**A4**

**COMMITMENTS AND RESPONSIBILITIES OF PRINCIPAL/CO-INVESTIGATORS**

**REQUIRED FOR RESEARCH THROUGH THE FACULTY OF HEALTH SCIENCES RESEARCH ETHICS COMMITTEE, UNIVERSITY OF PRETORIA**

**DECLARATION BY INVESTIGATOR:**

I agree to **personally** conduct or supervise the described investigation.

I understand as principal investigator that I am **totally responsible** for the study and am legally bound by the contract signed with the sponsor and **will not inappropriately delegate my responsibilities** to the rest of my study team.

I have **read and understand the information in the investigator’s brochure**, including the potential risks and side effects of the drug.

I agree **to ensure** that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments, without relinquishing my total responsibility for the study.

I confirm that I am **suitably qualified and experienced** to perform and/or supervise the study proposed.

I agree to conduct the study in accordance with the relevant, current protocol and will only make changes in the protocol after approval by the sponsor and the Ethics Committee, except when urgently necessary to protect the safety, rights, or welfare of subjects.

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and **I will ensure that the ICH GCP Guidelines and Ethics Committee requirements relating to obtaining informed consent are met.**

I agree to timeously report to the sponsor and Ethics Committee adverse experiences that occur in the course of the investigation according to the time requirements adopted by the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

I agree to maintain **adequate and accurate** records and to make those records available for inspection by the appropriate authorized agents, be it EC, FDA or sponsor agents.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in the Declaration of Helsinki and South African and ICH GCP Guidelines and am conversant with these guidelines.

I agree to inform the Ethics Committee in advance should I go on leave together with an agreed plan of action regarding an alternate principal investigator or sub-investigator to take responsibility in my absence.

I understand that the study may be audited at any time and that deviation from the principles in this declaration will be put before the Ethics Committee for action which may include disqualification as an investigator and rehabilitation before being accepted as an investigator in other studies.

I confirm that there is no conflict of interest whatsoever in my participation in this study. I have no shares in the sponsoring company and my participation and interests are as defined in the financial agreement.

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**SIGNATURE OF INVESTIGATOR NAME (Printed) DATE**