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Annexes

Annex A: Lists of participating schools

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

<table>
<thead>
<tr>
<th>School Name</th>
<th>Community</th>
<th>RCT Group</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulumko Secondary</td>
<td>Khayelitsha</td>
<td>Intervention</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Chris Hani S.S.S.</td>
<td>Khayelitsha</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Dr. Nelson Mandela</td>
<td>Crossroads</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>ID.Mkhize</td>
<td>Gugulethu</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Intlanganiso</td>
<td>Khayelitsha</td>
<td>Intervention</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Intshukumo</td>
<td>Gugulethu</td>
<td>Intervention</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Joe Slovo High School</td>
<td>Khayelitsha</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Khulani</td>
<td>Langa</td>
<td>Intervention</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Langa High</td>
<td>Langa</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Manyano S.S</td>
<td>Khayelitsha</td>
<td>Intervention</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Masiyile S.S.S.</td>
<td>Khayelitsha</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Matthew Goniwe</td>
<td>Khayelitsha</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Sithembele Matiso</td>
<td>Gugulethu</td>
<td>Intervention</td>
<td>Cape Town</td>
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<tr>
<td>Sivile High</td>
<td>Khayelitsha</td>
<td>Intervention</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Thembelihle</td>
<td>Khayelitsha</td>
<td>Control</td>
<td>Cape Town</td>
</tr>
<tr>
<td>Uxolo High</td>
<td>Khayelitsha</td>
<td>Intervention</td>
<td>Cape Town</td>
</tr>
</tbody>
</table>
Table 2: List of Port Elizabeth schools participating in the GOAL Trial

<table>
<thead>
<tr>
<th>School Name</th>
<th>Community</th>
<th>RCT Group</th>
<th>Site</th>
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</thead>
<tbody>
<tr>
<td>Chubekile</td>
<td>Kwazakhele</td>
<td>Intervention</td>
<td>Port Elizabeth 1</td>
</tr>
<tr>
<td>Cowan</td>
<td>New Brighton</td>
<td>Control</td>
<td>Port Elizabeth 1</td>
</tr>
<tr>
<td>Ithembelihle</td>
<td>New Brighton</td>
<td>Intervention</td>
<td>Port Elizabeth 1</td>
</tr>
<tr>
<td>Khwezi Lomso</td>
<td>Zwide</td>
<td>Intervention</td>
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</tr>
<tr>
<td>Loyiso</td>
<td>Zwide</td>
<td>Control</td>
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<tr>
<td>Lwandle Kazi</td>
<td>New Brighton</td>
<td>Intervention</td>
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<tr>
<td>Lwazilwethu</td>
<td>Zwide</td>
<td>Control</td>
<td>Port Elizabeth 1</td>
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<td>Masibambane</td>
<td>Kwazakhele</td>
<td>Control</td>
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<tr>
<td>Ndzondelelo</td>
<td>Zwide</td>
<td>Intervention</td>
<td>Port Elizabeth 1</td>
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<tr>
<td>Newell</td>
<td>New Brighton</td>
<td>Control</td>
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<tr>
<td>Sakhisizwe</td>
<td>Zwide</td>
<td>Control</td>
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<td>Sophakama</td>
<td>New Brighton</td>
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<td>Thamsanqa</td>
<td>Kwazakhele</td>
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<td>Zwide</td>
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<td>Control</td>
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<td>KwaDwesi</td>
<td>Intervention</td>
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<td>Masiphathisane</td>
<td>Motherwell</td>
<td>Control</td>
<td>Port Elizabeth 2</td>
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<td>Mfesane</td>
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<tr>
<td>Mlungisi</td>
<td>Uitenhage</td>
<td>Control</td>
<td>Port Elizabeth 2</td>
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<tr>
<td>Molly Black Burn</td>
<td>Uitenhage</td>
<td>Intervention</td>
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<td>Motherwell High School</td>
<td>Motherwell</td>
<td>Intervention</td>
<td>Port Elizabeth 2</td>
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<td>Ncedo</td>
<td>Motherwell</td>
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<td>Uitenhage</td>
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<td>SEK Mqhayi</td>
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<td>V.M.Khwinana</td>
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<td>Zanolwazi</td>
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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 Funding Source: MAC AIDS Fund
Telephone number: 071 590 0820 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. The young person 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

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**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.

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**Signature of Participant’s Parent/Guardian** ____________________________________________________________________________

**Date**

---

**Printed Name of Parent/Guardian** ____________________________________________________________________________

**Name of study participant** ____________________________________________________________________________

**Address:** ____________________________________________________________________________

**Phone:** ____________________________________________________________________________

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**Annexes**
Goal Trial Assent Form

<table>
<thead>
<tr>
<th>Wits Institute for Reproductive Health &amp; HIV (WRHI)</th>
<th>London School of Hygiene and Tropical Medicine (LSHTM)</th>
</tr>
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<tbody>
<tr>
<td>HREC # Mxxxxxx</td>
<td>REC Study #</td>
</tr>
<tr>
<td>Assent to Participate in a Research Study</td>
<td></td>
</tr>
<tr>
<td>Grade 9 learners</td>
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</table>

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-Morelwe 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

*Annexes*
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 as 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-Moretjwe

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...
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:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tr>
<td>LSHTM ethics application</td>
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<td>Protocol</td>
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<td>23/02/12</td>
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<tr>
<td>Information Sheet</td>
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<td>Consent form</td>
<td>V1.0</td>
<td>23/02/12</td>
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</tbody>
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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

Annexes 227
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
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:

<table>
<thead>
<tr>
<th>Insurer</th>
<th>Non Negligent Compensation</th>
<th>Medical Malpractice</th>
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<tr>
<td>Lloyds (MarketForm)</td>
<td>11/00066390 £5 million</td>
<td>Lloyds (MarketForm)</td>
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<td>pounds sterling</td>
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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

V3; 05/09/2011
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 OA/OQC 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

[Signature]

Elizabeth A. Butteny, 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.HHSN271200522001C.
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 talked less than usual
During the past week I thought my life had been a failure
During the past week I felt that everything I did was an effort
During the past week I felt depressed
During the past week I had trouble keeping my mind on what I was doing
During the past week I felt I could not cheer myself up even with the help of family and friends

Section 4: Depression

I have talked about HIV with a parent or guardian in the past 2 months
I have talked about HIV with a friend in the past 2 months
I am comfortable talking about sex with my friends
I would consider getting circumcised at a clinic.
A man who gets circumcised at a clinic is not a real man.
A teacher with HIV should not be allowed to work in a school.
People with HIV should be ashamed of themselves
I would be willing to care for a family member with HIV
I would not want to sit near a classmate with HIV.
I want to know my HIV status and am willing to take a test
If my partner did not want to use a condom, I could convince him or her to use one
I am confident that I could use a condom correctly
I am certain I can avoid having a sexual relationship with an older man even if he offers me gifts or
It is hard for me to resist peer pressure
I am certain I can stick to only one sexual partner at a time
I am certain I can avoid getting HIV

Section 3: HIV Attitudes and Communication

Someone is most likely to spread HIV during the first 6-8 weeks after they get infected
Drinking alcohol can increase your risk of getting HIV
Legally, men are allowed to beat their wives.
Having only one mutually faithful partner reduces your risk of getting HIV
You are more likely to get HIV if you already have an STI
An HIV-positive mother would never give birth to an HIV-negative baby.
Using condoms during sex reduces your risk of getting HIV
Male circumcision reduces a man's risk of getting HIV
Legally, men are allowed to beat their wives.
Using condoms during sex reduces your risk of getting HIV
Someone is most likely to spread HIV during the first 6-8 weeks after they get infected

Section 2: HIV Knowledge

I can tell if someone has HIV by looking at him or her
Having an older sexual partner increases your risk of getting HIV
Using condoms during sex reduces your risk of getting HIV
An HIV-positive mother would never give birth to an HIV-negative baby.
You are more likely to get HIV if you already have an STI
Having only one mutually faithful partner reduces your risk of getting HIV
Male circumcision reduces a man's risk of getting HIV
Legally, men are allowed to beat their wives.
Using condoms during sex reduces your risk of getting HIV

Section 1: Basics & Demographics

What is your sex? Male Female
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 a telephone in your household? Yes or No
Do you have a running car at 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 own an email address? Yes or No
Do you have a facebook account? Yes or No
Do you have a phone 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

Great - Swipe the screen to start.

Intro:
Start Time
Phone ID
Date of survey
Participant ID Number
Question/Item
type of data or possible values

Example: This phone survey tool is pretty cool, isn't it?
ANNEX F: GOAL TRIAL BASELINE QUESTIONNAIRE (ENGLISH)

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 man should obey his husband's wishes. Strongly Agree - Strongly Disagree
A man should choose his own friends even if his boyfriend or husband disapproves. Strongly Agree - Strongly Disagree
A woman 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: Forced Sex
Now I'm going to ask some questions about your sexual history.

Have you ever forced a woman or girl who was not your girlfriend to have sex with you? Yes or No
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 7: 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? One, 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 8: 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 week, 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 do you have six or more drinks on one occasion? Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often do you drink after drinking alcohol? Never, Less than monthly, Monthly, Weekly Daily or almost daily
How often do you have six or more drinks on one occasion? Never, Less than monthly, Monthly, Weekly Daily or almost daily
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 do you drink after drinking alcohol? Never, Less than monthly, Monthly, Weekly Daily or almost daily
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 do you drink after drinking alcohol? Never, Less than monthly, Monthly, Weekly Daily or almost daily

Section 9: Acceptability of Open Data Kit
You're done with all the tough stuff! Just a couple more questions about 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 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.

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