Dear Editor

F6 Publishing

24 April 2021

SAMAREC – WAIVER OF CONSENT FOR RETROSPECTIVE STUDY

Please note that informed patient consent was waived for this retrospective study by SAMAREC in South Africa where the study was performed. Please refer to point 2 on page 2 of the attached ethics approval document.

No signed informed consent form was required for this retrospective study.

Yours faithfully

Dr. Etienne Rabe
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  

<table>
<thead>
<tr>
<th>Protocol Number:</th>
<th>LIVERRADIOIMICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Title:</td>
<td>Can the Radiomics Analysis of Liver Metastases from Colorectal Cancer predict the Response to Therapy with First Line Chemotherapy?</td>
</tr>
</tbody>
</table>

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:
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 waive 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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof J R Snyman</td>
<td>MBChB, M Pharm Med, MD, Male, Pharmacologist, SAMA Member</td>
</tr>
<tr>
<td>Dr M Groenewald</td>
<td>MBChB, DCH (SA), PG Dip Int Res Ethics, Female, General Practitioner, SAMA Member</td>
</tr>
<tr>
<td>Prof M Kakaza</td>
<td>MBChB, Mmed(Neuro), Female, Specialist Neurologist, SAMA Member</td>
</tr>
<tr>
<td>Mrs B Fineberg</td>
<td>BSc (Hons); H.D.E, Female, Educator</td>
</tr>
<tr>
<td>Ms U Behrte</td>
<td>BL.C.LLB, Cert MedLaw, PG Dip Int Res Ethics, Female, Attorney</td>
</tr>
<tr>
<td>Ms W Massangaie</td>
<td>LLB Cert Medical Negligence and Health Sector Mediation, Female, Attorney</td>
</tr>
<tr>
<td>Mr M le Roux</td>
<td>B.Th, M.Div, Male, Legal Secretary</td>
</tr>
<tr>
<td>Dr T Lengana</td>
<td>MBBCh, MSc Med (Bioethics &amp; Health Law), FCNP (SA), MMed (Nuclear Medicine), Male, Specialist Nuclear Physician, SAMA Member</td>
</tr>
<tr>
<td>Ms T Coetzee</td>
<td>PG Dip (Health Res Ethics); M Phil (Applied Ethics), Female, Research Integrity Officer</td>
</tr>
</tbody>
</table>
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 RADIOIMICS**  
The SoPHiA Radiomics – List of Texture Feature which can be evaluated was noted and approved.

Yours Sincerely

[Signature]

Adri van der Walt  
SAMAREC Officer  
SA Medical Association  
Tel: (012) 481 2046  
samarec@samedical.org