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| **An electronic copy of the original application (saved as a PDF) is to be submitted to the relevant Faculty Biosafety Committee as per the details below:**  **ENQUIRIES AND SUBMISSIONS TO:**  **Faculty of Health Sciences**  Olivia Langenhoven;  Telephone: 021 650 5677  [Fhs.fbc@uct.ac.za](mailto:Fhs.fbc@uct.ac.za)  **Faculty of Science**  Dr Thomas Oelgeschläger;  Telephone: 021 650 4115 [thomas.oelgeschlager@uct.ac.za](mailto:thomas.oelgeschlager@uct.ac.za)  **Faculty of Engineering and the Built Environment**  Please submit to the Faculty of Science (see above) | ***For office use only*** | |
| F/IBC Reference Number |  |
| Request for expedited review? (YES/NO)  *(Note: Expedited Review will only be granted in exceptional circumstances, and will require strong motivation; please attach separate motivation letter;* ***late/delayed submission of F/IBC application does not constitute valid grounds for expedited review****)* |  |
| Risk Assessment:  (guidance categories) |  |
| Highest Containment level required  (BSL1, BSL2, BSL3) |  |
| Date complete amendment application received by FBC |  |
| Date FBC approved the amendment |  |
| Date IBC approved the amendment |  |

# Key information

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|  | **Please complete all fields** |
| 1. Name and Surname of PI |  |
| 1. Department |  |
| 1. Email address of PI |  |
| 1. Project Title |  |
| 1. Start date of Project |  |
| 1. End date of Project |  |
| 1. F/IBC Reference number |  |
| 1. Date of original F/IBC approval |  |
| 1. Cover letter required – confirmation that this has been attached to the amendment application form. (YES/NO) |  |
| 1. Request for expedited review? (YES/NO)   ***(Note: Expedited Review will only be granted in exceptional circumstances, and will require strong motivation; please attach a separate motivation letter;******late/delayed submission of F/IBC application does not constitute valid grounds for expedited review****)* |  |

# When to complete this form

This amendment application is used to request approval for ANY changes regarding the organisms, biological agents, and/or experimental procedures associated with an approved F/IBC project, which may alter the biosafety risks or scope of the project. It is also used to change the Principal Investigator responsible for the research project, the personnel involved, and/or the location of any part of the research project.

***\*Note: If substantial changes are proposed, a new application form must be completed.***

# ****Purpose of the amendment request****

# **Indicate which elements of the approved project will change. Provide all the required information corresponding to the selected elements in Section 2 by clicking on the relevant hyperlink/s in the table below:**

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|  | **Tick all relevant boxes** |
| [GMMs](#_2.1_GMMs:_Describe) |  |
| [GMOs](#_2.2_GMOs:_Describe) |  |
| [Biological agents](#_2.3_Biological_agents:) |  |
| [Animals](#_2.4_Animals:_Describe) |  |
| [Experimental procedures](#_2.5_Experimental_procedures:) |  |
| [Location of work or storage of biological agents](#_2.6_Describe_changes) |  |
| [Personnel changes](#_2.7.2_Addition_or) |  |
| [Facility registrations or permits](#_2.8_Were_any) |  |
| Temporary Extension of study (Note: this is limited to 12 months maximum; requests for extension exceeding 12 months will require submission of a full renewal application) |  |

# Complete the following section for each proposed change indicated in Section 1.

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| 2.1 GMMs: Describe the proposed changes to the host microorganism, source of DNA, the vector used, gene inserted, or any other change to the GMM. |
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| After conducting a biological risk assessment of the new GMM (see F/IBC application form), do you conclude that the risk category/classification of the GMMs developed or handled in this study will change? (Consider the containment/biosafety level, required containment equipment, dual-use potential, etc.) YES or NO. If “YES”, describe the additional risk mitigation measures that will be implemented. If “NO”, please justify briefly. |
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| 2.2 GMOs: Describe all proposed changes to the initial plan to develop or use GMOs. |
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| After conducting a biological risk assessment of the new GMO (see F/IBC application form), do you conclude that the risk category/classification of the GMOs developed or handled in this study will change? (Consider the containment/biosafety level, required containment equipment, dual-use potential, etc.) YES or NO. If “YES”, describe the additional risk mitigation measures that will be implemented. If “NO”, please justify briefly. |
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| 2.3 Biological agents: Describe the proposed changes regarding the biological agents used in the study (e.g., collect a different type of biological/clinical sample, include a different pathogen, parasite, or cell line, etc.). |
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| After conducting a biological risk assessment of the new biological agents (see F/IBC application form), do you conclude that the risk category/classification of the biological agents handled in this study will change? (Consider the containment/biosafety level, required containment equipment, etc.) YES or NO. If “YES”, describe the additional risk mitigation measures that will be implemented. If “NO”, please justify briefly. |
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| 2.4 Animals: Describe the proposed changes regarding animals that will be used or handled in the project. |
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| After conducting a biological risk assessment of the new animal/s (see F/IBC application form), do you conclude that the risk category/classification of the animals used or handled in this study will change? (Consider the containment/biosafety level, required containment equipment, etc.) YES or NO. If “YES”, describe the additional risk mitigation measures that will be implemented. If “NO”, please justify briefly. |
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| 2.5 Experimental procedures: Describe the proposed changes to the methods, reagents, or scale of operation. |
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| After conducting a biological risk assessment considering the microorganisms, animals or biological agents used in the study and the proposed new procedure, do you conclude that the risk category/classification of this part of the study will change? (Consider the containment/biosafety level, required containment equipment, etc.) YES or NO. If “YES”, describe the additional risk mitigation measures that will be implemented. If “NO”, please justify briefly. |
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| 2.6 Describe changes in the location of the work (e.g., a different laboratory or facility, a different containment level, etc.), collection of samples (e.g., from a different area within South Africa) or storage of biological materials. |
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| Describe any new or additional risk mitigation measures that will be implemented. Consider whether the proposed new location of the work and/or storage of samples provides adequate containment (biosafety level) or whether the new sampling site is located within an area flagged for a controlled disease. |
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| 2.7 Personnel changes2.7.1 New Principal Investigator. Provide the details of the new PI (Name, staff number, department, contact details, etc.), and attach the new PI’s completed Reg.Work1: Registration of Personnel Using Biological Material Form. |
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| 2.7.2 Addition or removal of personnel. Provide the details of the new personnel (name, staff/student number, contact details) and the names of personnel who must be removed. Each person added to the project must complete the Reg.Work1: Registration of Personnel Using Biological Material Form. Attach the forms to the Amendment application. |
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| 2.8 Were any statutory facility registrations or permits issued for this study? YES or NO. If YES, has the permit or certificate issuing office been informed of these changes? |
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| 1. **DECLARATION BY APPLICANT (Principal Investigator)** |
| * Biological risk assessments of all the proposed changes to the organisms and procedures in this study have been carried out as required and are described or attached. * All new Research Workers on this project will automatically be registered following the approval of the project by the Faculty and Institutional Biological Safety Committee (F/IBC). I understand that work involving Genetically Modified Organisms (GMOs) and some work involving biological agents/materials that are not genetically modified must await authorisation from the Institutional Biosafety Committee before work can commence.   Applicant Signature: Date: |

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| 1. **DECLARATION BY APPLICANT’S HEAD OF DEPARTMENT** |
| **I confirm that I have read and understood the risk assessment relating to this project;** in my opinion, the Principal Investigator is competent to perform and oversee the work described which will be performed in a facility(ies) which complies with all relevant biosafety requirements. I therefore support this application.  HoD Signature: Date:  Department: |