



HEALTH RESEARCH ETHICS COMMITTEE 1 AND 2

**INVESTIGATOR'S DECLARATION**

*(INFORMATION SHOULD BE TYPED)*

*The principal investigator, supervisor, as well as all sub- & co-investigators must each sign a separate declaration.*

| SECTION 1: INVESTIGATOR DETAILS and ROLE IN THIS RESEARCH   |                        |  |                 |  |  |            |
|---|------------------------|--|-----------------|--|--|------------|
| Title, First name, Surname:   |                        |  | SU number:      |  | PROJECT ID NUMBER<br><i>(HREC office use only)</i> |            |
| Professional Status:  |                        |  |                 |  |  |            |
| University DIVISION and DEPARTMENT:   |                        |  |                 |  |  |            |
| Telephone No:   |                        |  | E-mail address: |  |  |            |
| Role <i>(mark with x)</i>   | Principal investigator |  | Co-investigator |  | Sub-investigator                                   | Supervisor |
| SECTION 2: PROJECT TITLE <i>(maximum 250 characters for database purposes)</i>  |                        |  |                 |  |  |            |
|   |                        |  |                 |  |  |            |
| SECTION 3: CONFLICT OF INTEREST DECLARATION (OBLIGATORY)  |                        |  |                 |  |  |            |
| I, <i>(Title, Full name)</i> ..... declare that:  |                        |  |                 |  |  |            |
| <input type="checkbox"/> I have <b>no financial or non-financial interests</b> , which may inappropriately influence me in the conduct of this research study; <b>OR</b><br><input type="checkbox"/> I <b>do have the following financial or other competing interests</b> with respect to this project, which may present a potential conflict of interest: <i>(Please attach a separate detailed statement)</i>   |                        |  |                 |  |  |            |
| Signature: ..... Date: .....  |                        |  |                 |  |  |            |
| SECTION 4: DECLARATION (OBLIGATORY)   |                        |  |                 |  |  |            |
| I, <i>(Title, Full name)</i> ..... declare that:  |                        |  |                 |  |  |            |
| <ul style="list-style-type: none"> <li>• I have read through the submitted version of the research protocol and all supporting documents and am satisfied with their contents</li> <li>• I am <b>suitably qualified and experienced</b> to perform and/or supervise the above research study.</li> <li>• I agree to conduct or supervise the described study <b>personally</b> in accordance with the relevant, current protocol and will only change the protocol after approval by the <b>HREC</b>, except when urgently necessary to protect the safety, rights, or welfare of subjects. In such a case, I am aware that I should notify the HREC without delay.</li> <li>• I agree to timeously report to the HREC <b>serious adverse events</b> that may occur in the course of the investigation.</li> <li>• I agree to maintain <b>adequate and accurate records</b> and to make those records available for inspection by the appropriate authorised agents when and if necessary.</li> <li>• I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in the Declaration of Helsinki (2013), as well as South African and ICH GCP Guidelines and the Ethical Guidelines of the Department of Health as well as applicable regulations pertaining to health research.</li> <li>• I agree to comply with all regulatory and monitoring requirements of the HREC.</li> <li>• I agree that I am conversant with the above <b>guidelines</b>.</li> <li>• I will ensure that every patient (or other involved persons, such as relatives), shall at all times be <b>treated in a dignified manner and with respect</b>.</li> <li>• I will submit all required reports within the stipulated <b>time frames</b>.</li> </ul> |                        |  |                 |  |  |            |
| Signature: ..... Date: .....  |                        |  |                 |  |  |            |