**FORM 4 RESEARCH ETHICS REVIEW REPORT**

1. **Reference number**

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1. **Full name of applicant**

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1. **Title or provisional title of the study**

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| **4.** | **Is the application of an acceptable standard?** |

**YES NO**

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| **a)** The application that was submitted may be **approved.**  |  |
| **b)** The application that was submitted should be **referred back for the following revisions/modifications.** |  |
| *(please specify below)* |
| **Suggested revisions/modifications:** |
|  |
| **c)** The research application should be **disapproved** for the following reasons |  |
| *(please specify below)* |
| **Reasons for disapproving the proposal:** |

**5. ASSESSMENT OF THE REASONABLE GUARANTEES AND SAFEGUARDS**

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| **5.1** | **Checklist to ensure that all the reasonable guarantees and safeguards for the ethics of this study have been covered** (adapted from Amdur, Kornetsky & Khan, 2011) | **YES** | **NO** | **N/A** | **FORM****REF. #** |
| *(Place x in box)* |  |
| a) | Do the new proposed amendments in the study raise the study risk level?  |  |  |  | 2.3 & 2.8 |
|  | **Comment** |  |  |  |  |
| b) | Are the risks well mitigated? |  |  |  | 2.8 |
|  | **Comment** |  |  |  |  |
| c) | Has the research procedures been implemented as detailed in the proposal or has there been a deviation? |  |  |  | 2.7 |
|  | **Comment** |  |  |  |  |
| d) | Has the cause of deviation been adequately explained? |  |  |  | 2.7 |
|  | **Comment** |  |  |  |  |
| e) | Has any of the participants suffered unexpected adverse harm?  |  |  |  | 2.12 |
|  | **Comment** |  |  |  |  |
| f) | Did the researcher give an adequate explanation of how (s)he dealt with the unexpected harm? |  |  |  | 2.12 |
|  | **Comment** |  |  |  |  |
| g) | Did the researcher report the harm to the ERC and in time? |  |  |  | 2.12 |
|  | **Comment** |  |  |  |  |
| h) | Did any of the participants lodge a complaint with the researcher or against the researcher? |  |  |  | 2.13 |
|  | **Comments** |  |  |  |  |
| i) | At this stage of the research study, has there been any ethical issues with the study; if so, is there an explanation of how they were dealt with? |  |  |  | 2.14 |
|  | **Comments** |  |  |  |  |
| j) | If there has been any ethical issues, did the researcher give sufficient explanation of how (s)he has dealt with them? |  |  |  | 2.14 |
|  | **Comment** |  |  |  |  |
| k) | Does he or she/they have a conflict of interest? |  |  |  | 2.9 |
|  | **Comment:** |  |  |  |  |
| l) | Are the objectives likely to be achievable within the requested time period? |  |  |  | 2.4 & 2.6b |
|  | **Comment:**  |  |  |  |  |
| m) | Is the scientific design adequate to answer the research question and accommodate the proposed amendments? |  |  |  | 2.4 & 2.6b |
|  | **Comment:** |  |  |  |  |
| n) | Is the scientific design described and adequately justified? |  |  |  | 2.4 |
|  | **Comment:** |  |  |  |  |
| o) | Is the choice of additional participants appropriate for the question being asked? |  |  |  | 2.4 & 2.9 |
|  | **Comment:** |  |  |  |  |
| p) | Is participant selection equitable (distributive justice/fairness)? |  |  |  | 2.4 & 2.9 |
|  | **Comment:** |  |  |  |  |
| q) | Are the methods for recruiting additional potential participants acceptable? |  |  |  | 2.4 & 2.9 |
|  | **Comment:** |  |  |  |  |
| r) | Are the rationale and the proposed number of participants reasonable? |  |  |  | 2.4 & 2.9 |
|  | **Comment:** |  |  |  |  |
| s) | Are the risks and benefits adequately identified, evaluated and described? |  |  |  | 2.3, 2.4 & 2.8 |
|  | **Comment:** |  |  |  |  |
| t) | Is the risk/benefit ratio acceptable for proceeding with the research? |  |  |  | 2.3, 2.4, 2.8 & 2.12 |
|  | **Comment:** |  |  |  |  |
| u) | Did the new requested amendments give rise to the need to amend the informed consent form and has it been amended accordingly?  |  |  |  | 2.8 - 2.10 |
|  | **Comment:** |  |  |  |  |
| v) | Is there a systematic well-explicated line of congruence and internal consistency? |  |  |  |  |
|  | **Comment:** |  |  |  |  |
| **Comments:** |

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| **5.2** | **Are all reasonable guarantees and safeguards for the ethics of this study covered?** |

**YES NO**

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| **5.3** | **The study presents:** |

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| **Minimal risk**  |  |
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| **More than minimal risk**  |  |

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| **Comments:** |

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| **5.4** | **If frequent reviews are necessary, when should the next review occur?** |

**6. ASSESSMENT OF TECHNICAL ASPECTS OF APPLICATION:**

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| **Comments and recommendations:**  |

I have reviewed this application and am satisfied that the review it is in compliance with the Unisa policy on research ethics.

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| **Member of the CEMS ERC****Ethics Review Committee** | Signed:  |  |
| Name:  |  |
| Date:  |  |