**FORM 2: 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? (Complete and providing sufficient information to guide your ethical judgement)**

**YES NO**

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| **4.1** | **Comments:** |
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**5. Outcome of the review**

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| **5.1** | **Approved** |

**YES NO**

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| **5.2** | **Referred back for amendments/clarifications** |

**YES NO**

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| **5.2.1** | **Identify the required amendments/clarifications** |
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| **5.3 Disapproved** |
| **YES NO**   |  |  | | --- | --- | |  |  |   *(please specify below)* |
| **Reasons for disapproval:** |

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

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| **6.1** | **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) | Is the researcher(s) adequately qualified? |  |  |  | 1.1 – 1.4 |
|  | **Comment:** |  |  |  |  |
| b) | Is there a scientific justification for this research? |  |  |  | 2.3 |
|  | **Comment:** |  |  |  |  |
| c) | Is the scientific design adequate to answer the research question? |  |  |  | 2.3 & 3.10 |
|  | **Comment:** |  |  |  |  |
| d) | Has the source of data been identified, as well as the original purpose for which primary data was collected and is it related to the purpose of the current study? |  |  |  | 3.2 |
|  | **Comment:** |  |  |  |  |
| e) | Are data available in the public domain? |  |  |  | 3.3 |
|  | **Comment:** |  |  |  |  |
| f) | If data are not in the public domain, are there any conditions or restrictions for accessing the data? If so, can the researcher meet those conditions? |  |  |  | 3.4 |
|  | **Comment:** |  |  |  |  |
| g) | If the data contain identifiers: |  |  |  | 3.5 & 3.6 |
| i | Did the researcher provide sufficient evidence that the data will be de-identified? |  |  |  | 3.5 & 3.6 |
| ii | Did he/she identify a gatekeeper who will de-identify the data on his/her behalf? |  |  |  | 3.5 & 3.6 |
| iii | Is de-identification a necessary condition for protecting individuals/institutions against anticipated risks of harm in this study? |  |  |  | 3.5 & 3.6 |
|  | **Comment:** |  |  |  |  |
| h) | If relevant, did the researcher indicate how permission or access will be obtained from organisations if the secondary data sources are not in the public domain? |  |  |  | 3.7 |
|  | **Comment:** |  |  |  |  |
| i) | Did the researcher indicate how he/she would deal with and/or report relevant limitations of the data? |  |  |  | 3.8 & 3.9 |
|  | **Comment:** |  |  |  |  |
| j) | Did the researcher provide adequate evidence that ethics approval was granted for the original data gathering and if it was not required, is the justification adequate? |  |  |  | 4.1 |
|  | **Comment:** |  |  |  |  |
| k) | Did the original participants give permission for future use(s) of the data in related research studies? If the answer is no or unknown, did the researcher adequately address this risk? |  |  |  | 4.2 |
|  | **Comment:** |  |  |  |  |
| l) | Is there sufficient evidence of the safe storage of identifiable data? |  |  |  | 4.3 |
|  | **Comment:** |  |  |  |  |
| m) | Is there sufficient evidence of how identifiable data will eventually be safely disposed of? |  |  |  | 4.4 |
|  | **Comment:** |  |  |  |  |
| n) | Are the risks and benefits adequately identified, evaluated, described and mitigated? |  |  |  | 5.1 – 5.5 |
|  | **Comment:** |  |  |  |  |
| o) | Is there a systematic well-explicated line of congruency and internal consistency? |  |  |  |  |
|  | **Comment:** |  |  |  |  |
| **Any additional comments?** | | | | |

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| **6.2** | **Are all reasonable guarantees and safeguards for the ethics of this study covered?** |

**YES NO**

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| **6.3** | **The study presents:** | **YES** | **NO** |
| **6.3.1** | **Negligible risk** |  |  |
| **6.3.2** | **Low risk** |  |  |
| **6.2.3** | **Medium risk** |  |  |
| **6.2.4** | **High risk** |  |  |

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| **6.3.5 Justify your risk assessment:** |
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**7. ASSESSMENT OF TECHNICAL ASPECTS OF APPLICATION:**

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| **Comments and recommendations:** |

I have reviewed this application and I am satisfied that the review meet the minimum requirements of the Unisa policy on research ethics and the SOP for research ethics risk assessment:

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