

Annexes

Annex A: Lists of participating schools

Table 1: List of Cape Town schools participating in the GOAL Trial

School Name	Community	RCT Group	Site
Bulumko Secondary	Khayelitsha	Intervention	Cape Town
Chris Hani S.S.S.	Khayelitsha	Control	Cape Town
Dr. Nelson Mandela	Crossroads	Control	Cape Town
ID.Mkhize	Gugulethu	Control	Cape Town
Intlanganiso	Khayelitsha	Intervention	Cape Town
Intshukumo	Gugulethu	Intervention	Cape Town
Joe Slovo High School	Khayelitsha	Control	Cape Town
Khulani	Langa	Intervention	Cape Town
Langa High	Langa	Control	Cape Town
Manyano S.S	Khayelitsha	Intervention	Cape Town
Masiyile S.S.S.	Khayelitsha	Control	Cape Town
Matthew Goniwe	Khayelitsha	Control	Cape Town
Sithembele Matiso	Gugulethu	Intervention	Cape Town
Sivile High	Khayelitsha	Intervention	Cape Town
Thembelihle	Khayelitsha	Control	Cape Town
Uxolo High	Khayelitsha	Intervention	Cape Town

Table 2: List of Port Elizabeth schools participating in the GOAL Trial

School Name	Community	RCT Group	Site
Chubekile	Kwazakhele	Intervention	Port Elizabeth 1
Cowan	New Brighton	Control	Port Elizabeth 1
Ithembelihle	New Brighton	Intervention	Port Elizabeth 1
Khwezi Lomso	Zwide	Intervention	Port Elizabeth 1
Loyiso	Zwide	Control	Port Elizabeth 1
Lwandle Kazi	New Brighton	Intervention	Port Elizabeth 1
Lwazilwethu	Zwide	Control	Port Elizabeth 1
Masibambane	Kwazakhele	Control	Port Elizabeth 1
Ndzondelelo	Zwide	Intervention	Port Elizabeth 1
Newell	New Brighton	Control	Port Elizabeth 1
Sakhisizwe	Zwide	Control	Port Elizabeth 1
Sophakama	New Brighton	Intervention	Port Elizabeth 1
Thamsanqa	Kwazakhele	Intervention	Port Elizabeth 1
Thembalabantu	Zwide	Control	Port Elizabeth 1
Tyhilulwazi	Zwide	Control	Port Elizabeth 1
Cingani	Motherwell	Intervention	Port Elizabeth 2
Kwa Magxaki	Kwa Magxaki	Control	Port Elizabeth 2
Lungisa	KwaDwesi	Intervention	Port Elizabeth 2
Masiphathisane	Motherwell	Control	Port Elizabeth 2
Mfesane	Motherwell	Control	Port Elizabeth 2
Mlungisi	Uitenhage	Control	Port Elizabeth 2
Molly Black Burn	Uitenhage	Intervention	Port Elizabeth 2
Motherwell High School	Motherwell	Intervention	Port Elizabeth 2
Ncedo	Motherwell	Control	Port Elizabeth 2
Nkululeko	Uitenhage	Control	Port Elizabeth 2
SEK Mqhayi	KwaDwesi	Intervention	Port Elizabeth 2
Solomon Mahlangu	Uitenhage	Intervention	Port Elizabeth 2
Thanduxolo	Uitenhage	Intervention	Port Elizabeth 2
V.M.Khwinana	Uitenhage	Control	Port Elizabeth 2
Zanolwazi	Despatch	Control	Port Elizabeth 2

Wits Institute for Reproductive Health & HIV (WRHI)	London School of Hygiene and Tropical Medicine (LSHTM)
HREC # Mxxxxxxx	REC Study #
Parental/Guardian Consent Form for Study Participant	

Consent Form Version Date: 20 FEBRUARY 2012

Title of Study: GOAL Trial: Sport-based HIV prevention in South African Schools

Principal Investigator: David Ross, PhD (LSHTM), Sinead Delany-Moretlwe MBBCh, PhD

LSHTM Department: Infectious Disease Epidemiology

LSHTM Phone number: +44 20 7927 2264

Email Address: david.ross@lshtm.ac.uk

Co-Investigators: Zachary Kaufman, MSc

Telephone number: 071 590 0820

Funding Source: MAC AIDS Fund

Contact email: zachary.kaufman@lshtm.ac.uk

Hello. I am currently working for Grassroot Soccer, the Wits Reproductive Health and HIV Institute, and the London School of Hygiene and Tropical Medicine on a project with young people in Cape Town and Port Elizabeth. We are interested in exploring HIV risk among young people. We would like to invite you to invite your child or the young person in your care to participate in this study.

Some general things you should know about research studies

The young person is being asked to take part in a research study. You will also need to give permission for the young person in your care to be in this study. Your decision to allow him/her to join the study is voluntary—that means it is up to both of you. You may refuse to allow him/her to join, or you may withdraw him/her from the study, for any reason and at any time. The decision to refuse to participate or withdraw from the study will not affect the ability of the young person in your care to attend school or any other services you or he/she normally receive. If the young person decides he/she does not want to consent to participate in the study, even if you have already given consent, the young person will not be enrolled in the study.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from him/her being in the research study. There also may be risks to being in some research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You can ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to assess the effectiveness of a sports-based HIV prevention intervention being delivered in South African schools.

If you agree for him/her to participate in this study, we will ask the young person to complete a 45-minute questionnaire and to provide a dried blood spot.

What will participants enrolled in the study be asked to do?

All participants in the study will be asked to complete a questionnaire that will ask the young person information about some personal issues such as your family, HIV knowledge and sexual behaviour. Participants will enter their answers to the questionnaire using a mobile phone to give them more privacy during the self-interview. Trained study team members will be present to assist participants in completing the questionnaire and answer any questions they may have.

All participants will also be asked to provide a blood sample. We will collect a very small amount of blood (less than 5 ml, or about a teaspoon full) using one finger prick. The blood will be put on filter paper, which will be securely stored for at least the next three years. The stored dried blood spot may be tested for HIV and/or other infections or health conditions as part of this or other research studies. This will only be done with the written approval of the Wits and LSHTM Research Ethics Committees.

At the end of the study (in 2015), the young person will have the opportunity to be told the result of his/her HIV test. If he/she chooses to be told the result, he/she will receive counselling before and after the test. Prior to 2015, it will not be possible for our study staff to tell the young person their HIV status because tests will not run on the blood samples until 2015. If he/she tests positive at the end of the study, he/she will be linked to a qualified local treatment provider for support.

Study Significance

HIV infection is common among young people across the world and in our community. South Africa has the largest number of people living with HIV of any country in the world. In this study we are interested in assessing whether a sports-based intervention is effective so that we can inform future efforts to prevent HIV.

How many people will take part in this study?

There will be approximately 9,600 learners at 48 secondary schools in Cape Town and Port Elizabeth participating in this research study.

How long will this study last?

The young person's participation in this study will last a maximum of one hour in this first stage. He/she will complete a questionnaire and be asked to provide a small blood sample. This will take place after school hours. We will want to interview the young person at least once per year for at least the next three years, asking him/her to complete the questionnaire again. At the end of the study in three years' time, he/she will be asked to provide another blood sample.

What are the possible benefits from being in this study?

There are no direct monetary benefits to participating in the study. However, the young person's school may be selected to receive a special sport-based HIV prevention programme and he/she may have the opportunity to participate. He/she will also benefit from receiving HIV counselling in 2015, and if he/she wants to, he/she will learn his/her HIV status, and, if necessary, be referred to treatment, care, and support services. Additionally, he/she will receive refreshments and a small token of appreciation (like a wristband) each time he/she completes a questionnaire as part of this study.

What are the possible risks or discomforts from being in this study?

It is possible the young person may find some of the questionnaire questions distressing. He/she does not have to answer any question he/she does not wish to answer. If the questions raise concerns of a personal nature we can refer him/her to professional organisations that will try to assist him/her. Whether or not he/she takes up this referral will be his/her choice. Finger prick HIV tests do not result in much discomfort. The young person's finger may slightly sting for a second. The young person may experience anger or distress if he/she learns that he/she is infected with HIV. We will refer him/her to a government clinic for care if he/she is infected with HIV and he/she will be provided free HIV treatment and care at the clinic.

How will privacy be protected?

All efforts will be made to keep the young person's personal information confidential. He/she will be identified by a code number known only to the study staff. This number – not his/her name – will be used on all information about him/her. The young person's name will not be written on any blood spots or test results. The young person's name will never be used in any publication or presentation about the research study. Personal information about the young person will not be released without his/her written permission.

It is important for you to know that all information the young person provides to study staff during the study is confidential. We cannot disclose any information to you as the parent/guardian. In addition, the result of HIV and HSV-2 testing is confidential and we cannot provide the results to you, but only to the young person and, with his/her permission, to healthcare workers he/she wishes to consult.

Will it cost you anything to be in this study?

There will be no costs for being in the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. I will be happy to answer any questions you have about the study. We will be holding a parents' meeting on _____ at _____. If you have questions or concerns after that, you should contact the researchers listed on the first page of this form. The young person will be given an opportunity to ask any questions before each session begins.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the University of the Witwatersrand Human Research Ethics Committee. Please phone 011-717-2301 to be directed to one of the chairpersons of the committee. If you have questions about this specific research project please call the study manager, Zak Kaufman on 071 590 0820 or the co-Principal Investigator Dr. Sinead Delany-Moretlwe at WRHI on 082 377 6275 or email sdelany@wrhi.ac.za

Parent/Guardian Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to allow my child/the young person to whom I am guardian to participate in this research study.

Signature of Participant's Parent/Guardian

Date

Printed Name of Parent/Guardian

Name of study participant

Address: _____

Phone: _____

Goal Trial Assent Form

Wits Institute for Reproductive Health & HIV (WRHI)	London School of Hygiene and Tropical Medicine (LSHTM)
HREC # Mxxxxxx	REC Study #
Assent to Participate in a Research Study	
Grade 9 learners	

Assent Form Version Date: 23 JANUARY 2012

Title of Study: GOAL Trial: Sports-based HIV prevention in South African Schools

Principal Investigator: David Ross, BMBCh, PhD (LSHTM), Sinead Delany-Moretlwe MBBCh, PhD (WRHI)

LSHTM Department: Infectious Disease Epidemiology

LSHTM Phone number: +44 20 7927 2264

Email Address: david.ross@lshtm.ac.uk

Co-Investigators: Zachary Kaufman, MSc

Funding Source: MAC AIDS Fund

Study Contact telephone number: 071 590 0820

Study Contact email: zachary.kaufman@lshtm.ac.uk

Hello. My name is _____ and I am currently working for Grassroot Soccer, the Wits Reproductive Health and HIV Institute, and the London School of Hygiene and Tropical Medicine on a project with young people in _____. We are interested in exploring HIV risk among young people. I would like to invite you to participate in this study.

Some general things you should know about research studies

You are being asked to take part in a research study. Your parent or guardian needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission. Your decision to join the study is voluntary—that means it is up to you. You may refuse to join the study, or you may withdraw from the study, for any reason and at any time. The decision to refuse to participate or withdraw from the study will not affect your ability to attend school or to receive any other services you normally receive.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in some research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You can ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to assess the effectiveness of a sports-based HIV prevention intervention being delivered in South African schools.

If you agree to participate in this study, we will ask you to complete a 45-minute questionnaire and to provide a very small blood sample.

What will participants enrolled in the study be asked to do?

All participants in the study will be asked to complete a questionnaire that will ask you information about some personal issues such as your family, HIV knowledge and sexual behaviour. You will enter your answers to the questionnaire on a mobile phone to give you more privacy during the self-interview. Trained study team members will be present to assist you in completing the questionnaire and answer any questions you may have.

All participants will also be asked to provide a blood sample. We will collect a very small amount of blood for this test (less than 5 ml, or about a teaspoon full) using one finger prick. The blood will be put on filter paper, which will be securely stored for at least the next three years. The stored dried blood spot may be tested for HIV and/or other infections or health conditions as part of this or other research studies. This will only be done with the written approval of the Wits and LSHTM Research Ethics Committees.

At the end of the study (in 2015), you will have the opportunity to be told the result of your HIV test. If you choose to be told the result, you will receive counselling before and after the test. Prior to 2015, it will not be possible for our study staff to tell you your HIV status because tests will not run on the blood samples until 2015. If you test positive at the end of the study, you will be linked to a qualified local treatment provider for support.

Study Significance

HIV infection is common among young people across the world and in our community. South Africa has the largest number of people living with HIV of any country in the world. In this study we are interested in assessing whether a sports-based intervention is effective so that we can inform future efforts to prevent HIV.

How many people will take part in this study?

There will be approximately 12,000 learners at 60 secondary schools in Soweto, Cape Town, and Port Elizabeth participating in this research study.

How long will your part in this study last?

Your participation in this study will last a maximum of two hours in this first stage. You will complete a questionnaire and be asked to undergo HIV counseling and testing. This will take place after school hours. We will follow-up with you at least once per year for at least the next three years and ask you to complete the questionnaire again. At the end of the study in three years' time, you will be asked to provide another blood sample.

What are the possible benefits from being in this study?

There are no direct monetary benefits to participating in the study. However, your school may be selected to receive a special sport-based HIV prevention programme and you may have the opportunity to participate. If you choose to receive your test results at the end of the study, you will benefit from receiving HIV counselling, learning your HIV status, and, if necessary, being referred to treatment, care, and support services. Additionally, you will receive refreshments and a small incentive (like a wristband) each time you complete a questionnaire as part of this study.

What are the possible risks or discomforts involved from being in this study?

It is possible you may find some of the questionnaire questions distressing. You do not have to answer any question you do not wish to answer. If the questions raise concerns of a personal nature we can refer you to professional organisations that will try to assist you. Finger prick HIV tests do not result in much discomfort. Your finger may slightly sting for a

second. You may experience anger or distress if you learn that you are infected with HIV. We will refer you to a government clinic for care if you are infected with HIV and you will be provided free treatment and care at the clinic.

How will your privacy be protected?

All efforts will be made to keep your personal information confidential. You will be identified by a code number known only to the study staff. This number – not your name – will be used on all information about you. Your name will not be written on any blood samples or test results. Your name will never be used in any publication or presentation about the research study. Personal information about you will not be released without your written permission. Even your parents will not be told the information that you share with us, unless you ask us to share it.

Will it cost you anything to be in this study?

There will be no costs for being in the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or concerns, you should contact the researchers listed on the first page of this form. You will be given an opportunity to ask any questions before the questionnaires begins.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research participant you may contact, anonymously if you wish, the University of the Witwatersrand Human Research Ethics Committee. Please phone 011-717-2301 to be directed to one of the chairpersons of the committee. If you have questions about this specific research project please call the study manager, Zak Kaufman on 071 590 0820 or the co-Principal Investigator Dr. Sinead Delany-Moretlwe at WRHI on 082 377 6275 or email sdelany@wrhi.ac.za

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

Signature of Research Participant

Date

Printed Name of Research Participant

Signature of Person Obtaining Assent

Date

Printed Name of Person Obtaining Assent



THE SOUTH AFRICAN
COCHRANE CENTRE

SOUTH AFRICAN COCHRANE CENTRE

PO Box 19070, Tygerberg, 7505, South Africa;
Francie van Zijl Drive, Parow Valley, Cape Town
Tel: +27 21 938 0438; Fax: +27 21 938 0836
E-mail: cochrane@mrc.ac.za



THE COCHRANE
COLLABORATOR

11 February 2014

To Whom It May Concern:

RE: GOAL Trial: Behavioural Effectiveness of Sport-based HIV Prevention in South African Schools.

As project manager for the Pan African Clinical Trial Registry (www.pactr.org) database, it is my pleasure to inform you that your application to our registry has been accepted. Your unique identification number for the registry is **PACTR201402000767141**

Please be advised that your trial is registered under an initiative within our system that allow us to capture data of trials that are already in progress or completed. As such, your trial registration may not adhere to the mandates set forth by the International Committee of Medical Journal Editors for registration requirements, and it is your duty to be transparent to any journal that may ask about the retrospective status of your registration.

Please note you are responsible for updating your trial, or for informing us of changes to your trial. Additionally, please provide us with copies of your ethical clearance letters; we must have these on file (via email, post or fax) at your earliest convenience if you have not already done so.

Please do not hesitate to contact us at +27 21 938 0835 or email epienaar@mrc.ac.za should you have any questions.

Yours faithfully,

Elizabeth D Pienaar
www.pactr.org Project Manager
+27 021 938 0835



UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mr Zachary Kaufman

CLEARANCE CERTIFICATE

M111192

PROJECT

Sports -Based HIV Prevention in South African
Schools: A Cluster-Randomised Trial

INVESTIGATORS

Mr Zachary Kaufman.

DEPARTMENT

Wits Reproductive Health Research unit

DATE CONSIDERED

25/11/2011

M1111920DECISION OF THE COMMITTEE*

Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 29/02/2012

CHAIRPERSON
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr S Delany-Moretlwe

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...



OBSERVATIONAL/INTERVENTIONS RESEARCH ETHICS COMMITTEE

23 February 2012

David Ross & Zachary Kaufman

Dear David and Zachary

Study Title: GOAL Trial: Sport-based HIV prevention in South African schools
LSHTM ethics ref: 6131
Department: Epidemiology and Population Health

Thank you for your email of 22/02/12, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair>.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
LSHTM ethics application	n/a		
Protocol	V2.0	23/02/12	
Information Sheet	V1.0	23/02/12	
Consent form	V1.0	23/02/12	

After ethical review

Any subsequent changes to the application must be submitted to the Committee via an E2 amendment form.

Yours sincerely,

Professor Andrew J Hall
Chair



WESTERN CAPE Education Department

Provincial Government of the Western Cape

**RES
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CH**

awyngaar@pgwc.gov.za

tel: +27 021 476 9272

Fax: 0865902282

Private Bag x9114, Cape Town, 8000

wced.wcape.gov.za

REFERENCE: 20111908-0033

ENQUIRIES: Dr A T Wyngaard

Mr Zac Kaufman
London School of Hygiene and Tropical Medicine
London

Dear Mr Zac Kaufman

RESEARCH PROPOSAL: SPORTS BASED HIV PREVENTION IN SOUTH AFRICAN SCHOOLS A CLUSTER RANDOMISED TRIAL

Your application to conduct the above-mentioned research in schools in the Western Cape has been approved subject to the following conditions:

1. Principals, educators and learners are under no obligation to assist you in your investigation.
2. Principals, educators, learners and schools should not be identifiable in any way from the results of the investigation.
3. You make all the arrangements concerning your investigation.
4. Educators' programmes are not to be interrupted.
5. The Study is to be conducted from **19 January 2012 till 30 September 2013**
6. No research can be conducted during the fourth term as schools are preparing and finalizing syllabi for examinations (October to December).
7. Should you wish to extend the period of your survey, please contact Dr A.T Wyngaard at the contact numbers above quoting the reference number.
8. A photocopy of this letter is submitted to the principal where the intended research is to be conducted.
9. Your research will be limited to the list of schools as forwarded to the Western Cape Education Department.
10. A brief summary of the content, findings and recommendations is provided to the Director: Research Services.
11. The Department receives a copy of the completed report/dissertation/thesis addressed to:

**The Director: Research Services
Western Cape Education Department
Private Bag X9114
CAPE TOWN
8000**

We wish you success in your research.

Kind regards.

Signed: Audrey T Wyngaard

for: **HEAD: EDUCATION**

DATE: 06 October 2011

MELD ASSEBLIEF VERWYSINGSNOMMERS IN ALLE KORRESPONDENSIE / PLEASE QUOTE REFERENCE NUMBERS IN ALL CORRESPONDENCE /
NCEDA UBHALE IINOMBOLO ZESALATHISO KUYO YONKE IMBALELWANO

GRAND CENTRAL TOWERS, LAER-PARLEMENTSTRAAT, PRIVAATSAK X9114, KAAPSTAD 8000
GRAND CENTRAL TOWERS, LOWER PARLIAMENT STREET, PRIVATE BAG X9114, CAPE TOWN 8000

WEB: <http://wced.wcape.gov.za>

INBELSENTRUM /CALL CENTRE

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VEELICE SVOL ESAREE SCHOOLS ☎ 0800 45 46 47

London School of Hygiene & Tropical Medicine

Research Grants & Contracts Office

Keppel Street, London WC1E 7HT

Tel +44 (0) 20 7927 2626 (direct) Fax +44 (0) 20 7580 5636

e-mail: patricia.henley@lshtm.ac.uk

www.intra.lshtm.ac.uk/trials



Our ref: QA371

16 January 2012

Mr Zachary Kaufman
PhD Candidate
Faculty of Epidemiology and Population Health
LSHTM

Dear Mr Kaufman,

Re: Sports-based HIV prevention in South African schools: a cluster-randomised trial

As the authorised representative for the London School of Hygiene & Tropical Medicine (LSHTM), I can confirm that LSHTM will act as the identified Research Sponsor, the organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial, for the above titled project. I can confirm that the research proposal has been reviewed, assessed and registered by the Clinical Trials Sub-Committee.

It is the Chief Investigator's responsibility to ensure that members of the research team comply with all local regulations applicable to the performance of the project, including, but not limited to: the Declaration of Helsinki (2008), ICH Good Clinical Practice Guidelines (1996), and for projects conducted in the UK: the Medicines for Human Use (Clinical Trials) Regulations (2004), the Research Governance Framework for Health and Social Care (2005), the Data Protection Act (1998) and the Human Tissue Act (2004).

LSHTM carries Non Negligent Harm Insurance and Professional Negligence Insurance applicable to this study:

	Non Negligent Compensation	Medical Malpractice
Insurer	Lloyds (MarketForm)	Lloyds (MarketForm)
Certification No.	11/00066390	11/00066391
Finance Cover	£5 million pounds sterling	£10 million pounds sterling

The Non-Negligent harm policy is worldwide, with the exception of the United States and Canada. The policy is subject to terms, conditions and exceptions.

LSHTM Sponsorship is conditional on the project receiving applicable ethical and regulatory approval, complying with LSHTM policies and procedures, as well as successful contract and agreement negotiations from the Research Grants and Contracts Office, where relevant, before the study commences.

A copy of the ethics and regulatory approval letters **must** be sent to the Clinical Trials QA Manager prior to the study commencing. Sponsorship is dependent on obtaining local approval for all sites where the research is being conducted. It is recommended that all members of the study team attend Good Clinical Practice (GCP) training every two years.

Yours sincerely,


Patricia Henley
Clinical Trials QA Manager
on behalf of the Clinical Trials Sub-Committee

POLICY DOCUMENT COVERING SPONSORSHIP, WITH REGARD TO CLINICAL TRIALS

The main responsibilities of Sponsor delegated to the Chief/Principal investigator are:

(i) Authorisations

- Obtain favourable opinion from ethics committee
- Request clinical trial authorisation (CTA) from Regulatory Authority (as required)
- Study submitted to public database (eg www.clinicaltrials.gov)
- Give notice of amendments to the protocol
- Give notice a trial has ended

(ii) Good Clinical Practice and conduct (GCP)

- Put and keep in place arrangements to adhere to GCP
- Ensure all members of study team receive appropriate training in GCP
- Take appropriate urgent safety measures

(iii) Pharmacovigilance

- Keep records of all adverse events reported by investigators
- Ensure recording and prompt reporting of suspected unexpected serious adverse reactions (SUSARS)
- Ensure investigators are informed of SUSARS
- Ensure all SUSARS including those in third countries entered into European database
- Provide annual list of suspected serious adverse reactions and a safety report

(iv) Trial Management

- Quality Control (monitoring)
- Medical Expertise
- Data Handling, and Record Keeping
- Investigator Selection
- Delegation of Responsibilities
- Record access for QA/QC and regulatory inspectors
- Clinical Trial/Study Reports
- Study Design

(v) Investigational Medicinal Product (IMP)

- Ensure Investigational Medicinal Products are available to participants free of charge
- Information on IMP kept up to date
- Manufacturing, Packaging, Labelling, and Coding of IMP
- Supplying and Handling of IMP

The main responsibilities retained by the Sponsor are:

(i) RGCO / Finance

- Contracts & Agreements
- Compensation to Subjects and Investigators
- Financing
- Confirmation of indemnity

(ii) Clinical Trials QA Manager

- Project review and organisational risk assessment
- Quality Assurance (audits)
- Investigation of non-compliance



NIDA Clinical Trials Network

Certificate of Completion

is hereby granted to

Zachary Kaufman

to certify that you have successfully completed the six hour, required course on

Good Clinical Practices

Expires: 03 October, 2015



Elizabeth A. Buttrey, Training Coordinator
Clinical Coordinating Center

*This training has been funded in whole or in part with Federal funds from the National Institute on Drug Abuse,
National Institutes of Health, Department of Health and Human Services, under Contract No.HHSN271200522081C.*

Note: This questionnaire is completed via a handheld mobile phone using Open Data Kit software. Some questions will have longer picklists of values than can fit on this summary document. This document is meant to summarize the questionnaire items in a printable view.

Question/Item	Type of data or possible values
Participant ID Number	Number
Date of survey	Date
Phone ID	Number
Start Time	Date/Time
End Time	Date/Time
Please answer as honestly as possible.	
Example: This phone survey tool is pretty cool, isn't it?	
Great - Swipe the screen to start.	
Section 1: Basics & Demographics First, I'm going to ask some questions about yourself and your household.	
What is your sex?	MaleFemale
How old are you?	Number
In what year were you born?	Year
In what month were you born?	Month
On what day of the month were you born?	Day
How would you describe your race?	Black, coloured, indian, white, other
What language do you speak most at home?	Xhosa, afrikaans, english, zulu, sotho, other
What best describes your living quarters?	Shack, flat, house, other
Do you live with your mother?	Yes or No
Do you live with your father?	Yes or No
Is your mother alive?	Yes or No
Is your father alive?	Yes or No
How many people live in your household?	Number
Who is the head of your household?	Mother, father, brother or sister, myself, other family member, other non-family member
What is your mother's highest level of education?	None, some primary, completed primary, some secondary, matric, higher
What is your father's highest level of education?	None, some primary, completed primary, some secondary, matric, higher
Do you have a television in your household?	Yes or No
Do you have a radio in your household?	Yes or No
Do you have piped water in your household?	Yes or No
Do you have a running car at your household?	Yes or No
What is the main type of toilet facility used in your household?	Yes or No
Do you own a mobile phone?	Yes or No
Do you own a sim card?	Yes or No
Do you have an email address?	Yes or No
Do you have a facebook account?	Yes or No
Do you have a Mxit account?	Yes or No
How often do you use facebook, Mxit or other social networks?	Never- Daily or almost daily
How often do you use the internet for reasons other than social networking?	Never- Daily or almost daily
Does someone else in your household own a mobile phone?	Yes or No
Is there anyone in your household who you know or think has HIV?	Yes or No
Is there anyone you know personally who has or had HIV?	Yes or No
Do you know anyone personally who died of HIV or AIDS?	Yes or No
Section 2: HIV Knowledge Now, I'm going to present some statements about HIV.	
I can tell if someone has HIV by looking at him or her	TrueFalse
Having an older sexual partner increases your risk of getting HIV	TrueFalse
Using condoms during sex reduces your risk of getting HIV	TrueFalse
An HIV-positive mother would never give birth to an HIV-negative baby.	TrueFalse
You are more likely to get HIV if you already have an STI	TrueFalse
Having only one mutually faithful partner reduces your risk of getting HIV	TrueFalse
Male circumcision reduces a man's risk of getting HIV	TrueFalse
Legally, men are allowed to beat their wives.	TrueFalse
Drinking alcohol can increase your risk of getting HIV	TrueFalse
Someone is most likely to spread HIV during the first 6-8 weeks after they get infected	TrueFalse
Section 3: HIV Attitudes and Communication Thanks! Now, I'm going to ask some questions about how you feel in general.	
I am certain I can avoid getting HIV	Strongly Agree - Strongly Disagree
I am certain I can say no to sex if I don't want it	Strongly Agree - Strongly Disagree
I am certain I can stick to only one sexual partner at a time	Strongly Agree - Strongly Disagree
It is hard for me to resist peer pressure	Strongly Agree - Strongly Disagree
I am certain I can avoid having a sexual relationship with an older man even if he offers me gifts or money	Strongly Agree - Strongly Disagree
I am confident that I could use a condom correctly.	Strongly Agree - Strongly Disagree
If my partner did not want to use a condom, I could convince him or her to use one	Strongly Agree - Strongly Disagree
I want to know my HIV status and am willing to take a test	Strongly Agree - Strongly Disagree
I would not want to sit near a classmate with HIV.	Strongly Agree - Strongly Disagree
I would be willing to care for a family member with HIV	Strongly Agree - Strongly Disagree
People with HIV should be ashamed of themselves	Strongly Agree - Strongly Disagree
A teacher with HIV should not be allowed to work in a school.	Strongly Agree - Strongly Disagree
A man who gets circumcised at a clinic is not a real man.	Strongly Agree - Strongly Disagree
I would consider getting circumcised at a clinic.	Strongly Agree - Strongly Disagree
I am comfortable talking about sex with my friends	Strongly Agree - Strongly Disagree
I am comfortable talking about sex with a parent or guardian	Strongly Agree - Strongly Disagree
I have talked about HIV with a friend in the past 2 months	Yes or No
I have talked about HIV with a parent or guardian in the past 2 months	Yes or No
Section 4: Depression Keep up the good work! Now I'm going to ask some questions about how you felt during the last week.	
During the past week I was bothered by things that usually don't bother me.	Rarely - All of the time
During the past week I did not feel like eating, my appetite was poor	Rarely - All of the time
During the past week I felt I could not cheer myself up even with the help of family and friends	Rarely - All of the time
During the past week I had trouble keeping my mind on what I was doing	Rarely - All of the time
During the past week I felt depressed	Rarely - All of the time
During the past week I felt that everything I did was an effort	Rarely - All of the time
During the past week I thought my life had been a failure	Rarely - All of the time
During the past week I felt fearful	Rarely - All of the time
During the past week my sleep was restless	Rarely - All of the time
During the past week I talked less than usual	Rarely - All of the time

ANNEX F: GOAL TRIAL BASELINE QUESTIONNAIRE (ENGLISH)

Question/Item	Type of data or possible values
Section 5: Gender Norms You're halfway done! Now, I'm going to ask some questions about relations between men and women in society.	
A woman should obey her husband.	Strongly Agree - Strongly Disagree
A woman should choose her own friends even if her boyfriend or husband disapproves.	Strongly Agree - Strongly Disagree
Men should share the work around the home such as doing the dishes or cleaning or cooking.	Strongly Agree - Strongly Disagree
Sometimes a man may have a good reason to hit his girlfriend or wife.	Strongly Agree - Strongly Disagree
A woman can refuse to have sex with her husband if she does not want it for any reason.	Strongly Agree - Strongly Disagree
If a wife does something wrong she should expect her husband to punish her.	Strongly Agree - Strongly Disagree
A man cannot control himself when he gets sexually aroused.	Strongly Agree - Strongly Disagree
A woman should expect to be taught how to behave by her husband.	Strongly Agree - Strongly Disagree
A woman should not expect the fathers of her children to give her money	Strongly Agree - Strongly Disagree
A woman has the right to refuse to have sex if she knows her partner is having sex with other women.	Strongly Agree - Strongly Disagree
Section 6: Sexual History Now I'm going to ask some questions about your sexual history.	
Some people your age have had sex and others have not. Have you ever had sex?	Yes or No
Which of the following best describes your experience the first time you had sex?	Willing, persuaded, tricked, raped
How old were you the first time you had sex?	Number
Have you ever used a condom?	Yes or No
Did you use a condom the first time you had sex?	Yes or No
How many sexual partners have you had in your lifetime?	1, 2, 3 or 4, 5 to 7, 8 to 10, More than 10
How many sexual partners have you had in the last 12 months?	1, 2, 3 or 4, 5 to 7, 8 to 10, More than 10
Do you currently have a sexual partner?	Yes or No
Did you use a condom the last time you had sex?	Yes or No
In the past 12 months, have you had sex after drinking alcohol?	Yes or No
In the past 12 months, have you given or received money, drugs, food, transport or a place to stay in exchange for sex?	Yes or No
In the past 12 months, have you ever had more than one sexual partner at the same time?	Yes or No
How old was the oldest partner you had sex with in the last 12 months?	Number
How old was the youngest partner you had sex with in the last 12 months?	
Some men have sex with other men. Have you ever had sex with another man?	Yes or No
The first time you had sex with a man did you have sex against your will?	Yes or No
Section 7: Forced Sex I have a few more questions about things you may have done with current or previous girlfriends.	
Have you ever forced your current or previous girlfriend to have sex with you when she did not want to?	Yes or No
Have you ever forced your current or previous girlfriend to do something sexual that she did not want to do?	Yes or No
Have you ever forced a woman or girl who was not your girlfriend to have sex with you?	Yes or No
Have you ever had sex with a woman or girl when she was too drunk or drugged to say whether she wanted it or not?	Yes or No
Have you done any of these things in the past 12 months?	Yes or No
Section 8: Medical History Now I'm going to ask some general questions about your medical history.	
Are you currently pregnant?	Yes or No
Have you ever been pregnant?	Yes or No
How many times have you been pregnant?	once, twice, 3 times, more than 3 times
What was your age at first pregnancy?	Number
Have you ever been told by a female partner that you have made them pregnant?	Yes or No
Have you ever had a sexually transmitted infection (STI)?	Yes or No
Did you get it treated?	Yes or No
Are you circumcised?	Yes or No
Where were you circumcised?	Clinic/hospital, In the bush, don't remember
Have you ever been tested for HIV?	Yes or No
Have you been tested for HIV in the last 12 months?	Yes or No
How would you assess your own personal risk of getting HIV?	No risk, low risk, some risk, high risk
Section 9: Alcohol Use Now I am going to ask you some questions about your use of alcoholic drinks.	
How often do you have a drink with alcohol?	Never, Once a month or less, 2-4 times a month, 2-3 times a week, 4+ times a week
How many drinks with alcohol do you have on a typical day when you are drinking?	1 or 2, 3 or 4, 5 or 6, 7 to 9, 10 or more
How often do you have six or more drinks on one occasion?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you found that you were not able to stop drinking once you had started?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you failed to do what was normally expected from you because of drinking?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you had a feeling of guilt or remorse after drinking?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never, Less than monthly, Monthly, Weekly Daily or almost daily
Have you or someone else been injured as a result of your drinking?	No; yes, not in last year; yes during last year
Has a relative or friend or health worker been concerned about your drinking or suggested you drink less?	No; yes, not in last year; yes during last year
I am going to ask some questions about this.	
Have you ever threatened to hurt a partner?	Yes or No
Have you ever slapped a partner or thrown something at her that could hurt her?	Yes or No
Have you ever pushed or shoved a partner?	Yes or No
Have you ever hit a partner with a fist or with something else that could hurt her?	Yes or No
Have you ever kicked, dragged, beaten, choked or burned a partner?	Yes or No
Have you ever threatened to use or actually used a gun, knife or other weapon against a partner?	Yes or No
Have you done any of these things in the past 12 months?	Yes or No
physical. I am going to ask some questions about this.	
Has a partner ever threatened to hurt you?	Yes or No
Has a partner ever slapped you or thrown something at you that could hurt you?	Yes or No
Has a partner ever pushed or shoved you?	Yes or No
Has a partner ever hit you with a fist or with something else that could hurt you?	Yes or No
Has a partner ever kicked, dragged, beaten, choked or burned you?	Yes or No
Has a partner ever threatened to use or actually used a gun, knife or other weapon against you?	Yes or No
Have any of these things happened in the past 12 months?	Yes or No
Section 11: Acceptability of Open Data Kit: You're done with all the tough stuff! Just a couple more questions for feedback.	
How easy or difficult was it to use this phone for the survey?	Very difficult - Very easy
How well do you feel you understood the questions on this survey?	Not at all - All questions
How well were you able to answer questions on the survey HONESTLY?	Not at all - All questions
How comfortable did you feel taking this survey?	Very uncomfortable - Very comfortable
Do you prefer this type of survey (on a phone) or a pen-and-paper survey?	Phone, Pen-and-Paper, No preference
Thanks for participating in the survey. You can now hand your phone back to the administrator.	