



THE SOUTH AFRICAN MEDICAL ASSOCIATION

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19 August 2020

Bay Radiology Cancercare Oncology Centre
1 Mangold Street
Newton Park
Port Elizabeth
6001

Attention: Dr E Rabe
Etienne.Rabe@gmail.com

Dear Dr E Rabe

FINAL APPROVAL

Protocol Number:	LIVERRADIOMICS
Protocol Title:	Can the Radiomics Analysis of Liver Metastases from Colorectal Cancer predict the Response to Therapy with First Line Chemotherapy?

Your application dated 29 May 2020 for ethical evaluation of the abovementioned study was considered by the South African Medical Association Research Ethics Committee.

The study was considered for review by the Committee at the recent meeting held on 10 June 2020.

The Ethics Committee is a registered IRB at the Office of Human Research Protection of the USA. Federal Wide Assurance was also received from the Office of Human Research Protection (Office of Human Research Protection –Group).

SAMAREC follows the standards adopted by the latest version of the American Food & Drug Administration (FDA) and ICH Harmonized Tripartite Guidelines for Good Clinical Practice; and conforms to the guidelines laid down by the World Medical Association, in particular, the Declaration of Helsinki (October 2013), the Belmont Report, the National Department of Health and the SA Medical Research Council.

Protocols are approved for a maximum period of one year only. For projects, which continue beyond one year, it is the responsibility of the principal investigator and the sponsor to submit to SAMAREC an Application for Continuing Review supported by the study progress report. The SAMAREC Application for Continuing Review must be submitted in time to allow for review and approval no later than 12 months from the initial review date. Upon receipt of the application for Continuing Review SAMAREC will review and approve, if appropriate, continuation of the project for the subsequent approval period.

The following members of the committee were present during the meeting:



Prof J R Snyman MBChB, M Pharm Med, MD	Male, Pharmacologist, SAMA Member
Dr M Groenewald MBChB, DCH (SA), PG Dip Int Res Ethics	Female, General Practitioner, SAMA Member
Prof M Kakaza MBChB, Mmed(Neuro)	Female, Specialist Neurologist, SAMA Member
Mrs B Fineberg BSc (Hons); H.D.E	Female, Educator
Ms U Behrtel BLC.LLB, Cert MedLaw, PG Dip Int Res Ethics	Female, Attorney
Ms W Massangaie LLB Cert Medical Negligence and Health Sector Mediation.	Female, Attorney
Mr M le Roux B.Th, M.Div	Male, Legal Secretary
Dr T Lengana MBBCh, MSc Med (Bioethics & Health Law), FCNP (SA), MMed (Nuclear Medicine)	Male, Specialist Nuclear Physician, SAMA Member
Ms T Coetzee PG Dip (Health Res Ethics); M Phil (Applied Ethics)	Female, Research Integrity Officer

Resolution

After noting and considering the input of the evaluators on the above-mentioned study, the Committee **RESOLVED** that the application be **approved**.

1. COVERING LETTER, dated 29 May 2020

The Covering Letter, dated 29 May 2020 was noted and accepted.

SAMAREC commended Dr Rabe on a very well written and presented protocol and submitted documents.

2. WAIVER OF CONSENT

The request to waiver consent for the collection of retrospective data was noted and approved.

3. CHECKLIST

The SAMAREC Checklist was noted and accepted.

4. THESIS PROTOCOL

The following document was noted and approved:

- **The Protocol LIVERRADIOMICS001 – Version 2 dated 12 June 2020**

5. SIGNATURE OF PRINCIPAL INVESTIGATOR

The signature of the Principal Investigator was noted and accepted.

6. STUDY STAFF

The Committee noted the study Staff and resolved as follows:



Site Address	Staff Member	CV and other supporting document/s	Status
Bay Radiology Cancercare Oncology Centre 1 Mangold Street Newton Park Port Elizabeth 6001	Dr E Rabe Principal Investigator	Noted and accepted.	Approved.
	Dr L Dupper Oncologist	Noted and accepted.	Approved.
	Dr SA Basson-Bowden Radiologist	Noted and accepted.	Approved.

- Kindly take note that all health professionals who dispense medicines are required to have a dispensing licence, unless a pharmacist is on site to dispense such medicines. In addition, medical practitioners with dispensing licenses are only permitted (legally) to dispense on their own prescriptions
- Kindly ensure that GCP Training is renewed in due course
- Take note that Pharmacists dispensing medicines require Malpractice Insurance
- Kindly ensure that expired registrations with Statutory Councils must be updated/renewed as appropriate
- Clinical trial information on CV's should have the names-of sponsors, abbreviated titles and protocol numbers of all studies listed.
- Kindly take note that all registered nurses who will be performing duties which fall within the scope of the nursing profession, are required to hold professional indemnity insurance in their personal capacities, unless their professional actions will be indemnified / covered by the insurance held by the sponsor. The onus is on the sponsor to ensure that the necessary and adequate insurance and professional indemnity coverage is in place, before commencement of the study.

7. DR LOUIS DUPPER AND DR SA BASSON-BOWDEN

The signed Declaration for Dr L Dupper dated, 17 June 2020 was noted and accepted.

On page 6 of 16 Dr Louis Dupper is listed as the local Oncologist at Cancercare Post Elizabeth and will be supplying the Principal Investigator with clinical patient information if this is unavailable on the radiology information system.

In principle, sharing of patient information during standard care is allowed.

However, within a research setting, the Committee recommends that Dr Dupper sign and adhere to the Declaration attached, as to ensure that patient confidentiality and Ethical Principles during biomedical research is maintained.

The signed Declaration for Dr SA Basson-Bowden dated 18 August 2020 was noted and accepted.

Dr Basson-Bowden (Radiologist) will be verifying the segmentation and validity of the liver metastases which the Principal Investigator has chosen to include in the radiomics analysis.

In principle, sharing of patient information during standard care is allowed.

However, within a research setting, the Committee recommends that Dr Dupper sign and adhere to the Declaration attached, as to ensure that patient confidentiality and Ethical Principles during biomedical research is maintained.

8. LETTER OF EMPLOYMENT

The Confirmation Letter of Employment dated 26 May 2020 was noted and accepted.

9. UNIVERSITY OF PISA LETTER

The University of Pisa Letter dated 18 May 2020 was noted and accepted.

10. UNIVERSITY OF PISA REGISTRATION

The Screenshot of the Student Registration page for Dr E Rabe was noted and accepted.



11. THESIS BUDGET

The Thesis Budget was noted and approved.

12. DE-IDENTIFIED PATIENT DATA WORKSHEET

The Excel document: De-identified patient data worksheet was noted and approved.

13. DE-IDENTIFIED PATIENT COMPUTED TOMOGRAPHY DETAILS

The Excel document; de-identified patient computed tomography details was noted and approved.

14. SOPHIA RADIOMICS

The SoPHiA Radiomics – List of Texture Feature which can be evaluated was noted and approved.

Yours Sincerely

Adri van der Walt
SAMAREC Officer
SA Medical Association
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