**FHS026: Application for UCT Sponsorship and**

**Insurance for Clinical Research**

**(Risk Assessment Form)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***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:**

|  |  |
| --- | --- |
| 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. | | | |  |
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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. | | |