**FHS026: Application for UCT Sponsorship and**

**Insurance for Clinical Research**

**(Risk Assessment Form)**

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| ***Office use only – Research Governance Officer (RGO)*** |
| **Noted and filed**. This serves as acknowledgement of the Risk Assessment Form for UCT No-Fault Insurance for Research-related Bodily Injury. |
| **FHS026 form** | [ ]  | Accepted | **Sponsorship decision** | [ ]  | UCT will sponsor |
| [ ]  | Returned for revision | [ ]  | Other entity will sponsor |
| **Comment(s) to Principal Investigator:** |
|  |
| **RGO Signature** |  | **Date** | Click or tap to enter a date. |

**Principal Investigator to complete the following:**

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| 1. General information |
| *eRA Pre-Award Application Number )* |       |
| Date submitted to Departmental Research Committee (DRC) | Click or tap to enter a date. |
| Protocol Title |       |
| Protocol Number |       |
| Principal Investigator |       |
| PI Department / Office Internal Mail Address |       |
| PI Email Address |       |
| PI Contact number |       |

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| 2. Protocol information |
| 2.1. Is this a clinical research protocol for which insurance for research-related bodily injury (no-fault insurance) would be appropriate? | [ ]  | Yes |  |
| [ ]  | No |
| 2.2. If ‘No’, please select why:**Note:** *If any of these reasons are selected, skip the rest of sections 2, 3 and 4; only complete section* [*6: Signature*](#Section6SIgnature) *and submit the form.* | [ ]  | Patient folder/document review |
| [ ]  | Study involves secondary data analysis only |
| [ ]  | No human participants are involved in the study |
| 2.3. Who is the Funder of the research? |       |
| 2.4. Who will own the intellectual property (IP) arising from the research? |       |
| 2.5. Will the UCT investigators be publishing the results, as primary or secondary authors? Are there any conditions set by the Funder? |       |

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| 3. Protocol-specific risk assessment |
| 3.1. Total number of participants to be enrolled: |       |
| 3.2. Study duration: | Predicted Start date: | Click or tap to enter a date. |
| End date: | Click or tap to enter a date. |
| 3.3. Will this study be submitted to SAHPRA (formerly MCC)? | [ ]  | Yes | [ ]  | No |       |
| 3.4. Will this study enrol minors? | [ ]  | Yes | [ ]  | No |       |
| 3.5. Will this study enrol pregnant women? | [ ]  | Yes | [ ]  | No |       |
| 3.6. Will this study have site(s) located outside the borders of South Africa? If yes- please specify: | [ ]  | Yes | [ ]  | No |       |
| **Note:***If ‘Yes’ is selected for 3.4, 3.4 or 3.6 above, you will be contacted for more information.* |
| 3.7. **Hazard Description:**Briefly outline the type of **bodily injury** that *may* occur to participants in this study and *may* result in medical costs that need to be covered by UCT insurance (trial procedures/ side effects/hospitalisations etc.): |       |
| 3.8. **Likelihood:**Please rate the likelihood of bodily injury occurring in this study (in the opinion of the Principal Investigator): | [ ]  | 1. Remote |
| [ ]  | 2. Unlikely |
| [ ]  | 3. Possible |
| [ ]  | 4. Likely |
| [ ]  | 5. Certain |
| 3.9. Describe what control measures will be put in place to reduce the risk(s) to the lowest possible level: |       |
| 3.10. Please list the protocol version and date which you have attached to this submission: |       |
| 4. Professional Indemnity Insurance |
| Will any study staff members (those with **direct participant** contact) require confirmation of UCT professional indemnity insurance? | [ ]  | Yes |
| [ ]  | No |
| If yes, please list these staff members below (add more rows if required): |
| Title, Name & Surname | Department | Role on study | \*UCT number | SA ID number or passport number | Current GCP certificate expiry date | HPCSA number |
|       |       |       |       |       | Click or tap to enter a date. |       |
|       |       |       |       |       | Click or tap to enter a date. |       |
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| *\*if not a UCT employee/student the PI needs to provide an agreement/MoU/declaration indicating that this staff member is required to perform duties within the specified role on a UCT sponsored study* |
| 5. Checklist |
|  | [ ]  | Protocol (version as per submission to DRC) |
|  | [ ]  | Non UCT-Employee agreements/declaration (if applicable) |
| 6. Signature |
| My signature certifies that the above is complete and correct. |
| Signature of PI |  | Date | Click or tap to enter a date. |