project but who occupy the same facilities or share equipment?**[ ]  **Yes** [ ]  **No**If ‘Yes’, what are:a) the possible hazard(s) to other personnel, animals or insects within the facilities,b) the likelihood of harm (See [Appendix 1](#_Appendix_1) for definition of likelihood) |
|  |
| **In the event of unintended release outside of biocontainment, are there any possible hazards to the environment above that which already exist in the environment?**[ ]  **Yes** [ ]  **No**If ‘Yes’, please describe the environmental hazards. |
|  |

|  |  |
| --- | --- |
| **8** | **Risk Minimisation** |
| **Spills****What spills procedures will be enacted in the event of a spill?** |
|  |
| **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. |
|  |

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| --- |
| **Importation Into Australia** |
| **Has the hazardous biological material previously been imported into Australia or might be imported into Australia in the future, either by the Project Leader, Academic Unit, Centre, Institute, or any third-party importers?**[ ]  Yes [ ]  No [ ]  Unsure*If ‘Yes’, complete the following details:* |
| Material | Importation Permit Number | Already Imported | To be Imported | Country | Post entry/end use conditions |
|  |  | 0 | 0 |  |  |
|  |  | 0 | 0 |  |  |
|  |  | 0 | 0 |  |  |

|  |
| --- |
| **Importation**Are the goods being imported from a [Security Sanctioned Regime](https://www.dfat.gov.au/international-relations/security/sanctions/sanctions-regimes)? [ ]  Yes [ ]  No ☐ Unsure Are the goods being imported from interstate?☐ Yes ☐ No ☐ UnsureIf ‘Yes’, from which state or territory do you wish to import the biological material?State or Territory: Do any of the goods require an Approved Arrangement?☐ Yes ☐ No ☐ UnsureIf ‘Yes’, Which Approved Arrangement will be used:  |
| **Transport Within Australia** Will the hazardous biological material be transported out of UniSA but within Australia?[ ]  Yes [ ]  No If yes, to which biocontainment facility will the hazardous biological material 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**Will the hazardous biological material be exported outside of Australia?[ ]  Yes [ ]  NoIf yes, please complete the following details.Country: Facility and Institution or Company: Physical Containment level of the facility and Regulator/IBC Certification:  |
| **Storage - Describe the storage method and storage facilities.** |
|  |
| **Surface Decontamination****List all the surface disinfectants used, their concentration, contact time used and expiry.** |
|  |
| **Liquid Waste Decontamination****List all methods used to decontaminate liquid waste, their concentration, contact time and expiry.** |
|  |
| **Solid Waste Disposal****List all methods used to dispose of solid and sharps waste.** |
|  |
| **Vaccination****Does the Australian Immunisation Handbook recommend any vaccines for staff and students directly working with primary samples?**[ ]  Yes [ ]  NoIf yes:1. List the vaccines recommended by the Australian Immunisation Handbook.
2. If vaccination is medically contraindicated or declined, describe any additional procedures to be followed to reduce risk.
3. Describe how immunisations, medical advice and declination of vaccination will be recorded.
 |
|  |
| **Protection of Other People Not Directly Involved**Are other people not directly involved in the process but who work in the biocontainment facility, at risk of exposure?[ ]  Yes [ ]  NoIf yes, describe:a) the safety precautions that will be taken to protect them, andb) how will other personnel be notified of the risk? |
|  |
| **Incident Reporting**How will incidents, injuries or exposure be reported? |
|  |
| **Misconduct and Breaches**How will inadvertent or deliberate, misconduct or breach of biocontainment or biosecurity be reported? |
|  |
| **Other Human Health – Risk Minimisation Steps**Are there any other risk minimisation steps to be undertaken?[ ]  Yes [ ]  NoIf yes, please list. |
|  |
| **References relevant to the dangers or safe use of the material to be used.**  |
|  |

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| **9** | **Risk Assessment** |
| **Risk Assessment****What is the likelihood of harm after risk minimisation strategies have been applied?** **(See** [**Appendix 1**](#_Appendix_1) **for definition of likelihood)** |
|  |

| **10** | **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 Coordinator** |  |  |  |
| **Aspects of protocol to be performed in this facility** |  |  |  |
|  | **Facility 4** | **Facility 5** | **Facility 6** |
| **Room Number(s)** |  |  |  |
| **Building** |  |  |  |
| **Type of Facility** |  |  |  |
| **Facility Coordinator** |  |  |  |
| **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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| **11** | **Project Leader Declaration** |
| I declare that:I am aware of and have access to the Australian/New Zealand Standard 2243.3 (Safety in laboratories – Microbiological safety and containment).I have the experience and knowledge to identify biorisks within this process or have sought advice from other experts.I have identified and declared within this document all the biorisks involved in this process.Where a pathogenic organisms or material is received from sources outside the institution responsible for the project, I will take steps to confirm its identity.The biologically hazardous material(s) will be used, transported, stored and disposed as specified in this document. All staff and students directly under my supervision and involved in the process will be properly instructed in the safe use, transport, storage, and disposal of the biological material(s) specified in this document.All staff and students not directly under my supervision but exposed to potential hazards from this activity will be warned of the potential exposure hazards.If I become aware of any unidentified, unmanaged, or mismanaged biorisk I will take measures to rectify the issue and retrain staff and students under my supervision as necessary.If I become aware of any incident, breach, or misconduct I will notify my line manager (if not conflicted) and the University Biosafety Officer. |
| **Project Leader Name** | **Project Leader Signature** | **Date**  / /  |

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| --- | --- |
| **12** | **Facility Manager/Coordinator Declaration** |
| As the Manager: Technical Services/Laboratory Coordinator I declare that:I have been informed of the nature of and risks involved with this biological hazard(s).Appropriate safety equipment and resources are available and effective for this project. I will ensure that an Academic Unit/Central Unit/Institute biosafety manual is written and reviewed.Before granting facility access to personnel, I will ensure that personnel have completed their facility induction, including the reading of the biosafety manual and completion of any biosafety training.I will facilitate the establishment, implementation, maintenance, promotion and improvement of the biorisk management system within my facility. I will facilitate the review, audit, and reporting measures required to provide assurance that the requirements of biorisk management system are being implemented and maintained effectively. All staff directly under my supervision and involved in the process will be properly instructed in the safe use, transport, storage, and disposal of the biological material(s) specified in this document.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. If I become aware of any unidentified, unmanaged or mismanaged biorisk I will take measures to rectify the issue and if appropriate retrain staff and students using the facility.If I become aware of any incident, breach, or misconduct, I will notify my line manager (if not conflicted), the Project Leader (if not conflicted) and the University Biosafety Officer; andI will monitor/audit compliance to any corrective actions. |
| **Manager: Technical Services or Equivalent** |
| **Name** | **Signature** | **Date** |
| **Facility 1** | **Facility 1** |  / /  |
| **Facility 2** | **Facility 2** |  **/ /**  |
| **Facility 3** | **Facility 3** |  **/ /**  |
| **Facility 4** | **Facility 4** |  **/ /**  |

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| **13** | **Head of Academic Unit/Institute/Centre Declaration** |
| As the Senior Manager responsible for the activities of the Project Leader and Facility Manager/Coordinator, I declare that:I have been informed of the nature and risks involved with this biologically hazardous material and process. I will ensure the provision of appropriate and adequate workers, facilities and other resources deemed necessary for the safe use of the material(s) specified in this document.I will ensure the establishment, implementation, maintenance, promotion and improvement of the biorisk management system within my Academic Unit, Institute or Centre. I will ensure the review, audit, and reporting measures required to provide assurance that the requirements of biorisk management system are being implemented and maintained effectively. I hereby consent to the biological processes as outlined in this document, to be undertaken.If I become aware of any unidentified or unmanaged biorisk, incident, breach, or misconduct, I will notify the University Biosafety Officer. |
| **Dean of Research, Dean of Programs, Executive Dean or Director** |
| **Name** | **Signature** | **Date** |
|  |  |  / /  |

|  |  |
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| **14** | **Other Personnel Declarations** |
| I declare that:I have reviewed this risk assessment. I have been informed of the risks, required risk minimisation measures and provisions for any recommended precautionary medical practices.I agree to conduct all biological work in accordance with the Australian/New Zealand Standard 2243.3 (Safety in laboratories – Microbiological safety and containment), the approved risk minimisation measures as outlined in this document, and relevant biorisk policies and guidelines.I have completed all relevant facility inductions and University required biosafety training.If I become aware of any unidentified or unmanaged biorisk, I will notify the facility technical manager/coordinator and my line manager (if not conflicted). If I become aware of any incident, breach, or misconduct, I will notify my line manager (if not conflicted) and the University Biosafety Officer. |
| **Senior Research Staff** |
| **Name**  | **Organisation**  | **Role in The Biological Project**  | **Declaration Signature** |
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| **Post-Doctoral Staff** |
| **Name** | **Organisation** | **Role in The Biological Project**  | **Declaration Signature** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **Research and Senior Research Assistants** |
| **Name** | **Organisation** | **Role in The Biological Project** | **Declaration Signature** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **Postgraduate Students** |
| **Name** | **Organisation** | **Role in The Biological Project** | **Declaration Signature** |
|  |  |  |  |
|  |  |  |  |
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|  |  |  |  |
| **Hons/Undergraduate Students** |
| **Name** | **Organisation** | **Role in The Biological Project** | **Declaration Signature** |
|  |  |  |  |
|  |  |  |  |

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| --- | --- |
| **Section 15** | **Overseas-based Collaborators or Affiliates** |
| **Proposed or Actual, Overseas-based Collaborators or Affiliates Associated with This Project** |
| **Name** | **Organisation** | **Role in The Biological Project** |
|  |  |  |
| **Other Persons****e.g., UniSA Facility Personnel** |
| **Individual or Group Name****e.g. CAF Staff** | **Organisation** | **Role in The Biological Project** |
|  |  |  |
|  |  |  |
| **Office Use Only** | **Foreign Arrangement Approval** |
| Approval has been granted to conduct this dealing with the foreign entity listed below. |
| **Overseas-based Collaborators/Affiliates or Contract/Arrangement, potential or actual** |
| **Name** | **Organisation** | **Sanctioned Regime** |
|  |  |  |
|  |  |  |
| **Manager: Research Ethics and Compliance** |
| **Name** | **Signature** | **Date** |
|  |  |  / /  |

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| **16** | **Exposure Response**  |
| **First Aid**What first aid treatment or initial response must occur if at risk humans, animals, the environment, or the community are exposed to hazardous biological material used in this process? |
|  |
| **Medical Practitioner Information**List any relevant information which might be helpful to medical practitioners in an emergency response to exposure. |
|  |
| **Exposure Reporting**What reporting must be conducted if exposure occurs? |
|  |

# Appendix 1

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| --- | --- |
| **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 |