

# UNIVERSITY OF THE WESTERN CAPE

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## Ethics Clearance Application

Biomedical Research Ethics Committee (BMREC)

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<b>Project Title:</b>	ML Applications in Healthcare Diagnostics
<b>Applicant:</b>	Thabo Molefe
<b>Protocol No.:</b>	BM25/3/12
<b>Risk Level:</b>	Medium (human subject data)

### Study Design

Retrospective analysis of de-identified medical imaging data. No direct patient contact. Images will be sourced from existing hospital PACS archives under a data sharing agreement with Tygerberg Hospital and Groote Schuur Hospital.

### Participants

The study involves secondary analysis of existing medical records (chest X-ray images). No direct recruitment of participants. Images are de-identified at source by hospital radiography department staff. Estimated sample: 12,000 images from adult patients (18+) who had chest X-rays taken between 2020-2025.

### Informed Consent

A waiver of individual informed consent is requested as: (a) the data is retrospective and de-identified, (b) it is impracticable to obtain consent from approximately 12,000 individuals, (c) the research poses minimal risk. Hospital-level consent has been obtained via the data sharing agreement.

### Data Protection

All data will be stored on an encrypted, password-protected university server. No personally identifiable information (name, ID, date of birth) will be collected. Images are anonymized via DICOM header stripping before transfer. Research outputs will be reported in aggregate only. Compliance with POPIA is maintained throughout.

### Risk Mitigation

The primary risk is potential re-identification through rare pathology patterns. This is mitigated by: (1) removing all metadata, (2) applying data minimization principles, (3) restricting access to the research team only, (4) secure deletion of data after study completion (planned 2027).