

Ethics Clearance Application

Biomedical Research Ethics Committee (BMREC)

| | |
|------------------|---|
| Protocol Number: | BM25/3/12 |
| Project Title: | ML-Driven Diagnostic Imaging for TB Screening |
| Applicant: | Thabo Molefe (3847291) |
| Supervisor: | Prof. Sarah van der Berg |
| Faculty: | Natural Sciences |
| Risk Level: | Medium (de-identified human data) |
| Date Submitted: | 15 January 2026 |

1. Study Design

Retrospective analysis of de-identified medical imaging data from two tertiary hospitals in the Western Cape. No direct patient contact. All images are anonymised at source by hospital radiography staff before transfer to the research team.

2. Data Sources

Primary: 12,000 de-identified chest X-ray images from Tygerberg Hospital and Groote Schuur Hospital (2020-2025). Secondary: 3,000 images from the NIH ChestX-ray14 public repository for cross-validation.

3. Informed Consent

A waiver of individual informed consent is requested as the data is: (a) retrospective and fully de-identified, (b) impracticable to obtain consent from approximately 12,000 individuals, and (c) poses minimal risk. Institutional consent is documented via data sharing agreements with both hospitals.

4. Data Protection (POPIA Compliance)

All data stored on encrypted university servers. No personally identifiable information collected. DICOM headers stripped before transfer. Research outputs reported in aggregate only. Data deletion scheduled for December 2027.

5. Risk Assessment

Primary risk: potential re-identification via rare pathology patterns. Mitigation: metadata removal, data minimisation, restricted access (PI + 2 researchers only), secure deletion post-study. Residual risk assessed as LOW.