

UNIVERSITY OF THE WESTERN CAPE

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Informed Consent Form

Research Ethics Compliance Document

Study Title: ML Applications in Healthcare Diagnostics
Researcher: Thabo Molefe
Supervisor: Prof. Sarah van der Berg
Protocol No.: BM25/3/12
Version: 2.0 (Revised for minors)

1. Purpose of the Study

You are invited to participate in a research study that aims to develop and evaluate machine learning algorithms for automated analysis of medical imaging data. The study seeks to improve early detection of tuberculosis from chest X-ray images.

2. What Participation Involves

Your existing medical imaging records (chest X-rays) will be used in this study. No additional procedures, tests, or visits are required. Your images will be anonymised before use, meaning your personal identity will not be linked to any images used in the research.

3. Risks and Benefits

Risks: Minimal. There is a very small risk that anonymised images could theoretically be re-identified, although multiple safeguards are in place to prevent this. Benefits: You will not receive direct benefit, but the research may improve TB diagnosis for future patients in South Africa.

4. Confidentiality

Your personal information will be kept strictly confidential. Images are anonymised by removing all identifying information (name, ID number, date of birth) before the research team accesses them. Data is stored on encrypted, password-protected university servers. Only the research team (3 persons) has access.

4.3 Guardian Consent for Minors

If the participant is under 18 years of age, a parent or legal guardian must provide consent on their behalf. The minor should also provide assent (agreement) if they are old enough to understand the study (typically age 12 and above). A separate assent form is available.

5. Voluntary Participation

Participation is entirely voluntary. You may withdraw consent at any time without penalty or loss of benefits. If you withdraw, any images already anonymised and included in analysis will not be removed, as re-identification is not possible.

CONSENT DECLARATION

I have read and understood the information above. I have had the opportunity to ask questions and have received satisfactory answers. I voluntarily agree to participate in this study.

Participant Signature: _____ Date: ____/____/2026

Guardian Signature (if under 18): _____ Date: ____/____/2026

Researcher Signature: _____ Date: ____/____/2026