Protocol title	Social networks, sexual behaviour and HIV prevention: a cohort study of young rural South Africans and their social influences
Principal investigator	Dr Guy Harling
Version date	30 September 2019

Greetings

My name is _____ from the Africa Health Research Institute in Somkhele, Mtubatuba

We would like to invite you to participate in a research project. Before you decide to participate it is important for you to understand why the research is being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this project?

This project aims to understand the social lives of young people living in this area. In particular, we would like to understand how young people interact with their friends and family, how they learn new things from these social connections and how friends and family affect young people's sexual health decisions and risks. This research is intended to improve understanding of how young people in your area become infected with HIV and how we can better provide interventions that will reduce this risk. To do this we would like to interview you six times over three years to see how your life changes.

Why have I been chosen?

We plan to involve around 1500 people in this study, from three areas within Hlabisa sub-district. You are invited to take part in this research either: (1) because you are aged between 16 and 24 who is resident in _____; or (2) because someone aged between 16 and 24 who is resident in _____ named you as a social connection.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can leave at any time without giving a reason and without it affecting any benefits that you are entitled to. You are free to not answer some or all questions, and to decline to provide a blood specimen. If you decide to leave you will be asked what you wish to happen to the data you have provided up that point.

What will happen to me if I take part?

We will conduct an interview now. The interview will last about one hour. This interview will ask you questions about your life, including your close friends and family. It will also ask you about your health and sexual behaviour. When questions are personal, we will ask you to enter your answers on a computer, and the fieldworker will not be able to see your answers at the time or afterwards. If you prefer not to use a computer, the fieldworker will ask you

the questions. We will also ask you to help us contact the close friends and family that you name in your interview, by giving them a referral slip and asking them to call AHRI.

We will ask for two finger prick blood specimens: one for research purposes, and one to tell you your HIV status. For the research blood specimen, the blood will be put onto a dried blood spot (DBS) filter-paper card or into a very small tube. This takes a few minutes. The HIV finger prick test can be performed at home and give you your result in 15 to 20 minutes. This HIV test is described in more detail on the consent form below.

In the future we will then contact you by telephone every six months. Each time we will ask you to conduct another interview and provide finger prick specimens, at a time and place that is convenient to you. This interview may be conducted in part by telephone. In total we will ask you to complete no more than six interviews over thirty months (2.5 years).

What are the possible disadvantages and risks of taking part?

We do not expect big risks arising from taking part in this project. Some of the questions or experiences you recall might make you feel uncomfortable. You can always choose not to answer any question that makes you feel uncomfortable. Our fieldworkers are experienced and will try to minimize possible discomfort. All participants will be given a study contact card to let you reach the study team. You may use 'Please call me' to contact us to discuss any issues raised by your participation, and we can put you in touch with a trained counsellor if you would like. The needle used to collect blood specimens may cause a little pain, but this will soon go away without causing any damage.

What are the possible benefits of taking part?

You will have an opportunity to complete an HIV test at each interview. Knowing you HIV status can allow you to make decisions about your life that can benefit you and the people around you. In addition, it is hoped that this research will improve our understanding of how to provide information to young people, to reduce their risk of getting HIV.

Will I be paid for participating in this project?

We will offer you R20 phone credit for each interview that you complete, to compensate you for your time. If you are in stage 1 of this study, we will also offer you R10 phone credit for each of your social connections who use their referral slip to contact AHRI, to compensate you for your effort.

What will happen to the interview answers I give?

We will keep what you say during the interviews private. You will not be able to be identified in any ensuing reports or publications. Your answers will be stored on a secured AHRI computer server at the AHRI research offices in Somkhele, for at least five years. The files will be password protected and only accessible to the investigators of this study. Your identifiable information (such as your name, the place where you live or your ID number) will be kept separately. One person (Dr. Kobus Herbst, AHRI Chief Information Officer) has custody of this information. In this way the data are protected so that scientists cannot link the information they are analysing to named individuals.

The only exception to confidentiality is if you tell us something that makes us worried about you or another young person's safety, such as physical harm or neglect. In this case, we may have a duty of care to report this to the relevant authorities. If we think that we should tell someone else, we will talk to you about it first before taking the matter further.

What will happen to the finger prick blood that is collected?

The research specimen will be sent to a laboratory for several tests to help understand HIV better. This will include testing to see if HIV is present. If HIV is present, other tests may be done that will examine different 'family lines' of the virus (which helps us understand how the virus spreads through the community, 'from person to person'. By studying the HIV virus we may also find ways to help people with HIV to have even better treatments. In other words, it is important to provide a blood specimen even if you already know your HIV status. We are also asking permission to indefinitely store the remainder of your blood specimen in a secure specimen bank in Durban, so that as more is learned about health and illnesses we may be able to do other tests on these specimens. Such tests may result in findings which require health intervention and need to be communicated to you. Any future tests on any of your stored specimens will have to be approved by the research ethics committee if applications are made by bona fide researchers. You are free to ask, at a future date, that we do not use your specimens in this way.

What will happen after this research project is finished?

The results of this research will be prepared for publication in scientific journals and meetings in South Africa and abroad, so that the information you provide to us can help others. The results may also be used in presentations at AHRI roadshows and other community events, and will be presented to the AHRI Community Advisory Board. We will also inform the Department of Health at district, provincial and national levels of our findings. Such scientific communication is never about named individuals; you will not be identified in any presentation, report or publication. We take all possible steps to reduce the risk of people being identified from this data. If you would like a copy of the published results, you can contact Ncengani Mthethwa in the public engagement unit at AHRI on 035 550 7500.

We would also like to make the data collected in this project available to other researchers if they present a valid research plan to AHRI. You may agree or disagree to this data sharing. Any shared data would be anonymized prior to being provided to other researchers.

To maximise the value of your data, we would also like to link the information you give us to public sector records. This allows us to understand how people in this area use public services and how this impacts their health. These public sector records include those from the Department of Health, Department of Education, Department of Social Development, and Department of Home Affairs. AHRI protects government information in the same way as the information you give to us directly. Any findings from this research will not name you as an individual. We will also not give back any information about individuals to the government departments. You may agree or disagree to this data linkage.

After the study is complete, we would like to be able to recontact you, if the information you provide (including through linkage) suggests you might be able to help with a new research question. If you give your permission, you may be contacted in the future either by phone or by visiting you at home. If you agree to talk to the researchers, you will then be informed about the new study and be able to decide if you would like to take part.

United Kingdom data protection privacy notice

The UK controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. This 'local' privacy notice sets out

the information that applies to this particular study. Further information on how UCL uses participant information can be found in UCL's 'general' privacy notice: https://www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice. The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data that will be used by UK-affiliated individuals will be as follows: gender; age; residential area. The lawful basis that would be used to process your personal data will be performance of a task in the public interest. The lawful basis used to process special category personal data will be for scientific and historical research or statistical purposes. Your personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible. We will not provide your personal data from UCL to anyone outside the study investigator team.

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

Who is organising and funding the research?

This project is funded by the Wellcome Trust in the UK.

Who has ethically reviewed the research?

This study has been ethically reviewed and approved by the University of KwaZulu-Natal's Biomedical Research Ethics Committee (**approval number** _____). It has also been ethically reviewed by University College London's Research Ethics Committee (**approval number** _____).

Who can I talk to if I have any questions, concerns or complaints about this project?

You may contact the researcher (Dr Guy Harling) or Ncengani Mthethwa at AHRI's public engagement unit on 035 550 7500, or by email at guy.harling@ahri.org or ncengani.mthethwa@ahri.org.

If you feel that your concern has not been addressed, you may contact the chair of the UCL Research Ethics Committee by email at ethics@ucl.ac.uk or the UKZN Biomedical Research Ethics Committee, contact details as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Research Office, Westville Campus, Govan Mbeki Building
Private Bag X 54001
Durban 4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 2604609
Email: BREC@ukzn.ac.za

Thank you for reading this information sheet and for considering to take part in this research study. If you agree to participate, you will be provided with a copy of this information sheet and a signed consent form to keep.

Parental consent for child participation in this study

If participant is aged under 18 years.

A child is considered emancipated if they live in a child-headed household with no adults, is married or is a biological parent.

A.	Does the child live in a child-headed household with no adults	YES	NO
B.	Is the child married?	YES	NO
C.	Is the child a biological parent?	YES	NO

If 'YES' to any of the above the child is emancipated and parental consent is not required.

Otherwise parental consent is required:

I am the parent/guardian of_____

1.	Have you received enough information about the study?	YES	NO
2.	Have you been given an opportunity to ask questions about the study and been given answers to your satisfaction?	YES	NO
3.	Do you agree for your child to take part in this study?	YES	NO

If 'NO' to any of the above the child of this parent is ineligible for the study

4.	Do you agree for your child to be contacted by phone in order to make appointments for follow up discussions?	YES	NO
5.	Do you consent to us linking your cihld's information from this study with other studies conducted at AHRI?	YES	NO
6.	Do you consent to your child being contacted in the future based on information you provide in this study?	YES	NO
7.	Do you consent to us linking your child's information from this study with public sector records?	YES	NO
8.	Do you agree to let other researchers using the data collected in this project for future research studies after it has been anonymized so cannot be identified in it?	YES	NO

Consent to provide blood specimens in this study

1.	Do you consent to your child providing a research blood specimen?	YES	NO
2.	Do you consent to the indefinite storage of your child's specimens?	YES	NO
3.	Do you consent to allow future research to be conducted using your child's specimens, as approved by a research ethics committee?	YES	NO

I have received and understood the study information sheet. I have voluntarily chosen to consent or not to consent on behalf of my child as indicated above.

_____	_____	_____
Parent/guardian's name (print)	Parent/guardian's signature	Date

_____	_____	_____
Name of staff member who administered consent (print)	Staff member's signature	Date

_____	_____	_____
Witness' name (print)	Witness' signature	Date

WITNESS ONLY IF THE PARTICIPANT CANNOT WRITE OR AT THE PARTICIPANT'S REQUEST. Signature of witness to state: "I witnessed the information and consent process and confirm that the above-named participant consented of their own free will." Witness must be neither a child nor AHRI staff.

Tick box if participant is not literate and refuses to have witness present: □

Assent to participation in interviews in this study (under age 18)

1	Have you received enough information about the study?	YES	NO
2	Have you been given an opportunity to ask questions about the study and been given answers to your satisfaction?	YES	NO
3.	Do you agree to take part in this study?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the study

4.	Do you agree to be contacted by phone in order to make appointments for follow up discussions?	YES	NO
5.	Do you assent to us linking your information from this study with other studies conducted at AHRI?	YES	NO
6.	Do you assent to being contacted in the future based on information you provide in this study?	YES	NO
7.	Do you assent to us linking your information from this study with public sector records?	YES	NO
8.	Do you agree to let other researchers using the data collected in this project for future research studies after it has been anonymized so you cannot be identified in it?	YES	NO

I have received and understood the study information sheet. I have voluntarily chosen to assent or not to assent as indicated above.

_____	_____	_____
Participant's name (print)	Participant's signature	Date
_____	_____	_____
Name of staff member who administered consent (print)	Staff member's signature	Date
_____	_____	_____
Witness' name (print)	Witness' signature	Date

WITNESS ONLY IF THE PARTICIPANT CANNOT WRITE OR AT THE PARTICIPANT'S REQUEST. Signature of witness to state: "I witnessed the information and consent process and confirm that the above-named participant consented of their own free will."

Tick box if participant is not literate and refuses to have witness present: ☐

Consent to participation in interviews in this study

1	Have you received enough information about the study?	YES	NO
2	Have you been given an opportunity to ask questions about the study and been given answers to your satisfaction?	YES	NO
3.	Do you agree to take part in this study?	YES	NO

If 'NO' to any of the above the volunteer is ineligible for the study

4.	Do you agree to be contacted by phone in order to make appointments for follow up discussions?	YES	NO
5.	Do you consent to us linking your information from this study with other studies conducted at AHRI?	YES	NO
6.	Do you consent to being contacted in the future based on information you provide in this study?	YES	NO
7.	Do you consent to us linking your information from this study with public sector records?	YES	NO
8.	Do you agree to let other researchers using the data collected in this project for future research studies after it has been anonymized so you cannot be identified in it?	YES	NO

I have received and understood the study information sheet. I have voluntarily chosen to consent or not to consent as indicated above.

_____	_____	_____
Participant's name (print)	Participant's signature	Date
_____	_____	_____
Name of staff member who administered consent (print)	Staff member's signature	Date
_____	_____	_____
Witness' name (print)	Witness' signature	Date

WITNESS ONLY IF THE PARTICIPANT CANNOT WRITE OR AT THE PARTICIPANT'S REQUEST. Signature of witness to state: "I witnessed the information and consent process and confirm that the above-named participant consented of their own free will."

Tick box if participant is not literate and refuses to have witness present: □

Consent to provide blood specimens in this study

1	Do you consent to provide a research blood specimen?	YES	NO
2	Do you consent to the indefinite storage of specimens?	YES	NO
3.	Do you consent to allow future research to be conducted using your specimens, as approved by a research ethics committee?	YES	NO

I have received and understood the study information sheet. I have voluntarily chosen to consent or not to consent as indicated above.

_____	_____	_____
Participant's name (print)	Participant's signature	Date
_____	_____	_____
Name of staff member who administered consent (print)	Staff member's signature	Date
_____	_____	_____
Witness' name (print)	Witness' signature	Date

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Tick box if participant is not literate and refuses to have witness present: □

Assent to provide blood specimens in this study

1	Do you assent to provide a research blood specimen?	YES	NO
2	Do you assent to the indefinite storage of specimens?	YES	NO
3.	Do you assent to allow future research to be conducted using your specimens, as approved by a research ethics committee?	YES	NO

I have received and understood the study information sheet. I have voluntarily chosen to assent or not to assent as indicated above.

_____	_____	_____
Participant's name (print)	Participant's signature	Date
_____	_____	_____
Name of staff member who administered consent (print)	Staff member's signature	Date
_____	_____	_____
Witness' name (print)	Witness' signature	Date

WITNESS ONLY IF THE PARTICIPANT CANNOT WRITE OR AT THE PARTICIPANT'S REQUEST. Signature of witness to state: "I witnessed the information and consent process and confirm that the above-named participant consented of their own free will."

Tick box if participant is not literate and refuses to have witness present: □

Consent to conduct a rapid HIV test with result in this study

Only you can decide for yourself if you have a test to find out your HIV status. No one else can decide for you.

Once you have read this Information sheet, the fieldworker will sit with you, by yourself, in a private space and explain about the HIV test. Please ask if there is anything that is not clear or if you don't understand something or if you would like the nurse or fieldworker to give you more information. Whatever your age, if we assess that you understand what we are explaining, you have a right to be able to discuss HIV testing, and have the test, in privacy.

It is important that you are aware that if you decide not to take part there will be no consequences for you or any members of your family or household. We will not tell anyone, in the household or anyone else, if you decide to take part or not, and we will not tell them your result.

If you decide not to do a rapid HIV test, you may also tell the fieldworker your reason for declining a test if you prefer. We recommend strongly that everyone with HIV obtains care and treatment. Because this can protect you from sudden severe illness and from dying.

If the participant is under 18:

To parent guardian:

If your child wishes to test in private, then they have a right to keep the result confidential from you. Our fieldworker will offer support to your child. In addition, they will encourage and support your child to share their results.

To the child:

Your test can be conducted privately and there is no requirement for you to share your result with your parents or guardian. However, our fieldworkers will discuss with you how you might disclose and will support you in this process. They will also help and support you should you be found to be positive

The benefit of knowing your status – the benefits of treatment

We know from our research that HIV is an important and common health problem in this\ area. Many people living with HIV are taking ARV treatment and as a result most are recovering their health and leading normal lives again. When pregnant women with HIV take ARV treatment correctly, their babies can almost always be prevented from becoming HIV positive. We know that the number of people becoming seriously ill, or dying, from HIV has fallen a great deal because of ARV treatment. We also know that when people with HIV take their ARV treatment correctly, the risk of passing on the virus to someone else is reduced. However, we are aware that many people who know they have HIV are not obtaining treatment and these people remain at risk of sudden severe illness and at higher risk of dying.

However, while many people use the HIV testing services in the community, and are taking the important step of learning their HIV status, there are still many who have never tested, and many who may be at risk who have not had a recent test. For this reason, we decided to

offer you an HIV test with a result to help more people know their status, and to help more people benefit from ARV treatment. We will offer you an HIV test at each interview.

The benefits of knowing if you are HIV negative

Some people think they are HIV positive – perhaps they took risks in the past – only to find they are HIV negative. If you find you are HIV negative it is very reassuring and you may be less worried. You can then also take steps to stay HIV negative such as always using a condom if you have sex, as well as medical circumcision if you are male. Remember that if you took risks in the previous three months, you will need another test to be sure you were not recently infected.

What does the test involve?

We can give you the fingerprick test at home now and give you your result in 15 to 20 minutes. We will conduct the HIV test on two rapid test kits at the same time. Before you have the HIV test, the fieldworker will ask you some questions, and explain some things that you need to know before you confirm you wish to proceed with the test. This will be exactly the same as if you were having an HIV test in a clinic or any other place.

What if my result is HIV positive?

If both the HIV tests are positive, the person who took the test will explain what this result means for you, and will spend time listening to and answering any questions you may have. They will refer you to a clinic to obtain treatment and care. If the both tests give you different results (i.e. the results disagree) we will organise a full blood test with one of our nurses as fast as we can (within 1 to 3 days) so that we can tell you clearly whether you are HIV positive or HIV negative.

Your fieldworker or nurse will offer support, and should you have particular problems or concerns we will refer you for social help at Department of Social Development or for psychological help with a private consulting psychologist at no cost to you.

If you are found to be HIV positive and referred to the clinic, the fieldworker or nurse will explain what you can expect. We will give you a target day, in 7 to 10 days, to attend the clinic. With your consent, when you attend the clinic, we will record your visit. At the clinic visit we will draw blood for confirmatory HIV testing that will be done along with routine blood draw required at enrolment in HIV care. Also with your consent, if you have not attended the clinic in 2 weeks we will send an SMS reminder – this will have options for reply, for example if you are obtaining care elsewhere. If you have not attended in 4 weeks, we will contact you by phone to support you to obtain the tests and treatment that you need. When you are called, if you do not wish us to contact you again, you may tell us.

What if my result is HIV negative?

If your test is negative, this means you do not have HIV – unless you have had a risk for HIV in the last 3 months. Your fieldworker or nurse will discuss with you when repeat HIV testing would be advised for you, and where testing can be done.

Consent to conduct a rapid HIV test with result in this study

1	Do you consent to a rapid HIV test to know your HIV status?	YES	NO
2	Do you consent to us recording your attendance at clinic?	YES	NO
3.	Do you consent to us contacting you by SMS with a reminder?	YES	NO
4.	Do you consent to us making a phone call to follow up?	YES	NO

I have received and understood the study information sheet. I have voluntarily chosen to consent or not to consent as indicated above.

_____	_____	_____
Participant's name (print)	Participant's signature	Date
_____	_____	_____
Name of staff member who administered consent (print)	Staff member's signature	Date
_____	_____	_____
Witness' name (print)	Witness' signature	Date

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Tick box if participant is not literate and refuses to have witness present: ☐