**This application form should be completed for minor changes to biological hazardous dealings, approved by the UniSA Institutional Biosafety Committee. Minor changes are defined as changes to facilities, transport, storage, disposal or personnel. Changes to protocol or microorganism constitute a new Biological Hazard Dealing; and a new Biological Hazard Dealing application form will need to be completed and submitted to the IBC.**

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

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| ***NOTE: Confidentiality*****If you wish to make an application for a declaration that specifies information is Confidential Commercial Information (CCI) for the purposes of the Act, you must also complete the CCI application form available at** [**www.ogtr.gov.au**](http://www.ogtr.gov.au) **and place it at the end of this application.** |

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|  | **IBC Reference Number** |  |

|  |  |
| --- | --- |
| **1** | **Preliminary information** |
| **Project Title** |  |
| **Proposed commencement date** | **Date** / / |
| **Expected completion date** | **Date** / / |

|  |  |
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| **2** | **Person responsible for dealing** |
| **2A** | **Project Leader**  |
| **Project Leader** |  |
| **Email Address** |  |
| **Telephone Number** |  |
| **UniSA Academic Unit/Institute/Centre** |  |
| **Affiliations Other Than UniSA** |  |
| **2B** | **Preferred Contact Person** |
| **Same as above** | [ ]  Yes  [ ]  No If No, then complete the details below. |
| **Preferred Contact Person Name**  |  |
| **Email Address**  |  |
| **Telephone Number**  |  |
| **UniSA Academic Unit/Institute/Centre**  |  |
| **Affiliations Other Than UniSA** |  |

| **3** | **About the Modification** |
| --- | --- |
| **Import/Export****Do you intend to change the importation or exportation of the dealing?** | [ ]  Yes [ ]  NoIf ‘Yes’, give details below. |
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|  |  |
| --- | --- |
| **Transport****Do you wish to change the transport arrangements for transporting material outside a certified facility?** 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 processesNote: “Transport” includes importing and exporting to or from UniSA, through the Australian boarder, and between facilities within the same building. This applies to among other things, life stages of GMOs such as ova, sperm, embryos and seeds.  |  [ ]  Yes [ ]  NoIf ‘Yes’, how will the material be transported? |
|  |
| **Do you intend to change the storage conditions or locations of the material?**  |  [ ]  Yes [ ]  NoIf ‘Yes’, how and where will it now be stored? |
|  |
| **Do you wish to change the method of disposal?**  | [ ]  Yes [ ]  NoIf ‘Yes’, how do you wish to change the dispose? |
|  |

| **3** | **About the Modification** |
| --- | --- |
| **Risk Level****Will the proposed modifications change the biosafety risk to staff, students, animals or insects within the facility, both those involved in the project directly or indirectly (including those who share equipment)?** | [ ]  Yes [ ]  NoIf ‘Yes’, what are:1. the possible hazard(s) to personnel or animals within the facilities,

b) the likelihood of harmc) the safety precautions that will be taken to protect them, andd) how will staff and HDR students be notified of the risk |
|  |
| **Environmental Risks** **Is there any likelihood that the changes will increase the risk of release into the environment?**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. | [ ]  Yes  [ ]  No |
| If ‘Yes’, would the inadvertent release of the material outside of the contained facility, pose a risk above that which already exists in the environment? [ ]  Yes  [ ]  NoIf ‘Yes’, please list how the changes to the protocol: a) pose possible hazard(s) to the environment, b) the likelihood of harmc) what steps will be taken in the event of an unintentional release of the pathogenic organisms or material(s) |
|  |

| **4** | **Changed Facilities** ***(Leave blank if facilities will not be changed)*** |
| --- | --- |
| **All facilities to be used, including places of storage must be authorised. Storage of Risk Group 2 pathogenic organisms or materials outside of an IBC approved PC2 facility must be authorised by the IBC.**  |
|  | **Facility 1** | **Facility 2** | **Facility 3** |
| **Room Number(s)** |  |  |  |
| **Building** |  |  |  |
| **Type of facility**  |  |  |  |
| **Facility Manager** |  |  |  |
| **Experiments/aspects of dealing to be performed in this facility** |  |  |  |
|  | **Facility 4** | **Facility 5** | **Facility 6** |
| **Room Number(s)** |  |  |  |
| **Building** |  |  |  |
| **Type of facility** |  |  |  |
| **Facility Manager** |  |  |  |
| **Experiments/aspects of dealing to be performed in this facility** |  |  |  |
| **Will the dealing involve storage of Risk Group 2 pathogenic organisms or materials outside of an IBC Approved facilities listed above?** | [ ]  Yes [ ]  NoIf ‘Yes’, where? |
|  |

| **5** | **Change of Persons Undertaking the Dealing**  |
| --- | --- |
| **The IBC must assess whether the persons or categories of persons have appropriate training and experience to undertake the dealing. This includes persons beyond the persons conducting the research, such as persons involved in important, transportation and disposals of pathogenic organisms or material.** |
| **Additional Investigators**Indicate the categories of persons that will be involved with the dealing. For each relevant category, list the name and staff/student ID for persons know at the time of writing this application. |
| **Name** | **Signature of Additional Personnel****I declare that I:*** **have read and understood the IBC approved risk assessment and risk mitigation strategies.**
* **agree to comply with the risk mitigation strategies.**
* **will report any incidents or acts of non-compliance to my line manager, the Laboratory Manager and Biosafety@unisa.edu.au.**
 |
| **Hons/undergraduate students** **Name:**  |  |
| **Postgraduate students** Name:  |  |
| **Research staff** **Name:**  |  |
| **Overseas-based Collaborator/Affiliate or Contract/Arrangement****Name:** |  |
| **Other Persons**  **Name:** |  |
| **Personnel of the facilities listed on this application**  **Name:** |  |
| **Please list the training that persons involved in the project have received.**  |
|  |
| **Removal of Investigators****Have personnel ceased working on the project?** | ☐ Yes ☐ No If ‘Yes’, please list their names. |
|  |
| **Vaccination****Will the modifications require personnel (including persons who wish to join the project) to undertake vaccinations?** |  [ ]  Yes  [ ]  No |
| If ‘Yes’, please list the names of personnel who will require the vaccinations, and the vaccinations required against each name. |
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| **6** | **Project Supervisor Declaration** |
| **Please initial each of the following statements to indicate that you understand your responsibilities when dealing with pathogenic organisms or materials and then sign the application form.** |
| 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 will safely use, transport, storage and disposal of biologically hazardous material(s) specified in this document. |
| I am aware of my responsibilities in relation to ensuring that any personnel conducting this work are appropriately trained and are aware of and follow the relevant guidelines and regulations. |
| I have identified and declared within this document all the biorisks involved in this process; |
| 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. |
| 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. |
| 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. |
| I will inform my line manager (if not conflicted), the University Biosafety Officer and the IBC as soon as practicable of any infections, incidents, accidents or environmental releases involving pathogenic organisms or materials. |
| **Project Supervisor Name** | **Project Supervisor Signature** | **Date**  / /  |

Please submit this form to the IBC Executive Officer at biosafety@unisa.edu.au after completing Sections 1 to 6, and

before seeking the signature of facility manager/coordinator.

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| **7** | **Facility Manager Declaration** |
| As Facility Manager/Coordinator I declare that:I have been informed of the nature of and risks involved with this biological hazard(s);Appropriate safety equipment is available within the listed facilities 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 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; 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. 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;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** **Name** | **Manager: Technical Services** **Signature** | **Date** |
| **Facility 1** | **Facility 1** |  / /  |
| **Facility 2** | **Facility 2** |  **/ /**  |
| **Facility 3** | **Facility 3** |  **/ /**  |

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| **Office Use Only** | **Foreign Arrangement Approval** |
| **Approval has been granted by University of South Australia 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 Ethics and Compliance** | **Signature of Manager: Research Ethics and Compliance** | **Date** / /  |