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16 October 2012

FAXED

Dr R Benitha
SARAA
Private Bax X01
Honeydew
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Fax: 0117943294

ORIGINAL

Dear Dr Benitha,

PROTOCOL: SABIO 001

SOUTH AFRICAN RHEUMATISM AND ARTHRITIS ASSOCIATION (SARAA) REGISTRY OF PATIENTS ON BIOLOGIC DISEASE MODIFYING ANTI-RHEUMATIC THERAPIES (DMARDS) FOR RHEUMATIC DISEASE

ETHICS REFERENCE NO: 12095060

RE : ETHICS COMMITTEE APPROVAL

The above-mentioned Protocol was reviewed by the Pharma-Ethics Independent Research Ethics Committee Members on 19 September 2012, and CONDITIONAL APPROVAL was given for the Investigators to participate. This letter certifies that all conditions were met to the satisfaction of the commitee and constitutes the FINAL Ethics approval. Please refer to the attached schedule for a list of documents reviewed and investigators approved.

The Study has been accepted as complying to the Ethics Standards for Clinical Research with a new drug in participants, based on FDA, ICH GCP and the Declaration of Helsinki guidelines. The Ethics Committee (IRB) granting this APPROVAL is in compliance with the Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa (2006), ICH Harmonised Tripartite Guidelines E6: Note: for the Guidance in Good Clinical Practice (CPMP/ICH/135/95) and FDA Code of Federal Regulation Part 50, 56 and 312.

This approval is valid for a period of ONE YEAR. The Ethics Committee is to be supplied with a STATUS REPORT on the progress of the study at least ONCE A YEAR after which the study will be reviewed for annual re-approval. The FINAL REPORT on the outcome of the Study must be submitted upon study completion. If any SERIOUS ADVERSE EVENTS are reported, the Committee should be advised, as well as the relevant Regulatory Affairs Bodies.

Please refer to Pharma-Ethics Standard Operating Procedures for more information regarding applications, amendments, annual re-approval, SAE reporting etc.

The above has been noted for the Ethics Committee information and records.

KINDLY FORWARD TO THE RELEVANT INVESTIGATORS / CRA / SPONSOR / STUDY CO-ORDINATORS - WHERE APPLICABLE

Regards,

MRS MARZELLE HASKINS
For and on behalf of Pharma-Ethics