



Helping Empower Youth
Brought up in Adversity with their Babies and
Young children



Mzantsi Wakho Data Access and Sharing Policy V.1.0
And for associated studies like HEY BABY! and From STOP to GO!

1. Introduction

This document describes the Data Access and Sharing Policy for the “Mzantsi Wakho” study (and its associated studies like “Hey Baby!” and “From STOP to GO!”). Its purpose is to define policy and procedures to ensure adherence to established community principles on data policy - such as those set out by Research Councils UK (RCUK) - which govern appropriate data sharing for non-for-profit scientific research.

The **Mzantsi Wakho** study Data Access and Sharing Policy has been developed in concordance with MRC Data Sharing Policy, MRC Policy and Guidance on Sharing of Research Data from Population and Patient Studies and general principles promoted by the University of Oxford and the University of Cape Town.

2. Purpose of the Study

The study seeks to answer several research questions about child, adolescent, and youth health, with a focus on access to healthcare services, medicine-taking and sexual and reproductive health. It uses multiple methods and data sources to identify and investigate risk and resilience-promoting factors through linked qualitative and quantitative studies.

3. Specific Opportunities and Priorities for Sharing

The **Mzantsi Wakho** study welcomes proposals for collaboration with other investigators. This may be in the form of external investigators participating in projects that are already in progress or planned by the **Mzantsi Wakho** study, in leading new collaborative projects or using part of **Mzantsi Wakho** study dataset(s) for collaborative analyses.

4. Principles of Data Sharing

As data custodian, the **Mzantsi Wakho** study prioritises the integrity of the database for future use and regulates data access to comply with established community standards. Data security is an integral part of the **Mzantsi Wakho** study protocols and so data can be released outside the **Mzantsi Wakho** study only with appropriate security safeguards and approval of the Principal Investigator (PI). The procedures for data access reflect the general principles of:

- 4.1. Ensuring high quality research is fostered that will advance knowledge and help strengthen research capacity.
- 4.2. Ensuring compliance with UK and South Africa legal and regulatory requirements (eg, the UK Data Protection Act, 1998; The South Africa Protection of Personal Information Act 2013).
- 4.3. Protecting the confidentiality of participants and acting within the scope of their signed consent.



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5. Terms of Data Access

- 5.1. A University of Oxford “Data Sharing Agreement” will be required which outlines a) who will have access to the data, b) why the data is being accessed, c) which components of the data are needed for analysis, d) the time period for which access is granted , e) obligations of the data provider, f) obligations of the data recipient , g) data protection act obligations, h) conditions for publication and use of the joint dataset, i) conditions of confidentiality, j) limitations of liability, and l) general conditions for use of the data.
- 5.2. A separate “Confidential Disclosure Agreement “will also be required which outlines restrictions on use of any information exchanged.
- 5.3. Except if required by a court order, access will be permitted only for purposes consistent with the aims and ethics of the original study (including the original signed consent by all participants).
- 5.4. Applicants should be acting as members of a recognised academic institution, research organisation or health organisation as stipulated below. Requests should come from a recognised email domain (eg, ox.ac.uk) or on an appropriate letterhead.

6. Data Access Process

- 6.1. Informal discussion: Potential collaborators or data requesters are encouraged to approach the **Mzantsi Wakho** study informally in the first instance to discuss research ideas and feasibility. Key contacts are outlined in Annex 1.
- 6.2. Submission of proposal and Data Request Form: A proposal should be submitted to the **Mzantsi Wakho** study describing the background, objectives and methodology to be used. This proposal should complement the Data Request Form, specifying the research question, study objectives, analysis plan and outline of key variables of interest, research team (and expertise), timeline, financial resources (where relevant) ethics and data security considerations and planned dissemination including publication. Applications must be consistent with participants’ consent, the confidentiality requirements, and any prior conditions agreed with funders. It should also state whether at least some of the applicants have prior experience and peer-reviewed publications in this or related fields. Applications will be reviewed for feasibility, scientific significance, and for whether they overlap significantly with on-going research by the **Mzantsi Wakho** study or other investigators.
- 6.3. Ethics and research governance approval: Research ethics approval, if required, is the responsibility of the collaborator/data requester. Similarly, research governance approvals, if required, are the responsibility of the collaborator/data requester.
- 6.4. Data Sharing Agreement and Confidential Disclosure Agreement: Before any of the **Mzantsi Wakho** study data can be released, a formal Data Sharing Agreement and Confidential Disclosure Agreement will be enacted, detailing the mutually agreed terms and conditions attached to the data access in line with the **Mzantsi Wakho**



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study Data Access and Sharing Policy V1.0. Data Sharing Agreements will be drafted and approved by the University of Oxford's Research Services. Once the proposal is approved and the Data Sharing and Confidentiality Agreement signed, the data and its documentation will be generated and released using encrypted physical media or in a secure manner via the internet.

7. Suitability for Sharing

Once collected, cleaned and fully anonymised, quantitative data will be suitable for sharing following RCUK guidelines and the data sharing guidelines of the Universities of Oxford and Cape Town. Requesters should be employees or affiliates of a recognised academic institution, health service organisation or charitable research organisation. Requestors should have demonstrable relevant experience to be able to carry out the proposed study as stipulated in the Data Sharing Agreement and Confidential Disclosure Agreement. Their organisation should have formal policies and procedures to comply with any legal, ethical or data protection constraints and to ensure that the dataset is stored securely and used responsibly.

Data sharing will be based on the principles of ensuring that research is not-for-profit, has the goal of improving health outcomes and protects participants by acting within the scope of their informed consent and providing full anonymity, given the sensitivity of data collected in this study.

8. Privileged Use of Data by the Mzantsi Wakho Study Team

The data collected during this study will be used exclusively by the **Mzantsi Wakho** study research team, and collaborators with a Data Sharing Agreement and Confidential Disclosure Agreement in place, until the main study findings have been published. A further 3-6 months will be required following this preliminary period of exclusive use to ensure the data is appropriately anonymised and supporting documents are in place (e.g. scales and measures).

9. Discovery by Potential Users of the Research Data

Summary information on metadata, scales and measures and research findings will be readily available on the **Mzantsi Wakho** study [website](#). In order to protect participant confidentiality, researchers are encouraged to contact the Academic Advisory Committee as detailed in Annex 1, to discuss use of the data.

10. Conditions for Secure Management of Confidential and Sensitive Information

The **Mzantsi Wakho** study data is stored and shared in line with University of Oxford, University of Cape Town and RCUK principles and requirements. Data is secured at highly-secure password-protected and encrypted locations and back-ups of the data take place regularly. Data curation responsibilities are detailed in Annex 2.



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Collaborators are expected to curate and utilise any shared data in line with the conditions set out in the Data Sharing Agreement V1.0 and Confidential Disclosure Agreement which outlines that the data will in no way be reproduced, shared with a third party, reverse engineered or exploited without the prior written consent of the **Mzantsi Wakho** study and that data will be kept on a password protected computer, hard drive or USB or in a locked cabinet when in hard copy and remain in possession of the collaborator at all times.

11. Restrictions and Delays to Sharing

All data will be fully anonymised and de-identified before sharing can take place. This is especially important given the potential risk for participants (adolescents, children and their families) associated with unintentional identification of their HIV-status or other health issues which are stigmatised in their communities. The first priority of the research is to do no harm, and so the **Mzantsi Wakho** study team will ensure that no participant or their family can be identified through this data prior to sharing.

12. Governance and Access

Please refer to section 6. Data Access Process. Further to this, **Mzantsi Wakho** study Data Management Actors (Annex 2) provide oversight on any question regarding access.

13. Costs of sharing

Requesters will not be asked to contribute to the cost of data sharing unless this presents a significant financial burden to the **Mzantsi Wakho** study. Should there be a cost this will be agreed upon by all parties and incorporated into the Data Sharing Agreement and Confidential Disclosure Agreement to be signed prior to the sharing of data

14. Data Sharing Agreement and Confidential Disclosure Agreements

Data will only be shared with any external party if both a Data Sharing Agreement and Confidential Disclosure Agreement are in place. The agreements will be between the **University of Oxford** and the requestor and confirms The **Mzantsi Wakho** study ownership of the accessed data, outlines specific conditions for the sharing of the data, requires return of any new results to the **Mzantsi Wakho** study for possible incorporation into the database.

15. Previous/Current Data-sharing Collaborations and their most Significant Outputs (datasets and publications)

Please refer to the 'Publications' section of the study [website](#). For specific details please contact the **Mzantsi Wakho** study team.



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Annex 1: Membership of the Academic Advisory Committee

Chairperson:

Professor Lucie Cluver (PI) (Oxford, United Kingdom)
Department of Social Policy and Intervention
Barnett House
32 Wellington Square
Oxford
OX1 2ER
United Kingdom
Telephone: +44(0)1865 270325
Email: lucie.cluver@spi.ox.ac.uk

Members:

Dr Elona Toska (Cape Town, South Africa): elona.toska@uct.ac.za, Dr Rebecca Hodes (Cape Town, South Africa): rebecca.hodes@googlemail.com, Prof Lorraine Sherr (London, United Kingdom): l.sherr@ucl.ac.uk

Annex 2: Data Management Actors

Prof Lucie Cluver (PI), Dr Elona Toska and fieldwork team will oversee study-wide data management, and quality assurance of quantitative data.

Dr Rebecca Hodes, Mr Marius Coqui (AIDS and Society Research Unit, University of Cape Town) will provide qualitative data quality assurance & security.

Mr. Vinayak Kozhikotte (DSPI, University of Oxford) and fieldwork project management will be responsible for data security.