Guide on how to complete the Application for Biosafety Clearance Form

*Guidance notes:*

* *This form is required by the Swinburne Biosafety Committee for biosafety clearance.*
* *Please write from a biosafety perspective (while the science is interesting the job of the SBC is only to evaluate biosafety).*
* *Be future focused – For example if you currently work on heat stress genes and may in the future want to expand that to include cold tolerance record it as genes involved in abiotic stress responses.*
* *One form can be used to cover multiple projects/people. The SBC envisage each lab head having to fill this form in once to cover all their projects – unless there is a dramatic difference in the risk profile of their projects.*
* *The lab head completing the form is taking legal responsibility for all projects and people covered by the form.*

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| 1 | Project Title/High-level description of the activity (<100 words) |
| *The aim of this is to provide context for the risk assessments and SOPs.*  *Examples:*  *Expression of vaccine antigens in* Nicotiana benthamiana, tobacco, carrot and lettuce using standardAgrobacterium tumefaciens *mediated methods for the generation of stable-transgenic and transiently infiltrated plants* *. Individual genes from malaria and measles will be expressed. Measles and malaria pathogens will not be used (just cloned genes). The genes to be used do not encode toxins, virulence factors or pathogenic determinants.*  *Or*  *Investigation of microorganisms found in soil samples collected from around Victoria, Australia. It is expected that all microorganisms will be RG2 bacteria or lower.*  *Or*  *Investigation of the incidence of STDs, in clinical samples collected from Australian hospitals. The study will characterize the STDs with regard to their genotype and virulence in cell culture. Blood samples will be used to analyses host immune responses.* | |

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| 2 | Responsible Person Supervisor | | |
| **Name**: | | | |
|  | | **Other personnel associated with the project** \* | |
| **Role on project** *(e.g. PhD student, Research Assistant, Biosafety Officers, Laboratory Manager, co-CI)* | | | **Training/Qualification and/or supervision** |
| *PhD students* | | | *BSc(hons) or Masters. Supervision and training by postdocs and/or lab head.* |
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| 3 | Facility/Room where activity is occurring, and any certifications |
| *Certifications refers to, for example, OGTR PC2 certification* | |

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| 4 | Does the activity involve *(please tick all the boxes that apply)* |
| Genetically modified organisms (please also complete form for Exempt/NLRD)  Handling clinical or environmental samples (please complete question 4a)  Isolation, enrichment or culture of unknown microorganisms from clinical or environmental samples that are likely or are known to contain Risk Group 2 microorganisms (please complete question 4b)  Work involving Risk Group 3 or 4 microorganisms (please complete question 4b)  Work involving Security Sensitive Biological Agents (please complete question 4b)  Work involving Quarantine Materials (please complete question 4c)  Other (describe below) | |
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| 4a | What is the source of clinical or environmental samples |
| *Examples:*   * *Pre-screened blood samples from the Australian Red Cross blood bank* * *Blood and tissue biopsy samples from patients at the Alfred hospital HIV clinic* | |
| 4b | For known or suspected microorganisms – please provide species/strain details, and risk group classification |
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| 4c | Please provide the type of quarantine material, and permit number(s) |
| *Type of material = for example; antibody/cell lines/DNA/plant/animal (whole or part-thereof) etc* | |

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| 5 | Standard Operating Procedures/Risk Assessments (please list them here; if not using the Swinburne pre-approved SOPs/RAs, attach to this form) |
| *Please use approved SOPs/RAs where possible. New SOPs and RA should be attached to your application.*  *The following SOPs and RAs have been approved by the SBC and are available for use across Swinburne*   * *SOP and Risk Assessment: Working with human blood, plasma, tissue and other body fluids* * *Risk Assessment: General Risk Assessment for working with Risk Level 2 Bacteria in all Swinburne PC2 laboratories (according to Australian and New Zealand standard AS 2243.3)* * *Risk Assessment : Use and propagation of risk level 2 human and animal cells in all Swinburne PC2 laboratories (according to Australian and New Zealand Standard AS 2243.3)* | |

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| 6 | Project Supervisor declaration |
| I declare that:  • all current and new personnel working under this approval have undergone appropriately training and will be appropriately supervised. Training records will be maintained, and are available upon request  • Standard Operating Procedures and Risk Assessments will be completed as required, and will be read and understood by all personnel working on the project  • The SBC will be notified of any changes to the project, or if unexpected results alter the risks associated with the project  • facility access will be restricted to authorised personnel only  • all other regulatory requirements will be met. | |
| **Signature:** | |