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DECLARATION BY SUPERVISOR

Name and surname:

Protocol number:

Protocol title:

Designation:

1. I have thoroughly read, understood, and critically analysed (in terms of the South African context) the protocol, and all applicable documentations, including the Patient/Participant Information and Informed Consent Document(s).
2. I have read and reviewed my student's final research draft proposal and supporting documents before submission to SAMAREC. I am satisfied that under my supervision, this proposal meets a high standard of scientific merit
3. I have the relevant research and supervision experience to supervise a student at the respected level of research required to complete this study.
4. I will ensure that the study will not commence with the research study before written authorisations from the relevant ethics committee(s) have been obtained.
5. I declare that I have no financial or personal relationship(s) which may inappropriately influence me in supervising this research study. All conflicts of interest have been declared by me.
6. ***Delete the inapplicable option below:***
   I have not previously been involved in a research study which has been closed as a result of unethical practices.

OR

   I have previously been involved in a research study I which has been closed as a result of unethical practices and attach the relevant explanatory documents to this declaration.
7. I will ensure that all required reports are submitted within the stipulated timeframes.

I, (Supervisor's full name and surname), the Supervisor of (Student's full name and surname), confirm that the information included on this form is accurate and reliable, as on (Date).

DECLARATION BY RESEARCHER AND OTHER STUDY STAFF

Name:

Protocol number:

Protocol Title:

Designation:

1. I have thoroughly read, understood, and critically analysed (in terms of the South African context) the protocol, and all applicable documentations, including the Patient/Participant Information and Informed Consent Document(s).
2. I will conduct my role in the research study as specified in the protocol.
3. I will not commence with my role in the research study before written authorisations from the relevant ethics committee(s) have been obtained.
4. If applicable to my role, I will ensure that informed consent has been obtained from all participants, or if they are not legally competent, from their legal representatives.
5. I will ensure that every participant (or other involved persons, such as relatives) shall at all times be treated in a dignified manner and with respect.
6. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in conducting this clinical trial.
7. *[Conflict of interest exists when an investigator (or the investigator's institution) has financial or personal relationships with other persons or organisations that inappropriately influence (bias) his or her actions.]***Modified from: Davidoff, F. Et al Sponsorship, Authorship and Accountability.(Editorial) JAMA Volume 286 number 10 (September 12, 2001)
8. ***Delete the inapplicable option below:***
   I have not previously been involved in a research study which has been closed as a result of unethical practices.
   OR
   I have previously been involved in a research study l which has been closed as a result of unethical practices and attach the relevant explanatory documents to this declaration.
9. I will submit all required reports within the stipulated timeframes.

I, (Full name and surname), confirm that the information included on this form is accurate and reliable, as on (Date).

Signed By:

Date Signed: