

Study Protocol

Full Title Feasibility and Acceptability of home sampling kits to increase the uptake of HIV testing among Black Africans in the United Kingdom.

Short Title The Haus Study

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1. Glossary of Terms and Abbreviations

AE	Adverse Event
CA	Competent Authority
CBOs	Community Based Organisations
CI	Chief Investigator
CNWL	Central and North West London NHS Foundation Trust
CRF	Case Report Form
CSV	Comma Separated Values File
CW	Community Worker
GCP	Good Clinical Practice
GP	General Practice
FGD	Focus Group Discussion
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
IDHS	Data Safe Haven
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NHS R&D	National Health Service Research & Development

NIHR	National Institute of Health Research
PI	Principal Investigator
PIS	Participant Information Sheet
PN	Practice Nurse
REC	Research Ethics Committee
SOP	Standard Operating Procedure
SSK	Self-Sampling Kit
TDL	The Doctors Laboratory
TSC	Trial Steering Committee
TMF	Trial Master File
UCLH	University College London Hospitals NHS Foundation Trust

2. Signature Page

The clinical study as detailed within this protocol version 1.0 22 October 2015 or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health and Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and any current applicable regulatory requirements, GCP guidelines, the Sponsor's SOPs, and other subsequent regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date:...../...../.....

Name:

Position:

Chief Investigator:

Signature:

Date:15/02/16

Name: Dr Fiona Burns

3. Study Summary

Short Title	The Haus Study – Phase II
Methodology	This protocol describes a prospective, mixed methods, non-randomised study to determine the feasibility and acceptability of a provider initiated, HIV self-sampling kit (SSK) distribution intervention targeted at Black Africans. The study evaluates the effectiveness of self-sampling for HIV in increasing the uptake of HIV testing by Black Africans as well as the cost effectiveness of distributing the SSK among Black Africans over other screening methods. Feasibility, acceptability and intervention fidelity will also be assessed through a process evaluation.
Research Settings	GP practices and HIV Community Based Organisations (CBO)
Research Sites	GP Practices in South London and Greater Glasgow. HIV Community based organisations in both cities.
Aims and Objectives	Overall the study aims to develop an HIV SSK intervention to increase the provision and uptake of HIV testing among Black African communities using existing community and healthcare provision. The aim of Phase II is to evaluate an HIV self-sampling kit distribution intervention targeted at Black Africans. Phase II specifically assesses the feasibility and acceptability of GP practices and community based organisations for targeted HIV SSK distribution. Phase II will inform optimal intervention design for development of a protocol for a future substantive phase III evaluation where this is deemed feasible.
2	1580 kits will be distributed to 1580 participants. 600 kits will be distributed per distributor type in London (600 by GP practice nurses and 600 by community workers) and 380 distributed in Glasgow (via primary care only).
Main inclusion criteria	Black African people without diagnosed HIV, 18 years of age or older, who access the selected GP practices and services provided by Community organisations that already undertake HIV prevention interventions. GP practices in London and Greater Glasgow that have significant numbers of Black Africans registered with them and have not been recently involved in large scale HIV testing initiatives. Community based organisations in London that currently provide HIV prevention interventions for African people.
Main Outcomes	The primary outcome is HIV SSK return rate.
Data Analysis	Quantitative analysis to quantify HIV SSK return rate and other secondary quantitative outcomes. Framework Analysis of all qualitative data collected.
Proposed Start Date	4 th January 2016 (Phase II)
Proposed End Date	30 th September 2016

4. Introduction

4.1 Background and Rationale

Despite progress in treatment and care, Black Africans in the UK continue to present with advanced disease to HIV services. While barriers such as stigma and fear persist, research and experience suggests that when provided the opportunity, many Africans test for HIV (1, 2). In the UK, access to HIV testing is predominantly through sexual health clinics, a service not regularly accessed by African communities. Although primary care services are utilised by this population, these opportunities for earlier HIV diagnosis are often missed (3). African men in particular have high rates of undiagnosed infection and late presentation (1), partly because they have less contact with health services than women. Innovative methods to increase the uptake and opportunities for HIV testing in this population are required.

Self-collected specimens can be used reliably to test for HIV. Self-sampling kits (SSK), accessed via clinical settings and the internet have been shown to be an acceptable and feasible alternative to clinic attendance for HIV testing, and may increase testing among hard-to-reach men who have sex with men (4). Research among young men in the UK also demonstrated acceptability to SSK for HIV testing, with traditional healthcare settings being the preferred venue for accessing kits (5). No study, however, provides insights into preferences by ethnicity, or among women and older men. A survey using oral swabs for anonymous HIV testing among African men and women, in community settings detected high rates of undiagnosed HIV (6), indicating that if testing were offered in these settings, it could lead to new diagnoses and facilitate timely linkage to care. Currently, there are no data on the acceptability or feasibility of using SSK to increase the uptake of named HIV testing among black Africans in the UK. It is important to establish how best to embed SSK within existing services, to ensure acceptability to both provider and client, and to optimise uptake for cost effectiveness. For example linking the kits to existing health promotion and NHS screening opportunities, may facilitate uptake of HIV testing. In a recent cross-sectional study undertaken among Black Africans in England, nearly one third of participants without diagnosed HIV said that they would prefer to have a future HIV test at their GP surgery (7). It is also vital to establish acceptable pathways to confirmatory testing and specialist HIV care. Africans in the UK do not represent a homogenous group and it is important to place efforts to increase HIV testing within the wider social, political and cultural context (8, 9). In advance of undertaking a UK wide study, it is important to understand how distinct health care systems and differences in HIV and community services, as well as differences in local populations and proportions of Africans and HIV prevalence, may impact on the acceptability, feasibility, and cost effectiveness of the interventions. We aim to

improve the provision, acceptability and uptake of HIV testing by developing SSK distribution interventions within GP settings and community based organisations.

Throughout this proposal the term 'Black African' includes anyone who identifies themselves as Black African, whether they are migrants from Africa, African descendants or African nationals. Black African communities encompass diverse population groups including people who may be heterosexual, bisexual or homosexual.

We have named our study the 'Haus study' after the West African pidgin term for "home".

4.2 Phase 1 findings

This protocol and the intervention that will be described later have been informed by Phase 1 of this research. This involved a systematic review and extensive qualitative work conducted between June 2014 and December 2014. The first phase of the Haus Study aimed to develop acceptable SSK distribution pathways in community-based health and HIV prevention services already accessed by Black African people. The full findings are to be published in open access peer-reviewed journals but a summary of the key findings will be presented in section 4.2.2 below. The objectives of Phase 1 were to:

- Clarify barriers and facilitators to provision, access and use of HIV SSK by Black African people, in primary care, pharmacies and community outreach.
- Determine appropriate SSK-based intervention model(s) for different settings.
- Develop intervention manuals to enable intervention delivery in different settings.
- Build sustainable relationships with community service providers willing to distribute and evaluate SSKs as an add-on to existing services.

4.2.1 Qualitative work

We conducted twelve focus group discussions (FGDs) in London and in Glasgow. Six FGDs were conducted with Black Africans, three in Glasgow, and three in London.. We recruited purposively to ensure diversity of gender, age, region of origin and HIV testing experience. Our recruitment strategy enabled us to have the following FGDs:

- 1 group of people with diagnosed HIV (Glasgow)
- 1 men only group (London)
- 1 young person's group (less than 30 years old) (London)
- 3 mixed (gender, age and HIV testing experience) groups (London and Glasgow)

In total there were 47 lay participants (men n=23 and women n=24), including 18 participants who had never previously tested for HIV. In the group discussions we examined views towards SSK, rationales for selecting potential community settings, and key features of implementation.

We also conducted six FGDs with professionals who provide services to Black Africans (n=53).

Participants included:

- practice nurses;
- health care assistants;
- GPs;
- Pharmacists and pharmacy assistants
- Those working and volunteering in African community organisations
- African faith leaders.

The focus groups examined attitudes towards SSK, rationales for selecting potential settings, and key features of implementation. These same issues were explored in nine additional qualitative interviews with HIV clinicians and service commissioners in London and Glasgow.

In summary the key findings from the qualitative work in Phase 1 are:

1. Self-sampling was viewed as acceptable, convenient, anonymous, discrete, private and enabling patient autonomy. However there were some concerns about isolation, lack of counselling, security of samples in transit, accuracy and reliability of the result from a self-sampling kit.
2. It is a viable option to distribute the SSKs through GP practices and community based organisations (CBOs).
3. To enable the research team to track distribution and return of self-sampling kits, it was recognised that provider controlled distribution was required and was considered acceptable.
4. It appears that opportunistic offer of the kit by the staff nurse in the GP practice would be the most appropriate in this setting as it strikes a balance between privacy, confidentiality and busy surgery appointment schedules.
5. Staff in CBOs are regarded as having the requisite HIV skills, cultural competence and infrastructure which makes them well-placed to distribute SSKs.

6. There were significant concerns about the TINY¹ kit including:
 - The presumed large volume of blood required to process the sample.
 - Many people having a fear of needles.
 - Presumed difficulty in using the kit
 - Fear of contamination of the vial.
 - Fears about contaminating others.
7. For those familiar with SSKs, the oral swab was identified as an easier alternative to the use of the TINY kit. There were mixed views about the Dried Blood Spot kit as an alternative to the TINY kit.
8. Provider initiated targeting for offering HIV testing was understood as more likely to succeed than a patient initiated approach. However, consideration of the actual locations in which targeting conversations could take place was perceived as a vital component of the intervention.
9. It was regarded as very important that targeting conversations were initiated sensitively and the content of such conversations were considered in detail in order to avoid perceptions of racism.
10. Provider-initiated targeting which used appearance alone was generally understood as unacceptable. Targeting which addressed more detailed issues such as country of origin or national identity were understood as more acceptable however, they could still be understood as problematic.
11. Tailoring the intervention for individual circumstances was understood as reducing the key barriers of perceived racism and discrimination.
12. For service delivery, it would be better if personal details were not collected at the point of kit collection from a service provider however it was acceptable to have these collected for the purpose of a study and by a trusted professional.
13. It is acceptable for participants to receive a non-reactive result via text message.
14. It is acceptable for the standard NHS clinical governance mechanisms for HIV result management to be used for the study.

¹ TINY kit requires collection of a few drops of blood (obtained by pricking a finger with the supplied lancet) in a small collection vial. The test enables the specimen to be transported to a lab, by post, in a vial that contains preservatives, which stabilize the sample for up to 21 days if temperatures are between 4° C and 37° C.

4.2.2 Systematic Review

As part of the preparatory phase, we also conducted a systematic review of literature, legal, policy and regulatory publications on HIV self-sampling. A full paper on the systematic review is due to be submitted for publication in August 2015. In brief, 15 studies met the inclusion criteria for the systematic review. Below we summarise key findings which were important for informing the development of the intervention:

1. It is feasible and acceptable to use home self-collection kits for HIV testing. In the studies reviewed SSKs were seen as convenient; time saving; private (10, 11, 12, 13, 14, 15, 16).
2. Collection of kits from medical settings such as STI clinics, surgeries, and pharmacies is acceptable (10, 16).
3. SSKs can also be distributed in community settings and outreach services (11, 16).
4. The oral swab is preferred to kits that used blood specimens (15, 19).
5. Barriers to use of SSK include:
 - Concerns about accuracy of the test result (16, 17).
 - Embarrassment about being seen purchasing a kit or asking for it (11, 18).
 - Lack of counselling opportunity (16, 19)

We have developed the intervention and protocol to reflect the current body of knowledge with regards to the use of HIV self-sampling kits.

4.2.3 Professional Guidance relevant to development of HIV testing services

Throughout the design of the intervention and this protocol, we have had discussions with experienced senior NHS HIV service managers; community workers, practice nurses, GPs, HIV commissioners as well as managers from the HIV voluntary sector to assess the planned intervention and research. We have also drawn upon the expertise of the research team and members of the study steering committee to enable us to adopt validated components of the intervention.

The qualitative work, the systematic review and professional guidance suggested user and provider preference for use of a saliva based SSK. The OraSure kit is a commercially available oral fluid collection kit and it is CE marked, but there are no CE marked saliva based HIV assays currently available in the UK. The GENSCREEN™ ULTRA assay is used for the detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2, thus when used with plasma and serum it is considered a fourth-generation assay, and has a sensitivity of 100% (93.2% in the seroconversion scenario), so it is a reliable indicator when a result is negative, especially as

incident infection is likely to be low in this population. The assay's specificity has been assessed as 98.72% -99.95% depending on the study population. When used with saliva it is regarded as a third generation assay as it is unable to reliably detect p24 antigen. This means it is less sensitive to very recently acquired infection and is used to detect HIV that was caught more than 14 weeks ago. Despite this, commercial and NHS services throughout the UK have and continue to use the assay with saliva because of the reasons detailed above. In these instances the healthcare establishment takes on liability with reference to the device being used 'off-label' (20). To do this the clinical service usually performs an in house performance evaluation.

Despite the absence of a CE marked assay for saliva HIV testing, on 22nd May 2015 there was a call for expressions of interest in a national self-sampling tender from Public Health England. The call specifically included online distribution of a choice of saliva or blood-based self-sampling for HIV. Formal invitations to tender were issued on 28th July which again included preference for inclusion of a saliva-based option however on the 18th August some clarification on the national tender process were issued. These included the following statement.

“UK national standards (BHIVA 2008) set 4th Generation HIV as their standard. See <http://www.bhiva.org/documents/guidelines/testing/glineshivtest08.pdf>

The commissioning parties entering into this wish to adhere to this standard.

The recommended first-line assay is one which tests for HIV antibody AND p24 antigen simultaneously. These are termed fourth generation assays, and have the advantage of reducing the time between infection and testing HIV positive to one month which is one to two weeks earlier than with sensitive third generation (antibody only detection) assays.

In any event CE marked methods are required in the delivery of this service. Whilst this may restrict the range of home sampling methods that can be used during the initial period of delivery, it gives the provider opportunities to offer other methods, during the life of the contract, as other CE marked products become available.

There is no preferred test kit supplier or manufacturer.”

Thus despite the Orasure SSK being preferred by both service providers and users, University College London Hospitals NHS Foundation Trust (UCLH) and the processing laboratory (The Doctors Laboratory) felt unable to offer a saliva based SSK option and advised we use the CE approved, fourth generation TINY vial. The full intervention is described in section 6.4. In brief, the intervention involves using a designed script to opportunistically offer an HIV SSK to Black African service users during routine engagement with primary care and with services provided by community based organisations. The intervention will be provided by two types of distributors:

- **GP Practice:** Practice Nurses will offer the intervention.

- **Community Based Organisation:** Community workers will offer the intervention during routine outreach services.

Phase 2 will determine the feasibility and acceptability of this provider initiated, HIV self-sampling kit distribution intervention targeted at Black African people.

4.3 Potential Benefits

At an individual level, the potential benefits of the Haus study centre on increasing accessible HIV testing options for Black African people. The benefits of HIV testing are well documented in the literature (22, 23). These include reduction in HIV related morbidity, mortality and preventing onward HIV transmissions (22, 23). Early diagnosis enables patients to benefit from antiretroviral therapy more than those who are diagnosed late (22, 23).

At a public health level, the major advantage would be to expand access to HIV testing to a population who are at a considerably higher risk of HIV infection in the UK and who are more likely to be diagnosed with advanced HIV disease than their non-African counterparts (1). This would have the advantage of increasing the proportion of Black African people who are diagnosed early and receiving HIV treatment. From an economic perspective, targeted interventions mean HIV testing resources can be targeted at populations with the greatest need. If successful, such an intervention could reduce transmission and enhance timely identification of HIV. This impacts individuals and populations by optimising health outcomes and reducing onward transmission rates. There are also economic benefits to diagnosing HIV as soon as possible after infection (22, 23).

4.4 Risks from participating in the study

Our study does not present any elevated risks over the usual risk associated with HIV testing in standard care. It is possible that some patients may find the process of HIV testing distressing; our participant information sheet includes details of where participants can access further information and support. Participants will also have the option to ask the kit distributor if they have further questions about HIV or the SSK. Participants with a reactive result will be supported by experienced NHS staff, who are used to giving these results over the phone and supporting patients with linkage into care and support (see section 6.10 which has further details on results management). It is also possible that some people may object to and become upset at being targeted for the intervention because of their ethnicity (24). All recruiters will be provided training to ensure they are able to explain why Black African communities are being targeted and to reassure prospective participants that the intervention is intended as a health

opportunity for their community rather than a stigmatising activity. The contact details of the project manager and chief investigator are available on the patient information sheet should participants have any questions about the study.

5. Objectives and outcome measures

Hypothesis: Embedding self-sampling kits (SSKs) for HIV testing in existing services is an acceptable and feasible means to increase the provision and uptake of HIV testing among Black Africans residing in the UK.

5.1 Overall aims of phase 2

To assess feasibility, appropriateness of settings and optimal intervention design for future phase III evaluation.

5.2 Primary Objectives of Phase 2

To determine the acceptability and feasibility of a provider-initiated, HIV self-sampling kit distribution intervention targeted at Black African people in GP settings and community based HIV prevention organisations.

5.3 Secondary objectives of phase 2:

1. Determine appropriate SSK-based intervention models for GP settings and community based organisations.
2. Establish acceptability of interventions for providers and users.
3. Evaluate the effectiveness of self-sampling for HIV in increasing the uptake of HIV testing by Black African people.
4. Determine the cost effectiveness of distributing the SSKs among Black African people over other screening methods.
5. Build sustainable relationships with community service providers willing to distribute and evaluate SSKs as an add-on to existing services.
6. Monitor ability to trace participants with reactive results, confirmatory testing and linkage into specialist care.
7. Determine sample size parameters and control population for a phase III trial offering HIV SSK.
8. Determine the cost per person kit distributed and cost per HIV diagnosis per setting.

9. Assess the feasibility of collecting data for a lifetime cost-effectiveness model alongside a Phase III trial.
10. Assess feasibility, and if appropriate the optimal trial design for future phase III evaluation.

5.4 Primary Outcome Measure

Our primary outcome is HIV SSK return rate.

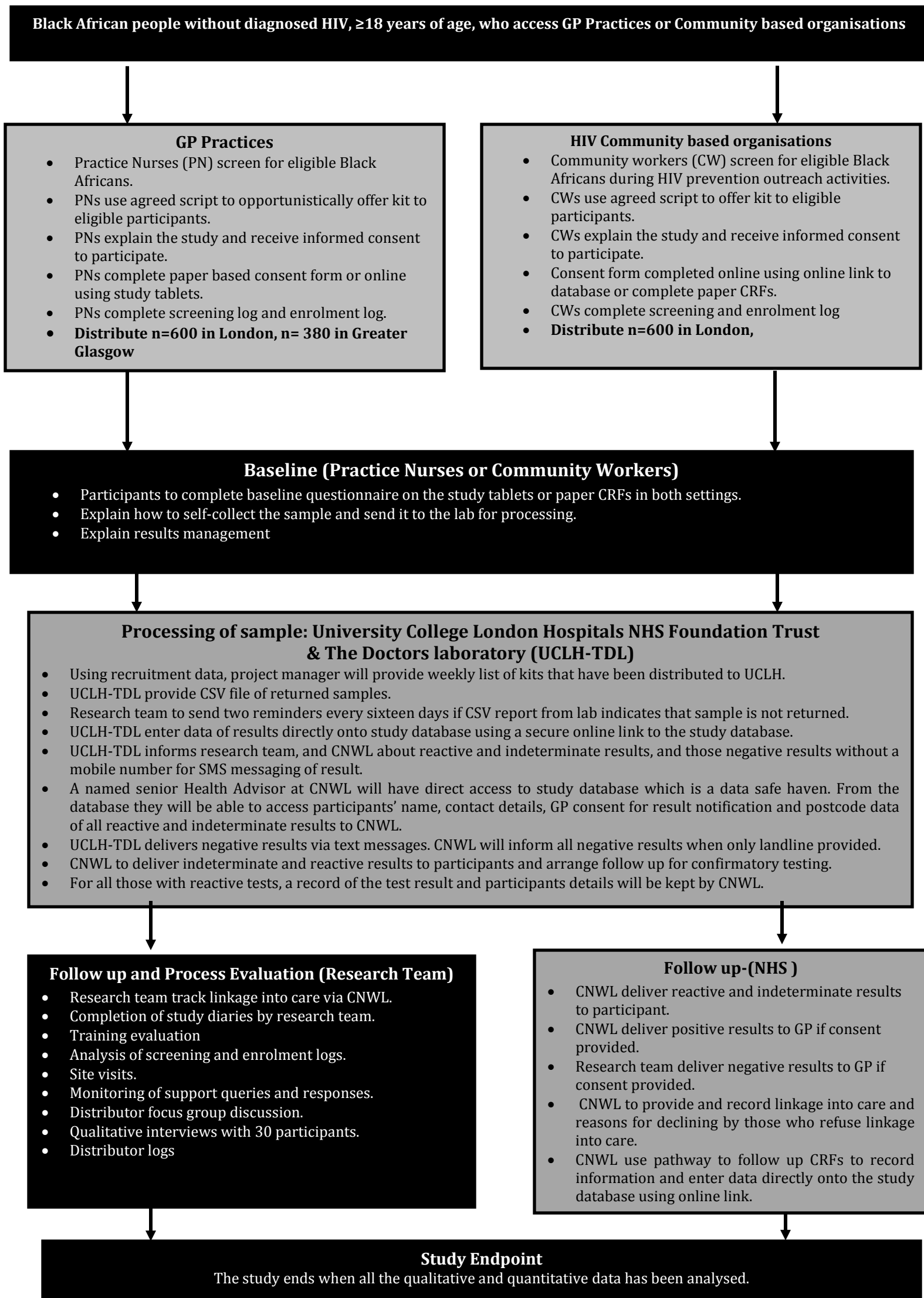
5.5 Secondary Outcome Measure

1. Point of delivery outcomes:
 - Acceptability of targeted HIV SSK distribution, including rationales for accepting or refusing the offer of an SSK
 - Acceptability and feasibility of targeted SSK distribution among specified service providers, including utility of protocols for SSK targeting, offers and intervention uptake.
2. Data collection outcomes:
 - Demonstration that intervention models and service provider training and support incorporates sufficient capacity to successfully record the numbers of: people offered SSK, accepting SSK, and returning SSK
 - Feasibility of collecting correct contact details enabling follow-up, reminders and communication of results
3. Pathway to care outcome measures:
 - Proportion of those whose samples are reactive who: a) are informed of results in person and b) who attend for confirmatory testing at an NHS setting of their choice
4. Overarching outcome measures:
 - Cost per person kit distributed and cost per HIV diagnosis per setting
 - Attrition rates and loss to follow up
 - Confirmatory testing, proportion of those receiving an HIV positive diagnoses, and clinical stage at diagnosis
 - Feasibility and sensitivity of outcome measures (testing, behavioural and economic) for a definitive trial.

6. Study Design

This is a prospective, mixed-methods, non-randomised study. The study evaluates the effectiveness of self-sampling for HIV as well as the cost effectiveness of distributing the SSK through GP settings and Community based organisations. Feasibility and acceptability will also be assessed through a process evaluation. Please see the fieldwork schematic diagram in section 6.1 for further information.

6.1 Fieldwork Schematic Diagram



6.2 Study Setting

The study will be conducted in GP Practices in London and Greater Glasgow. The NIHR Clinical Research Network in South London and the Scottish Primary Care Research Network in Glasgow, have been approached to assist with the recruitment of GP practices that can participate in the study. We will only approach GP practices which have relatively large numbers of Black Africans registered with them. The following clinic characteristics will be collected on all participating sites:

- The proportion of black Africans served by the practice.
- The known proportion of HIV positive patients and whether or not this information is collected.
- The number of practice nurses in each potential practice.
- Whether or not new patient checks occur and if these include HIV testing.
- Whether or not the practice has special interests e.g. travel or sexual health.

We will also recruit participants from community based organisations in London. We will only approach community based organisations with experience of targeting services for Black African people and delivering HIV prevention, and whose existing scale and scope of work with this population is strong.

6.3 Study Eligibility

6.3.1 Inclusion Criteria

To be recruited into the study, participants will need to be:

- Black African
- Without diagnosed HIV,
- 18 years of age or older
- Accessing GP practices or community based organisations that are taking part in the study.
- Able to provide informed consent.
- Able to read and understand English.

6.3.2 Exclusion Criteria

The following participants will be excluded from the study:

- Participants who do not provide a means of contact for result notification.
- Participants who are unable to provide informed consent.

6.4 Intervention Design

The HAUS study seeks to develop and test an intervention of targeted distribution of self-sampling kits (SSK) for HIV testing within health care and community services to determine if this will increase HIV testing in African communities. The kits will be distributed by Practice Nurses (PN) in GP clinics in both Glasgow and London, and in London also by Community Workers (CW) from community organisations as a part of their outreach. Those who distribute the kits will be supported by a programme of training on the delivery of the intervention and research governance. All procedures will also be outlined in an intervention manual (including data collection, result management and linkage to care- see appendix 6). Scripts will be provided to the distributors (see section 6.7) to facilitate study engagement. These resources will help the PNs/CWs to identify and approach black Africans, recruit participants to the study, explain the kit testing and study processes, collect baseline data and complete uptake and refusal logs. Participants will be given a plain language information sheet about the study and a description of how to take the sample (including a link to an online video of someone completing the test) and return the sample. UCLH will provide the clinical oversight for the study. They will subcontract The Doctors Laboratory (TDL) to process the samples. Samples will be sent to TDL via Royal Mail and negative results will be delivered directly to participants via text message (or phone call if only a landline number is provided). Management of all reactive results will be provided by Central and North West London (CNWL) NHS Trust as part of their existing clinical systems. Where a sample is reactive, the individual will be directly contacted by telephone by an experienced member of their clinical team to discuss the results, their implications and to make a clear referral for confirmation testing and care.

6.5 Self- sampling Kit

6.5.1 Description of Self-sampling Kit

The TINY collection device in conjunction with ROCHE Combi will be used for this study. The ROCHE Combi is a 4th generation assay, used for the detection of HIV p24 antigen and antibodies

to HIV-1 (Groups M and O) and HIV-2. This means it is suitable for detecting recently acquired HIV. It can detect HIV that was caught more than 4 weeks ago and is CE marked. The ROCHE Combi has a sensitivity of 100% (lower 95% CI 99.8%) and a specificity of 99.63% (95% lower CI 99.42). This test requires collection of a few drops of blood (obtained by pricking a finger with the supplied lancet) in a small collection tube. The test enables the specimen to be transported to a lab, by post, in a vial that contains preservatives, which stabilize the sample for up to 21 days if temperatures are between 4° C and 37° C.

Self-sampling negates the need for dedicated staff or special infrastructure for specimen collection. The kit can be used at a time and in a setting of the users' choice. Members of our study team have previously used the same or similar tests to screen MSM for HIV in England and Scotland. They have also developed instruction sheets, which provide a step-by-step guide to using the device.

6.5.2 Intended Use

The ROCHE Combi assay will be used to test for the presence of HIV antibodies in participants who consent to take part in the study. The package that will be handed to participants will include:

1. The TINY kit sample collection device (including self-retracting lancets)
2. A sample data form (see appendix 7) which requires three unique sample identifiers from the participants in order for the Laboratory to be able to process the sample and to enable result notification
3. Sample collection instruction sheet (please see appendix 8). This will provide the following details:
 - Information on how to collect the sample.
 - A link to a video demonstration of collecting the sample.
 - Information on labelling the sample and postage.
 - Information on what happens after the participant posts the sample to the laboratory.
 - Information on how the result will be communicated.
 - Information on various reasons why they may be contacted by clinical team
 - A reminder about completion of the acceptability questionnaire.
4. The acceptability questionnaire (see appendix 5).
5. Stamped addressed envelope for sample and questionnaire return to the lab.

6.5.3 Maintenance and Storage of Self Sampling Kits

UCLH-TDL will supply UCL with kits which have a unique identifier. This identifier will be unique to the city and the setting where it will be distributed, that is either GP or community setting in London or Glasgow. The kits will also have an expiry date which will be one month from the end of study recruitment.

The project manager will coordinate the delivery of kits to each study site, keeping records of distribution via the study database. Study sites will email the project manager when they anticipate that their kits will run out and these will be supplied to them by the project manager. The project manager will also record any requests for additional kits by study sites.

No special storage requirements are necessary for the kits however sites will need to keep all kits in a locked cupboard until distribution to avoid tampering and theft. As part of the study initiation of each site, the project manager will check that the kits are being stored correctly.

6.6 Screening Procedures

6.6.1 GP Practices

Practice nurses will go through their patient list each morning and identify patients scheduled to visit in each session who are potentially eligible to participate in the study. The eligibility criteria indicated in section 6.3.1 will inform the screening process. The details of potential participants will be entered onto the screening and enrolment log (appendix 3). Only patients on the screening log will be offered the opportunity to take part in the study. Data on patients who are known not to meet the eligibility criteria will not be collected. Reimbursement for the time taken to screen for potential participants will be met through CRN research support costs (NIHR CRN in London and the Scottish Primary Care Research Network in Glasgow).

6.6.2 Community Based Organisations

The eligibility criteria indicated in section 6.3.1 will be used to identify potential participants during routine outreach and the provision of other services by trained CBO workers. The details of these potential participants will be entered onto the screening and enrolment log (appendix 3). Reimbursement for the time taken to screen for potential participants will be met from the study budget.

6.7 Consent and Recruitment

6.7.1 Introduction

Any practice nurse or community worker delegated responsibility to participate in the informed consent process will be duly authorised, trained and competent to participate according to the ethically approved protocol and principles of Good Clinical Practice (GCP). During routine consultations or engagement with Black African people who fulfil the inclusion criteria, distributors will opportunistically provide information about self-sampling kits for HIV testing to eligible participants using the intervention script.

Distributors (PNs or CWs) will be required to use the appropriate script to guide them on how to initiate discussion about the study. The distributor will explain that their organisation is taking part in a research study looking at the acceptability and feasibility of using self-sampling kits for HIV testing among Black Africans. Interested eligible potential participants will be given the Participant Information Sheet (PIS) appendix 1 and asked to read it, and given the opportunity to ask any questions. If the eligible potential participant declines at this stage, the distributor will complete the information on the screening and enrolment log with as much information as the eligible potential participant is willing to provide. The distributor will enter this information from the screening log onto the study database using a link to the study database. The procedure for targeting and recruitment is detailed below.

6.7.2 Targeting and Recruiting

The distributor will aim to introduce and recruit eligible candidates to the research study. They will explain the benefits of participating and having an HIV. All distributors will answer questions and aim to alleviate any concerns participants may have. The script below initiates the recruitment process:

“We are currently involved in an important study that I wonder if you’d be interested in taking part in? We want to see if people will use HIV self-sampling kits. HIV treatments are so good now; that you can live a normal healthy life with HIV, and being on treatment also stops most people from passing on the infection. So we are trying to find new ways to offer testing as it’s the people who don’t know their HIV status who become unwell.

This study is looking at whether people from the Black African community would want to use these kits. It’s a great opportunity as most people don’t have access to them yet.

Testing is very easy. It's all in this kit, which you take home to use when it is convenient to you. Once you've collected the sample you put it in the envelope provided and pop it in the post.

A few days later you are contacted by a NHS health clinic via your mobile phone with the results. Most people testing will be negative. A few people will have a test suggesting they have HIV (this is called a 'reactive' test) and we would have to check the result is correct.

It's all completely private and confidential - no one, other than the clinic contacting you, will know your result unless you want them to. What do you think? Is this something that you may be willing to try?"

If answer = NO then go to section A

If answer = YES then go to section B

Section A

"That's absolutely fine. We would really like to understand why people do not want to participate in the study. On this card are some of the common reasons why people say no – "

(Hand participant card)

"Would you possibly be able to let me know if any of the numbers match with your own reason? And if so which numbers? Of course it is also ok if you do not want to give me a reason."

(Participant gives reason or declines to do so)

(If reason given then insert into participant screening and enrolment log)

(Contact ends)

Section B

"First we need to determine if you're eligible for the study. Are you aged 18 or older and do you consider yourself Black African?"

(NOTE: If asked, the term 'Black African' includes anyone who identifies themselves as Black African, whether they are migrants from Africa, African descendants or African nationals.

If answer = NO then go to Section B1

If answer = YES then go to Section B2

Section B1 Not eligible to participate

*“Thank you for taking the time to consider the study but you do not meet the eligibility criteria. If you would like to test for HIV then the easiest way would be to *.....”*

(NOTE: Answer varies according to options available e.g. standard blood test if in GP, referral to testing centre if in community)

Contact Ends

Section B2 – Eligible to participate

PN or CW hand participant the information sheet.

PN or CW copy SSK Unique ID to the consent form.

PN or CW hand participant the consent form and ask them to read it and consent to the statements to participate in the study.

PN or CW retrieve consent form from participant and check to make sure that all options marked as ‘essential’ have been consented to.

6.7.3 Consent Process

Participants who are eligible and agree to take part in the study will be given either the paper consent form to complete or they can be given study tablets to complete the consent form online.

Participants will consent to the following:

- a) Taking part in the study.
- b) Supplying a telephone number that can be used to contact them.
- c) Receiving reminder messages if their sample is not received at the laboratory (optional).
- d) Contact by NHS provider to provide them with their result.
- e) Notification of their GP of the result (optional) and only in the GP setting.
- f) Additional contact by phone or email for a telephone interview to explore the process and acceptability of self-sampling (optional).
- g) Audio recording of telephone interviews (optional)

The screening log (appendix 3) will also function as an enrolment log. In it, distributors will detail all eligible patients, whether or not they have approached them and if they have agreed to take part or not, and if not the reason for refusal if provided.

Please note it is not our intention to specifically notify the GP when a participant recruited in their practice consents to participate. We are specifically requesting consent to inform the GP of the

HIV test result (be it negative or reactive). If consent is obtained then the GP will be made aware of the result and that participation has occurred. If consent is not obtained or if the sample is not returned to the laboratory for processing then the GP will not be informed. The GP of all those recruited via community based organisations will also not be informed of either participation or test result.

6.7.4 Baseline data

Participants who are successfully recruited into the study should then be asked to self-complete a short baseline questionnaire. The baseline questionnaire (appendix 4) will collect kit specific identification number; name, contact details (mobile or landline number), demographics (age, gender, country of birth) and details about prior HIV testing and sexuality. The baseline questionnaire will be available in electronic and paper based formats. The mode used will depend on provider and user preference and whether internet access is available. If a paper based version is used, the data will need to be subsequently entered directly by the distributor onto the study database via a web link later that day. All study sites will be provided a study tablet by the research team.

6.7.5 Demonstration of the kit

Once they have completed the questionnaire, the distributor will give the participant a self-sampling kit and briefly explain the processes involved with kit use. See intervention manual (appendix 6) for supporting text and suggested script to accompany this process. Additional information on how to use the self-sampling kit, the importance of posting the sample to the laboratory for processing and the use of reminder texts to participants should the sample not be received at the lab will be highlighted in the participant information sheet and kit inserts. They will also explain how results will be communicated to the participants.

6.8 Follow up of participants

6.8.1 Quantitative

As detailed in section 6.5.2 every kit will contain a brief acceptability questionnaire (appendix 5). The questionnaire will explore acceptability of being offered a SSK in that setting, acceptability of targeting and the process of using the kit. Each kit will come with a unique ID number, this number will be entered onto the baseline and acceptability questionnaires as well as the recruitment log, and will allow the research team to link data from the two

questionnaires with that of the test result. These data will give insight into the key features and characteristics of acceptability among those who ultimately have used the kit.

6.8.2 Qualitative

During the recruitment and consenting process participants will be asked to consider taking part in optional follow up telephone interviews (n=30).

The participants will be purposively sampled to ensure a spread of those who:

- Agree to participate but do not return sample (x10)
- Agree to participate and return sample (x20)

Of those 20 that have returned the SSK we seek to interview 10 people recruited in GPs and 10 recruited by CBOs. Ten to fifteen people will be recruited in London and five to ten recruited in Glasgow. This is an ideal sampling frame, and will depend on willingness to interview among participants in each category. Verbal consent to proceed with the interviews at a mutually convenient time will be obtained again when telephone contact is made. Interviews will be undertaken by phone and are anticipated to last up to 30 minutes. Those who take part will be sent a £10 voucher for their time. If consent is obtained interviews will be recorded and fully transcribed. All transcripts will be fully anonymised. Framework analysis will be undertaken with the use of NVivo 10. Interview data will enable assessment of outcomes indicators relating to the facilitative and inhibiting factors involved in participants' decisions to accept and utilise the SSK. Interviews with non-returners will specifically explore reasons for not returning the sample, satisfaction with the intervention; suitability, strengths and weaknesses of the intervention; willingness to use it in the future and suggested improvements.

6.9 Sample Collection and Analysis

Participants will be required to self-collect a sample of blood using the TINY vial in the kit provided to them. As indicated in section 6.5.3, there will be instructions including a video link on how to collect the sample. Participants will also be required to complete the form with three unique identifiers (that is initials, date of birth and unique ID number) to enable the sample to be processed at the laboratory. The ID number will be pre-populated on both the lab form and the acceptability questionnaire.

UCLH will be responsible for the following:

1. UCLH via TDL will process samples as soon as they are received.

2. UCLH-TDL will send a CSV file for the study manager of returned samples to enable the manager to send out two reminder texts to participants whose kits have not been returned. This will be sent as an encrypted email.
3. UCLH-TDL will send a CSV file with results for each of the samples returned so that these results can be entered on the database by the study team. This will be sent as an encrypted email.
4. UCLH-TDL will collect the acceptability questionnaires returned with the sample, store them in a locked cabinet and pass these onto the study team.

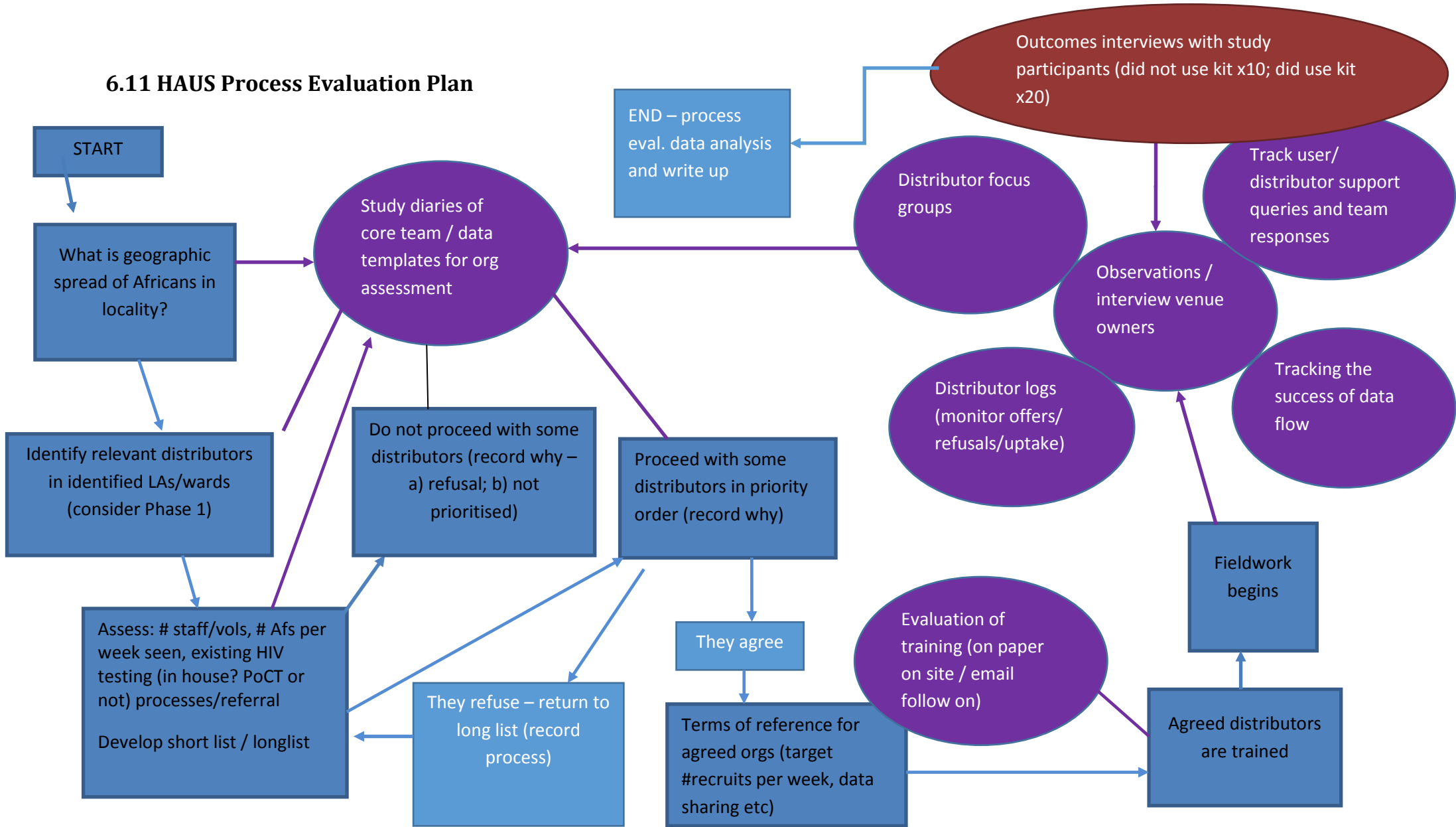
6.10 HIV Result Management

For each of the samples processed, the result can be reactive, non-reactive or no result/indeterminate. The results management will be shared between UCLH-TDL and CNWL:

1. In line with standard practice in most NHS sexual health clinics, negative results will be delivered by text message. UCLH-TDL will be responsible for the delivery of these messages. If a participant has only provided alternative contact means (landline or email) then UCLH will notify a named senior Health Advisor at CNWL who will assume responsibility for result notification as per clinic practice.
2. If consent to notify the GP has been provided (an option only applicable to those recruited via General practice) then the study manager will be responsible for informing the GP of negative results via secure email or registered address.
3. UCLH-TDL will let the senior study manager and CNWL know about any reactive results by secure encrypted email. Please note that at this stage, the names of participants with reactive samples are unknown to all parties as only initials are required with SSK return.
4. The Health Advisor at CNWL will use this information to retrieve personal information from the UCL Data Safe Haven (IDHS) to be able to link the sample to an individual. The Health Advisor at CNWL will retrieve the full name and contact details of the participant, and whether consent has been obtained to notify the GP.
5. The study manager will phone the Health Advisor to confirm access of test result and personal details.
6. The named CNWL Health Advisor will contact the participant by phone call and inform them of the reactive result and need for confirmatory testing. If consent is obtained from the participant they will arrange linkage into appropriate local services for confirmatory testing. Postcode data will be used by the Health advisor prior to contact to identify appropriate local services for any one participant. This will all be done without disclosure of participant details.

7. The Health Advisor will have follow up phone contact with all participants with a reactive result to ensure linkage to care has occurred. This will also provide an opportunity to identify any unexpected consequences of the testing process.
8. The Health Advisor will be responsible for completing the Pathways into care outcome measures CRF (appendix 10), this will involve follow up phone calls to HIV services and the participant to ensure linkage to care has occurred. This information will be directly entered into the IDHS using the secure UCL portal. They will also be responsible for notifying the GP of the result where consent has been provided; this option will only apply to those recruited through General Practice.
9. If the result is indeterminate, UCLH-TDL will highlight this result in the CSV file of results sent to the study Manager. The study manager will retrieve personal details from the IDHS database and pass these onto the clinic. One of the Health Advisors from the clinic will inform the participants of the indeterminate result and request permission for the study team to send them another kit or for them to attend an alternative testing venue. The Health Advisor will be responsible for completing the Pathways to care outcome measures CRF (appendix 10) again using the secure UCL portal to the IDHS.

6.11 HAUS Process Evaluation Plan



HAUS Process Evaluation Flowchart Key

Items in **BLUE** are key Phase II components

Items in **PURPLE** are process evaluation data collection points

Item in **BROWN** is outcome evaluation data which will also have implications for process evaluation

6.11.1 Study Diaries

The process evaluation incorporates information right from the start of Phase II planning. Using a standardised template format, the research team will routinely record decision making contributing to distributor selection, responses from potential distributors, rationales for inclusion / exclusion etc (see appendix 11). This will enable the process evaluation to capture the elements leading up to the start of distributor training and fieldwork.

6.11.2 Training Evaluation

At the training events, participants will be asked to complete a before / after survey assessing existing capacity and need with regard to approaching and persuading Black African people to use HIV self-sampling kits. The evaluation will focus on the extent to which the training meets its stated aims.

6.11.3 Fieldwork process evaluation

A. Screening and recruitment logs

Distributors will be asked to complete a daily screening and recruitment log. This will be completed throughout the day, capturing: basic information about potential participants approached (DOB, initials, Country of Birth/ gender) as well as refusals, reasons for refusal when known, and acceptances. This will assist in monitoring progress and help enable early intervention if further support in recruitment is required.

B. Distributor logs

Distributors will also be asked to complete a weekly log to monitor progress and detect problems with recruitment (see appendix 12). They will be asked to rate how they felt about the experience of undertaking targeting, recruitment, consent, fielding questions and use of behaviour change techniques to support uptake. These will be completed online, and will serve a dual purpose in the study. Firstly, it will be used to monitor progress and detect problems. Secondly, this information will be utilised for the purposes of the process evaluation.

C. Site Visits

A minimum of two site visits will be undertaken in each city to describe some of the environments and circumstances in which the intervention is being delivered. Observation templates will be completed which identify: special and temporal features which may facilitate or hinder the intervention, characteristics of the population and the nature of distributor targeting within this context, etc. The purpose of these visits is to ensure some enhanced awareness of distributor type issues and contexts, rather than trying to ascertain distributor behaviours and/or quality in each and every site. These site visits are distinct from routine site visits that will occur for study set up procedures or to support recruitment.

D. Data flow

We will monitor the speed and success of data flow through all elements of Phase II. Potential data bottlenecks will be identified and resolved at an early stage, and monitoring will help us to assess intervention feasibility.

E. Support queries and responses

Any contact made with project manager or other core team members by distributors, potential participants or study participants will be logged, as will the response given and action taken. Standard telephone summaries will be maintained by the project manager.

F. Distributor focus groups

Toward the end of the recruitment period, focus group discussions will be undertaken within CBO and GP settings in both Glasgow and London. Distributors and their managers will be invited to take part in groups held on each study site, and the focus will be on: acceptability of the intervention, distributors' experience of undertaking targeting, recruitment and consenting procedures, fielding questions, and using behavioural change techniques to support uptake (see appendix 15 for topic guide). Groups will also discuss future feasibility and any recommended changes, and consideration of targeting similar populations in other cities. The groups will be recorded, and a second facilitator will take notes throughout. Annotations will form the basis of analysis, with recordings providing backup where needed. Written consent (appendix 16) will be obtained from all those participating in the distributor focus group discussion.

G. Outcomes interviews with study participants

The outcomes interviews with study participants are described in detail in section 6.9.2. In addition to elaborating on outcomes indicators, we anticipate that a number of issues related to

intervention and study process will arise throughout these interviews that will be important to capture as a part of the process evaluation.

6.12 Subject Withdrawal

All participants will be informed during the consent process that they can withdraw from the study at any time and that this will not affect the standard of care that they receive from the organisations/care they are accessing. Should the participant request to be withdrawn from the study then they will have two options: 1. Withdraw from the study, and not be approached for further information. Samples and data already obtained however may still be retained and used. And 2: Participant requests no further contact, and for their samples and data to be destroyed.

Nevertheless, essential patient information, the sample and test result will be retained by the NHS if a consented participant returns a SSK that has already been processed before withdrawal. This information will not be destroyed even if the subject decides to withdraw from the research component of the study.

6.13 End of Study Definition

The end of the study will be when the final analysis of both the qualitative and quantitative data has been performed.

7. Statistical Considerations

7.1 Sample size calculation

Current HIV SSK projects in the UK, which primarily target men who have sex with men (MSM) online, have achieved return rates in the region of 60% (4, 23, 24). Given that in the UK HIV testing rates tend to be lower in Black African communities compared to MSM we have assumed a return rate of 50%. Distribution of a total of 600 kits per setting would enable a precision rate of at least $\pm 4.0\%$, and distribution of a total of 380 kits per setting would enable a precision rate of at least $\pm 5.0\%$ should the return rate be lower or higher with a fixed sample size the size of the standard error will be smaller and the resulting confidence intervals narrower.

We will have SSK distribution in both Glasgow and London however there will be more kits distributed in London than in Glasgow because London has a larger population of Black Africans and the recruitment is limited in Glasgow to primary care only. As such we will distribute 600 SSK in each site in London and 380 in via GP practice nurses in Glasgow. Although the power of the study (as reflected in the width of the confidence intervals around the parameter of interest)

increases as the response rate moves away from 50% due to the properties of the binomial distribution, the increase in power for plausible response rates is somewhat modest.

The study is driven by those subjects who engage with existing services provided by PNs and CWs. We will describe the characteristics of subjects who are recruited, alongside a minimum data set for those subjects who are eligible but elect not to take part in the study. Further, we will develop prognostic models to examine the extent to which participants with different characteristics achieve the primary outcome. The exact parameterisation of this model will be pre-specified with the project team prior to data base lock, and the maximum number of 'questions' asked will be derived from the available degrees of freedom such that they will not exceed the smaller of the events or non-events divided by 10, that way militating the risk of over-fitting. We will examine the functional form of continuous variables such as age, and use a conservative strategy to select from pre-specified transformation or restricted cubic splines, with the switch to a more complex functional form driven by observed significant improvement in model fit as derived by the Akaike Information Criterion. While necessarily exploratory given the primary aim of the study, the prognostic model will help us to develop an understanding of important characteristics such as age and gender in the probability that completed test kits will be returned.

7.2 Analysis

7.2.1 Quantitative

Descriptive analyses will profile the participants in each setting. The primary outcome will be HIV SSK return; secondary outcomes will include acceptability measures, linkage to care, attrition rates and intervention uptake. Analysis will determine feasibility and sensitivity of outcome measures (testing, behavioural and economic) (27) for a definitive trial in each setting for each city.

7.2.2 Qualitative

A framework approach to qualitative data analysis will be used with the assistance of NVivo 10 software (28, 29). Taking each of the substantive areas of the question guides and questionnaires with qualitative open fields as a starting point, members of the research team will work in pairs to list the emergent themes arising from each data source, undertaking constant comparison with the data until each list is exhausted – a method that utilises both inductive and deductive processes (30). The themes will then be collated to ensure consistency, ensuring the elimination of overlap prior to thematic coding and analysis of the data.

7.2.3 Economic Evaluation

A positive diagnosis of HIV has significant cost and quality of life implications, the measurement of which are beyond the remit of this project, but are a key consideration in assessing the cost-effectiveness of an intervention to distribute SSK among Black African people compared to current screening methods. We will assess the feasibility of collecting information to inform key parameters for a life decision analytical model of SSK as a screening method for Black African populations by setting. These variables will include (i) the cost of the test including postage and packaging and any costs to services of giving out the test including training (ii) return rates (iii) cost of processing returned tests (iv) proportion of reactive and subsequently positive tests of those returned (v) clinical stage at diagnosis (vi) cost of confirmatory and additional testing on all reactive results and insufficient samples respectively. From this information a cost per test returned and a cost per positive and negative diagnosis can be calculated.

Models of HIV screening and the lifetime costs and outcomes associated with different screening methods are currently in development. We will assess the possibility of using previously developed decision analytical models for cost-effectiveness analysis that can report a life time cost per quality adjusted life year (QALY) gained of SSK sampling in different settings compared to current practice in Black Africans in the UK. In addition to the information mentioned above, prevalence and incidence of disease in this group are also likely to be important parameters for the model, along with other characteristics that differ to the UK general population. If suitable decision analytical models do not already exist one would need to be developed as part of a full trial.

We will conduct a budget impact analysis to determine the cost to commissioners of screening for HIV in Black Africans across current settings based on the number of Black African people in their local community; test uptake rates; cost per test and cost per positive diagnosis as calculated above, by setting; and cost of HIV treatment dependent on stage of disease.

7.2.4 Process evaluation analysis

Process data will be analysed at the end of the first month of recruitment in order to ensure that any essential modifications that are needed can be implemented as soon as possible. Analysis will focus on ability to adhere to intervention fidelity and key lessons learned should a future Phase III evaluation be deemed feasible. The findings will be written up in light of ongoing policy and development in the wider field of HIV testing, self-sampling and self-testing. The quantitative and qualitative data from the process evaluation will be analysed as detailed above.

8. Ethical Considerations

The study will be carried out in accordance with the principles of the 2008 Declaration of Helsinki; the 2005 Research and Governance Framework for Health and Social Care as well as UCL relevant regulations and with Good Clinical Practice.

8.1 Informed Consent

Prior to patient participation in the study, informed consent will be obtained from each patient. This will be done prior to the participant undergoing procedures that are specifically for the purposes of the study and are out-with standard routine practice in the two settings. On the consent form (appendix 2), each signature must be dated by each signatory and the informed consent and any additional patient information form retained by the investigator as part of the study records. All CBOs will adhere to the university standards of Data Protection. All study related data collection forms will be returned to the study team by the time that Phase 2 recruitment ends.

For participants who indicate their consent electronically via the study tablets, this will be obtained by checking a box to indicate willingness to participate. This is standard practice in online surveys. Participants will be informed that their personal study-related data will be used by the research team in accordance with the data protection law. Although the research team would like sites to provide reasons why people decline to take part in the study, participants will retain their right to refuse participation without giving reasons. This will be respected by the study team. Participants will remain free to withdraw at any time from the trial without giving reasons and without prejudicing their further access to services provided by the study sites.

8.2 Approvals

This document, along with any subsequent modifications and with the sample informed consent documents will be reviewed by an NHS Research Ethics Committee. Should a substantial amendment to the protocol become necessary, the patient consent form and patient information form will also need to be revised to reflect the changes to the protocol. These will be submitted to the NHS REC for approval. These updated forms will be used by all patients subsequently entered into the study and those currently in the study, if affected by the amendment.

8.3 Duty of Care

University College London Hospitals NHS Foundation Trust will be the organisation providing care to all participants who return a self-sampling kit, this will include those recruited from general practice and community settings. Given the sensitivities around HIV we wanted to ensure clinical experience in self-sampling and the provision of HIV results. UCLH does not currently provide a self-sampling or HIV result notification service for patients however it has strong links with the Central & North West London NHS Foundation Trust (CNWL) who do. CNWL run the Mortimer Market Centre, a centre of excellence for the management of sexually transmitted infections and who also offer an HIV self-sampling service via Freedom Health. Thus duty of care will pass to CNWL for those with reactive and indeterminate results, and those who have not provided a mobile number so as to be able to receive negative results via SMS. Duty of care will pass to the health care institution attended for any confirmatory testing.

8.4 Patient and Public Involvement

Our study team has included community representatives from its inception, aiming to facilitate effective research design that will optimise community sensitisation and engagement. The representatives have actively contributed to discussions on the feasibility of proposed designs and highlighted methods to refine the proposal. Two of the programme's co-applicants are representatives from community based organisations (CBO): Memory Sachikonye coordinates UK Community Advisory Board (UKCAB), a network of community HIV treatment advocates across the UK that spans over 500 members from across 120 organisations; and Jabulani Chwaula has extensive experience of managing and coordinating African amplification of HIV prevention interventions in England, including for HIV prevention England through the BHA. They have each reviewed the plan of investigation and sought approval of the programme outputs through consultation with their community colleagues. It is through their input that we have ensured that the methods and proposed outcomes best reflect the needs, interests and social contexts of Black African people in the UK.

8.5 Expenses and benefits

Participants will not be expected to travel to any of the participating sites solely for the purpose of the study. As such there will be no reimbursements of travel costs. All qualitative interviews in Phase II will be over the phone and £10 voucher reimbursements will be arranged.

8.6 Reporting

The project manager will submit reports to the NIHR on behalf of the CI on request. At the end of the study, an end of study report and end of study notification will be submitted to the NHS REC, NIHR and UCL (study sponsor).

9 Safety Reporting

9.1 Patient safety

As indicated in section 4.4 we do not anticipate that the participants of the study will be exposed to risk which is significantly greater than the normal risk associated with taking an HIV test in standard practice. All participants with reactive and indeterminate results will be contacted by a senior health advisor with experience in giving these results by phone. They will also have expertise in providing or linking into any necessary support. This Health Advisor will also make a follow up phone contact with all participants with a reactive result to ensure linkage to care has occurred. This will also provide an opportunity to identify any unexpected consequences of the testing process.

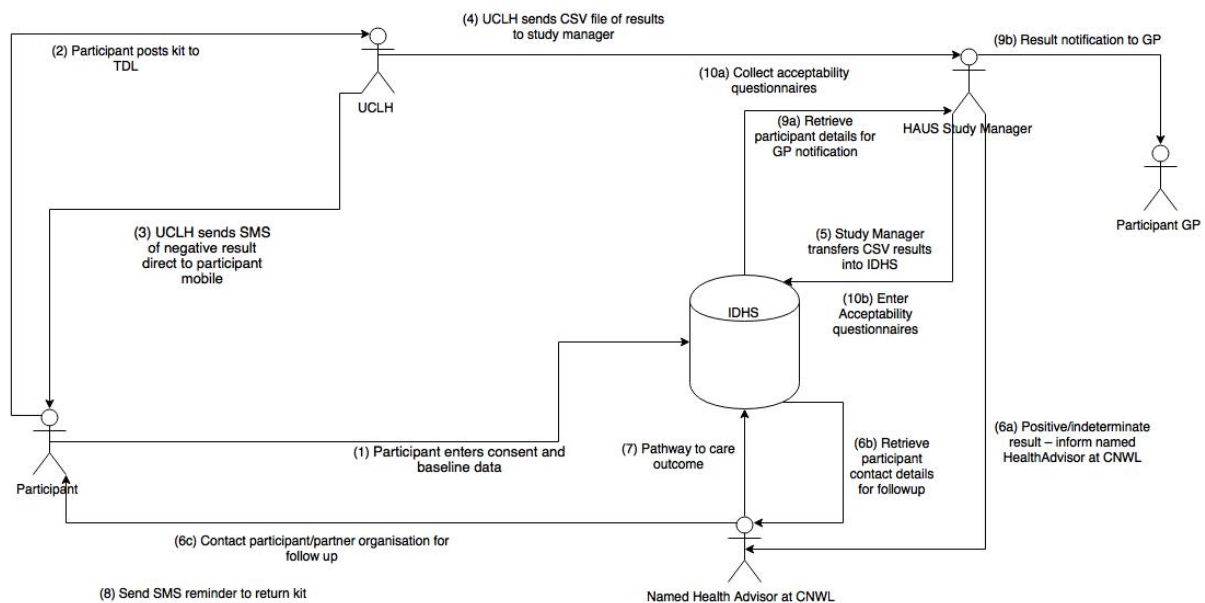
In the event that participants have further questions about the study, the patient information sheet (appendix 1) has the contact details of both the project manager and the principal investigator of the study. They will be able to deal with any queries or concerns about the study. We have provided links to further HIV information and support in the patient information sheet. It is also possible that some people may object to and become upset at being targeted for the intervention, as stated in section 4.4 all recruiters will be provided training to ensure they are able to explain why Black African communities are being targeted and to reassure prospective participants that the intervention is intended as a health opportunity for their community rather than a stigmatising activity. If any adverse events are reported during the qualitative interviews, participants will be referred to appropriate support services.

9.2 Research staff safety

The risk to staff will be minimal as they will not come into face to face contact with participants. Qualitative interviews will be conducted by telephone. The risk for sites is not anticipated to be higher than usual when they provide care or outreach services. As such their usual safety protocols will be used during the study.

10. Data Management

The diagram below indicates how the data will be managed in the study:



10.1 Source data

CRF entries will be considered source data in the settings detailed in this protocol where the CRF is the site of the original recording (e.g. there is no other written or electronic record of data). All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study number rather than by name.

10.2 Access to data

Direct access to the study data will be restricted to authorised members of the study team to enable them to carry out their duties. Access will also be granted to authorised representatives from the Sponsor, other host institution and the regulatory authorities to permit any study - related monitoring, audits and inspections.

10.3 Data recording and record keeping

One database will be used for quantitative data in this study. The study database will be hosted on the UCL IDHS. UCL have established secure data transfer technology via the UCL Information Data Safe Haven for the transfer of sensitive data collected as part of medical research. The technology meets all the requirements of the NHS Information Governance Toolkit. Data is transferred into the system via a secure gateway technology which uses SSL/TLS. The Data Safe

Haven can only transfer data via an integrated data transfer system. All data transfers are controlled by the Information Asset Owner (Principal Investigator) and are SSL/TLS AES256 encrypted in transit and logged. By default, the transfer is limited to one download and data is removed from the file transfer gateway once downloaded. The environment does not allow the use of email or any other means, such as removable USB storage, to transfer files. Data can be uploaded by clinics directly into the UCL data safe haven (encrypted). Research team members are the only people who can access this data (via a password fob). IDHS supports a MS SQL Server database including Excel and RedCap packages. All study data will be entered on to paper CRFs and/or directly onto the IDHS database or study database as described in the data collection section 6.6. Data will be stored on the UCL server and is backed up to remove threat of loss of data. The UCL policy indicates that research data from a study such as this one is stored for five years after the study ends.

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (30/09/16). The Chief Investigator confirms that he/she will archive the study master file at UCL IDHS for the period stipulated in the protocol and in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents for 5 years and in line with all relevant legal and statutory requirements.

10.4 Confidentiality

All information related to participants will be kept confidential and managed in accordance with the Data Protection Act 1998, The Caldicott Report & Caldicott Principles 1997, NHS Confidentiality Code of Practice 2003, The Freedom of Information Act 2000, The Research Governance Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval. During results management, any patient identifiable data, both transferred and stored, will be encrypted in line with NHS Information Governance 'Guidelines on use of encryption to protect person identifiable and sensitive information' 2008.

The unique ID number will identify all laboratory specimens, case record forms, and other records and no names will be used, in order to maintain confidentiality. All records will be kept in locked locations. Clinical information will not be released without written permission, except as necessary for monitoring by the study monitors. SMS use will adhere to the NHS and UCL Information Governance Information Risk Management guidance. Participant personal information will be stored on the secure university IDHS database. The software is designed to

securely collect the data from the online survey and ethical hacking will be used to ensure the level of security is maintained against current threats.

Semi-structured interviews with participants will be audio recorded and labelled with a unique number. All names (and other potentially identifying information) will be removed from audio recordings as soon as possible. Digital recordings and pseudonymised transcripts will be maintained in a password protected database on password protected UCL or LSHTM desktop computers. On transfer, the audio data will be deleted from the digital voice recorder. Digital recordings will be transcribed by a professional transcription company that provides secure encrypted data transfer within the UK, and has been deemed to meet UCL's data protection requirements. The subcontracted agency will be confirmed at a later date and a contractual arrangement will be put in place between the sponsor and transcription service. Recordings will be securely stored on password protected computers within a locked office and deleted after transcription. Transcripts will be kept in password protected computer files, and all potentially identifiable information (e.g. names) omitted from the transcripts.

11. Laboratory

The Doctors Laboratory (TDL), based at 60 Whitfield Street London W1T 4EU, will be contracted by UCLH (University College London Hospitals NHS Foundation Trust) to supply the kits and the processing of the samples for this study. TDL and UCLH already work together on a pathology joint venture, which aims to bring together the best aspects of all partners to ensure quality care for patients and best value for the health economy.

12. Study Committees

A study steering committee was established in August 2014. Study progress and interim analysis of data will be provided to the study steering committee every six months.

13. Finance and Insurance

The study is funded by the NIHR HTA Grant number 12/138/02. We will receive service support costs from the NHS in phase 2 for the NHS sites. The study is sponsored by the University College of London. UCL will provide insurance and indemnity cover for all participants.

University College London holds insurance against claims from participants for harm caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, if this clinical study is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the clinical study. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

14. Dissemination and outputs

14.1 Dissemination of findings

We plan a multi-stage, multimedia and audience specific approach to disseminating the research findings to ensure that all communication is accessible and relevant to the target audience at local, regional and national levels. The primary beneficiaries of this research will include: 1) those who will ultimately undertake the definitive trial that follows on from this preliminary feasibility investigation; 2) commissioners and services planning SSK for HIV testing rollouts; 3) Black African communities; and 4) healthcare professionals and policy makers.

Dissemination levels and outputs: In addition to the main project report and intervention manual, we will employ a range of dissemination activities to ensure the diverse stakeholder groups are informed of our findings.

National level: A minimum of two scholarly articles in peer-reviewed, open access journals, a four page briefing paper written in accessible language in print and pdf formats, and oral presentation of the findings at clinical and non-clinical HIV conferences at national level (such as the BHIVA and BASHH, the national HIV Prevention England conferences and the Scottish National Sexual Health and Blood Borne Viruses Framework events). Following publication, copies of the briefing (in print or pdf) will be available freely from co-investigator and other relevant websites (eg.<http://i-base.info/>).

Regional level: The project team hold influence with current and potential providers of community-based HIV testing and prevention interventions including Health Watch, CCGs, Health and Wellbeing Boards, Public Health England, sexual health & HIV networks, clinicians, and other members of the British HIV Association; primary health care providers; as well as additional stakeholders including the National AIDS Trust, MedFASH, NICE, HIV patient advocacy groups such as UKCAB and the population of Black African people in the UK who are

most likely to have undiagnosed HIV. In Scotland, dissemination will be facilitated by Dr L McDaid who is a member of the Scottish Government's National Sexual Health and Blood Borne Viruses Ministerial Advisory Committee.

Local level: Stakeholders and providers will be notified of project progress through strategic mailing lists, and targeted social media. These channels will be utilised to announce both the undertaking of the research process, as well as the release of the final report, journal articles and briefing sheets. We foresee that as a result of this, a minimum of 1,000 direct stakeholders will be informed of this work. Furthermore, to increase application and critique of the research results, we will hold two dissemination seminars (one in London, one in Glasgow) targeting invitations at a range of the most influential stakeholders (with attendees totalling approx 80).

The project team aims to enable practitioners and policy makers to apply our findings and guidance in a robust and timely manner. Our dissemination strategy has been developed to support this process. The strategy will leverage existing resources within the participating organisations, such as their academic infrastructure, professional relationships and community networks fully. We will work closely with UCL's well-established Public Engagement Unit. This unit and the UK-CAB will be integral to dissemination of findings beyond academic and policy forums.

14.2 Outputs

If our findings demonstrate that a Phase III trial is feasible then our primary output will be an intervention manual to enable replication in a subsequent UK wide Phase III RCT. The manual will include parameter estimates for the required sample size and a cost effectiveness analysis. It will provide guidance as to appropriate trial design for a given setting. The manual will enable a subsequent trial team to undertake the necessary processes for successful trial implementation.

We will compile a study report that summarises the key findings, and clearly outlines the methods utilised to design and deliver the intervention in each setting, for each population, and the rationales for the selection of study sites and sub-populations. The report will describe the processes of HIV SSK distribution, staff training, sample collection, communication of results and confirmatory testing.

Given that this is a feasibility phase II study, the routes to direct impact will follow through a subsequent trial and its outcomes. Nonetheless, there is little current evidence regarding the uptake of new HIV testing technologies among Black African people in the UK. This project will

provide evidence for NHS commissioners and service providers regarding the acceptability and feasibility of outcome evaluation and a budget impact analysis of screening for HIV across different settings. By examining the feasibility and acceptability within GP surgeries and community based organisations, we also provide evidence for alternate models for reaching Africans.

Trials and interventions to broaden access to HIV SSK are starting to emerge, but the proposed research offers an opportunity to extend the knowledge base. Additionally, we acknowledge that a range of statutory and commercial programmes seeking to expand distribution of SSKs to both narrowly and broadly targeted populations are already in place, and will continue to emerge throughout the course of the proposed research. The technology is already licensed and available (www.drthom.com, www.ruclear.co.uk).

We expect that community based organisation and clinical services may start using SSK for some groups. As such, the results from this study will be entirely relevant to statutory and voluntary sector agencies who are already, or who plan to expand SSK access to Black African people in the UK before the full RCT trial results are known. We have proposed a wide array of dissemination to ensure that a range of key stakeholders will be able to utilise the feasibility data we provide.

15. References

1. Health Protection Agency (2012) HIV in the United Kingdom: 2012 Report. London: Health Protection Services, Colindale.
2. Prost A et al. (2009) Feasibility and acceptability of offering rapid HIV tests to patients registering with primary care in London (UK): a pilot study. *Sex Transm Infect*; **85**: 326-329
3. Burns FM, et al. (2008) Missed opportunities for earlier HIV diagnosis and prevention within primary and secondary health care settings in the UK. *AIDS*; **22**: 115-122
- Department of Health (2012) Improving outcomes and supporting transparency Part 1: A public health outcomes framework for England, 2013-2016. London: Department of Health
4. Elliot E, et al. (2012) Home sampling through social network websites: can we reduce undiagnosed HIV? *Sexually Transmitted Infections*; **88**, A8-A8.
5. Saunders JM et al. (2012) Where do young men want to access STI screening? A stratified random probability sample survey of young men in Great Britain. *Sex Transm Infect*, **88**: 6, 427-.
6. Sadler K.E. et al. (2007) Sexual behaviour and HIV infection in Black -Africans in England: results from the Mayisha II survey of sexual attitudes and lifestyles. *Sex Transm Infect*. **83**, 523-529
7. Bourne A, Reid D, Weatherburn P. (2014) African Health and Sex Survey 2013-14: Headline findings. London: Sigma Research, London School of Hygiene and Tropical Medicine.
8. NICE (2011) Increasing the uptake of HIV testing among Black Africans in England. *NICE public health guidance 33*; guidance.nice.org.uk/ph33 NHS.
9. Burns F, Fenton KA. (2006) Access to HIV care among migrant Africans in Britain. What are the issues? *Psychology, Health & Medicine*; **11**:117-125
10. Belza, M.J., et al., (2012) Supervised blood-based self-sample collection and rapid test performance: a valuable alternative to the use of saliva by HIV testing programmes with no medical or nursing staff *Sexually Transmitted Infections* **88**(3): p. 218-21.
11. Bartholow, B.N., (2006) A comparison of consumer-controlled and traditional HIV counselling and Testing: Implications for screening and outreach among injection drug users. *Dissertation Abstracts International: Section B: The Sciences and Engineering*, **67**(4-B): p. 1942.
12. Colfax, G.N., et al., (2002) What happened to home HIV test collection kits? Intent to use kits, Actual use, and barriers to use among persons at risk for HIV infection. *AIDS Care*. **14**(5): p. 675-82.
13. Krause, J., et al., (2013) Acceptability of HIV self-testing: a systematic literature review. *BMC Public Health* **13**: p. 735.
14. Osmond, D.H., et al., (2000) Obtaining HIV test results with a home collection test kit in a

Community telephone sample. *Journal of Acquired Immune Deficiency Syndromes: JAIDS*, **24**(4): p. 63-8.

15. Spielberg, F., et al., (2000) Home collection for frequent HIV testing: acceptability of oral fluids, dried blood spots and telephone results. HIV Early Detection Study Group. *AIDS*, **14**(12): p. 1819

16. Wayal, S., et al., (2011) Home sampling kits for sexually transmitted infections: preferences And concerns of men who have sex with men. *Culture, Health & Sexuality*, **13**(3): p. 343-53.

17. Greensides, D.R., et al., (2003) Alternative HIV testing methods among populations at high risk for HIV infection. *Public Health Reports* **118**(6): p. 531-9.

18. Grispen, J.E., et al., (2011) To test or not to test: a cross-sectional survey of the psychosocial determinants of self-testing for cholesterol, glucose, and HIV. *BMC Public Health*, **11**: p. 112.

19. Skolnik, H.S., et al., (2001) Deciding where and how to be tested for HIV: what matters most? *Journal of Acquired Immune Deficiency Syndromes: JAIDS* 2001. **27**(3): p. 292-300.

20. MHRA (2013) Guidance on the In Vitro Diagnostic Medical Devices Directive 98/79/EC

21. PHE (2015) National HIV Self sampling Services: Available from https://www.eastmidstenders.org/procontract/emp/supplier.nsf/frm_opportunity?openForm&opp_id=OPP-HIS-9WVE-PFE5DS&contract_id=CONTRACT-9WGI-6XDET&org_id=ORG-EASD-979K25&from = Accessed 8 June 2015

22. Valdiserri RO, Holtgrave DR, West GR (1999). Promoting early HIV diagnosis and entry into care. *AIDS* **13**:2317–30.

23. Murphy EL, Collier AC, Kalish LA. Highly active antiretroviral therapy decreases mortality and morbidity in patients with advanced HIV disease. *Ann Intern Med* 2001; **135**:17–26.

24. Derald W. S., (2007) Racial Microaggressions in Everyday Life: Implications for Clinical Practice *American Psychologist* : **62**(4): 271–286

25. Dean St at home. Alan McOwan personal communication (March 2013)

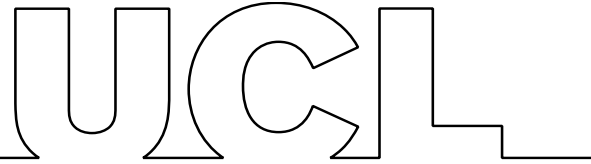
26. HIV postal test. THT. Michael Brady, personal communication (1/5/13)

27. Craig P, et al. (2008) Developing and evaluating complex interventions: new guidance. London: Medical Research Council.

28. Ritchie, J. and Lewis. J. (eds.) (2003) Qualitative Research Practice: A Guide for Social Science Students and Researchers. Sage Publications, London

29 Braun V., and Clarke V; (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3 (2): 77-101. doi: 10.1191/1478088706qp063oa

30 Layder D. (1998). *Sociological practice*. Sage: Thousand Oaks, California.



Appendix 1: Participant Information Sheet

We are inviting you to take part in the Haus study. Before you make your decision, we would like you to understand the study, and what is being asked of you. You can talk to the person who gave you this sheet about any questions you may have.

What is the purpose of the study?

In the UK, people of black African heritage make up about one in three of all the people with HIV. Unfortunately many are unaware that they have HIV and only find out when they become sick. We are looking into the best ways that people can find out whether or not they have HIV. One of the ways to find out is to use a self-sampling kit such as the TINY collection device, which lets you take your own small sample of blood. You then send the kit in the envelope provided to a laboratory be tested for HIV. You are contacted with the results a few days later. We want to find out whether people are happy to be given these tests in GP surgeries and in the community.

Why have I been invited?

We have selected some GP practices and community based organisations in London and Greater Glasgow to take part. All black African people who are 18 years or above; who are not known to have HIV and are attending these services are being asked to take part. We would like as many people as possible to take part.

Do I have to take part?

It is entirely up to you to decide whether or not to take part. If you decide to take part and are eligible you will be asked to provide written consent. You can still change your mind at any point and withdraw from the study and you do not need to give a reason for this. Only essential patient information will be kept by the NHS if you return a kit.

What will taking part involve?

If you do decide to take part, this is what will happen:

1. You will need to provide contact information (including mobile phone number). We will only use this to contact you by phone or by text to send reminders about this study and for delivery of your results once the sample is tested. Any messages sent will not mention your name or HIV. Your contact information will be held securely on the UCL University database by the research team until your results are delivered to you. After this, your contact details will be destroyed unless you will be taking part in a follow up interview. If you agree to an interview now but change your mind later, you can reply to any message and ask us to remove you from the contact list.

2. You will be asked to complete a short questionnaire before you leave. You can complete this on your own. It takes less than 5 minutes to complete.
3. You will be given the TINY self-sampling kit for HIV testing to take away. You will be able to use it at a time and place that suits you. The kit has detailed instructions on how to collect the blood sample and how to return the sample. The instruction sheet also has a link to an online video where you can see how to collect the sample. Only 0.4ml of blood is required, which is a very small amount. The sample will only be used for HIV testing. You need to complete a form confirming your initials, date of birth, and contact number, which you enclose with the sample when you return it. You will also need to write your initials, date of birth and date of collection on the vial label. Your sample cannot be processed without this information.
4. After you collect the sample, we would like you to complete a short questionnaire about how you have found the process. You enclose the completed questionnaire in the same envelope which you use to return your sample. This questionnaire is optional and you do not have to do it.
5. You have the option to take part in a further telephone interview. These are to find out what you thought about the study and using the kit. The interviews will be audio recorded and will last no more than 30 minutes. They will not include your name. Though the research team may publish direct quotes provided by those who are interviewed, they will not publish any identifying information whatsoever (as such, it would be impossible for a reader to tell who said what). Those who have an interview will be provided a £10 voucher. We will only interview 30 people so even if you consent to this you may not be asked to participate.
6. The research team (which includes staff outside of the direct healthcare team) needs to be able to collect the outcomes from this study. This means they will be informed of your anonymised (no name) test results including confirmatory testing and linkage to appropriate care where relevant. However, they will not have access to your medical records. The University College London Hospitals NHS Foundation Trust will be the NHS organisation responsible for providing care for all participants who return a kit. The Central & North West London NHS Foundation Trust will be responsible for contacting everyone who needs to be contacted by phone rather than by text as they already provide this service routinely.
7. If you collected your kit at a GP practice, you will be asked for permission to let your GP know about your result.

How will I get my test results?

1. If your HIV test is “negative”:

If your test is negative you will be given the result by phone. If you have a mobile phone this will be by text message, otherwise we will contact you on your landline. The TINY test is extremely reliable however it may not always indicate very recently acquired infection (within past 4 weeks). If you think you have been at risk of HIV in the last 4 weeks you may need to take another test after the four weeks have passed.

2. If your result is “reactive”

If you have a reactive result this suggests that you may have been exposed to HIV. This is a first result and needs checking. A reactive result means there is about a 90% chance that you have HIV,

so you will need to attend a clinic for further testing. You will be contacted over the phone and given information and support to attend a local specialist clinic where they will undertake a blood test to check whether or not you are HIV positive (diagnosed with HIV). If you are found to be HIV positive than it is much better to know sooner rather than later, as early access to treatment and care will help ensure a full and healthy life, and help prevent further spread.

If for some reason there is a problem with your sample and the laboratory is unable to do the test you will be contacted and the reason explained.

You can find further information and links to support organisations that specialise in HIV prevention on our study website: www.haus.org.uk

What are the possible disadvantages of taking part?

You may experience stress and anxiety while waiting for your HIV test results. This information sheet details where you may access further support. While the kit we use is extremely reliable it will not pick up very recently acquired infection. If you think you may have been exposed to HIV less than 4 weeks ago, you may need to take another test after the 4 weeks have passed.

What are the possible advantages of taking part?

Information provided in this study could be of use to you in the future. You may benefit from this personally through your test results. Most people will find out that they do not have HIV and this may help you evaluate your own decisions. If you are diagnosed with HIV then it is much better to know sooner rather than later, as early treatment and care will help ensure a full and healthy life, and help prevent further spread. This study aims to further medical knowledge and may support future wider availability of self-sampling kits for Black Africans. Many people find it beneficial to know that their participation will help others, as well as themselves.

Will my taking part in this study be kept confidential?

Yes. All information will be kept strictly confidential. We will remove all identifying details from the questionnaire responses and from interviews. If we use direct quotations from the interviews when we present the study results, they will be anonymous. We will keep all the study information securely at University College London. Your anonymised responses will be added to everyone else's responses. The data will only be analysed for groups and not for individuals. Anonymised data from this study may be made available to other genuine researchers in the future for further research, but that would be overseen by the University College London, in line with their strict rules of confidentiality.

A confidential record of your test results will be kept by University College London Hospitals NHS Foundation Trust and where relevant, Central & North West London NHS Foundation Trust.

What will happen to the results of the study?

The results will be presented in a form that does not allow any individual to be identified. They will be shared with health care services to help improve HIV related care and with community based organisations and service users. We will also publish the findings from this study in academic journals. If you are interested, copies of the study results will be available from the research team and we will post a summary of the findings on the study website www.haus.org.uk

What if there is a problem?

If you wish to complain, or have any concerns about how you have been approached or treated by members of staff you may have experienced due to your participation in the research, the National Health Service or UCL complaints mechanisms are available to you. Please ask the person who is approached you about the study. Otherwise, you can contact the study manager directly at the numbers below. In the unlikely event that you are harmed by taking part in this study, compensation may be available. If you suspect that the harm is the result of the Sponsor's (University College London) or the organisations' negligence then you may be able to claim compensation. After discussing with the person who has enrolled you into the study, please make the claim in writing to Dr Fiona Burns who is the Chief Investigator for the research and is based at the UCL Centre for Sexual Health & HIV Research. The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Should you want to withdraw from the study then they will have two options: 1. Withdraw from the study, and not be approached for further information. Samples and data already obtained however may still be retained and used, and 2. Request no further contact, and for your samples and data to be destroyed. However if you have already returned your self-sampling kit then a clinical record of the result will be retained by the University College London Hospital NHS Foundation Trust (UCLH), or by Central and North West London NHS Foundation Trust (for those with reactive results). This information belongs to the NHS and will not be destroyed even if you decide to withdraw from the research component of the study.

Who is organising and funding this research?

This study is funded by the National Institute for Health Research, UK which is part of the NHS. It is being led by researchers based at University College London (UCL), London School of Hygiene & Tropical Medicine, Glasgow Caledonian University, Glasgow University, and Central and North West London NHS Foundation Trust. Dr Fiona Burns from UCL is leading the project. Ethical approval for the study has been obtained from Cambridge South Research Ethics Committee (Project ID Number): 15/EE/E0412; IRAS # 184223.

Further information

Advice and information about HIV is available from the NHS Choices website:

<http://www.nhs.uk/Conditions/HIV>

or any of the following:

www.avert.org

<http://www.waverleycare.org>

<http://www.naz.org.uk/>

Thank you very much for taking the time to consider taking part in this study

If you would like to speak to someone about issues raised by this study please feel free to ask us.

For further information contact:

Ms. Maureen Seguin

Phone: 020 3108 2073 Email: m.seguin@ucl.ac.uk

Dr Fiona Burns

Phone: 020 3108 2060 Email: f.burns@ucl.ac.uk



Appendix 2: HAUS Study Consent form-Community Based Organisations

Researcher: **Dr Fiona Burns**

Please initial the boxes you agree with

STUDY CONSENT (all statements must be agreed with to participate in the study)

1.	I confirm that I have read and understand the information sheet dated 15/01/2016 (version 0.2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected	
3.	I agree to provide contact details (including mobile number) which can be used to contact me with my results by NHS staff from either UCLH or CNWL.	
4.	I understand that the research team will be informed of my anonymised results including confirmatory testing and linkage to care where relevant.	
5.	I understand and agree that anonymized data arising from this study may be made available to other genuine researchers in the future for further research, but that this would be overseen by the University College of London, in line with their strict rules of confidentiality.	
6.	I agree to take part in the above study.	

OPTIONAL CONSENT

7.	I agree to receive up to two text reminders to post the sample to the laboratory.	
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OPTIONAL CONSENT FOR FOLLOWUP INTERVIEWS BY TELEPHONE

8.	I agree to provide contact details (including mobile number and/or email address) and be contacted about participation in a follow up telephone interview to explore the process and acceptability of self-sampling for HIV.	
9.	I agree to the use of audio recording devices in a follow up telephone interview.	
10.	I understand that the research team may publish direct quotes from the telephone interviews.	

Name of participant

Date

Signature

Name of person taking consent

Date

Signature

Version 2.0: 14/01/2016

Appendix 2: HAUS Study Consent form-GP Practices

Researcher: **Dr Fiona Burns**

Please initial the boxes you agree with

STUDY CONSENT (all statements must be agreed with to participate in the study)

1.	I confirm that I have read and understand the information sheet dated 15/01/2016 (version 2.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3.	I agree to provide contact details (including mobile number) which can be used to contact me with my results by NHS staff from either UCLH or CNWL.	
4.	I understand that the research team will be informed of my anonymised results including confirmatory testing and linkage to care where relevant.	
5.	I understand and agree that anonymised data from this study may be made available to other genuine researchers in the future for further research, but that this would be overseen by the University College of London, in line with their strict rules of confidentiality.	
6.	I agree to take part in the above study.	

OPTIONAL CONSENT

7.	I agree to receive up to two text reminders to post the sample to the laboratory.	
8.	As is standard practice, I agree that my GP be notified of my test result.	

OPTIONAL CONSENT FOR FOLLOWUP INTERVIEWS BY TELEPHONE

9.	I agree to provide contact details (including mobile number and/or email address) and be contacted about participation in a follow up telephone interview to explore the process and acceptability of self-sampling for HIV.	
10	I agree to the use of audio recording devices in a follow up telephone interview.	
11	I understand that the research team may publish direct quotes from the telephone interviews.	

Name of participant

Date

Signature

Name of person taking consent

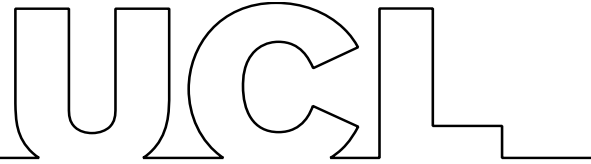
Date

Signature

Affix Kit
number here

Appendix 3 HAUS Study Participant Screening and Enrolment Log

Name of Person Screening and Enroling participants										
Site name and Address										
ID Number	Sex		Initials	Age (years)	Country of Birth	Screening Date (dd/mm/yy)	Enrolled?		Reason if not enrolled (insert number from list below) If Did Not Attend insert #11	Comments
	M	F					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
	<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/> Yes	<input type="checkbox"/> No		
1. Recently tested for HIV 2. Do not believe at risk of HIV 3. Prefer to test elsewhere 4. Prefer not to use a self-sampling kit 5. Prefer not to know HIV status 6. Do not like being offered an HIV test just because black African 7. Already knows is HIV positive 8. Prefer not to say 9. Other 10. Does not meet eligibility criteria 11. Did not attend										



Appendix 4: Baseline Questionnaire

Thank you for agreeing to be part of this study. Please complete the following information. The questionnaire is confidential and takes less than 5 minutes to fill in.

First Name _____

Surname _____

Affix Kit
number here

Are you: Male Female

What is your date of birth: //

Mobile number: What is the first half of your
postcode:

Alternative contact method (landline):

1. When did you last have an HIV test? (please tick one)

- Never
- Less than one year ago
- 1 – 2 years ago
- 2 – 5 years ago
- More than 5 years ago

2. In the last 12 months, who have you had sex with

- I have only had sex with men

- I have only had sex with women
- I have had sex with men and women
- I have not had any sex

3. In what country were you born?

Please write it down:

4. How long have you been living in the UK?

- Less than one year
- 1 – 2 years
- 2 – 5 years
- 5-10 years
- More than 10 years
- All my life

Once finished please return this to the person who is enrolling you in the Haus study.

Thank you.

Appendix 5: Acceptability Questionnaire

Please fill in this survey AFTER you have taken your sample. Thank you.

We would like to know your thoughts about this way of testing for HIV. Your answers will help us to improve this HIV testing service.

The questionnaire is confidential and takes only a couple of minutes to fill in.

1. Is it acceptable to be offered an HIV test in this manner? (circle a face below)

Acceptable      Unacceptable

2. Is it acceptable to be offered an HIV test because you are African?

Acceptable      Unacceptable

3. What did you think about the location where you were offered this kit?

Acceptable      Unacceptable

4. Did the offer of this kit help you to decide to test?

Yes No

5. Did the person who offered you the kit help you feel more confident about knowing your HIV status?

Yes No

6. Were the instructions in the kit easy to understand?

Very easy      Very difficult

7. How did you feel about taking the sample yourself?

Comfortable      Uncomfortable

Why did you feel that way? _____

8. Did you watch the online video about using this kit?

Yes

No

If yes - How did watching someone else use the kit make you feel?

Confident      Unsure

How helpful was the video?

Helpful      Unhelpful

9. How willing would you be to use one of these kits again in the future?

Very willing      Not at all willing

10. Can you tell us why you accepted this kit when it was offered to you?

11. We are very interested in your views on this service. Please tell us which aspects you particularly liked or you think we should change.

Please put this completed questionnaire in the free post envelope with your sample.

Thank you again for your time.

|

Date

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Glossary of Terms and Abbreviations

CNWL	Central and North West London NHS Foundation Trust
CSV	Comma Separated Values File
CW	Community Worker
GP	General Practice
HIV	Human Immunodeficiency Virus
HSL	Health Services Laboratory
PN	Practice Nurse
SSK	Self-Sampling Kit
TDL	The Doctors Laboratory
UCLH	University College London Hospitals NHS Foundation Trust

1 Introduction

1.1 Background

In the UK people of black African heritage account for almost one third of the 96,000 people estimated to have HIV, which means nearly four out of every 100 black Africans are HIV positive. Unfortunately, many are unaware that they are HIV positive and only come to medical attention at an advanced stage of infection. This is described as “late presentation” and is associated with a tenfold increased risk of death in the first year after diagnosis when compared to people who are diagnosed with less advanced infection. Reducing late presentation to HIV services is the single most useful way of decreasing the ill health and death associated with HIV. In the UK most HIV testing occurs in sexual health clinics (a service not regularly used by most Africans), or antenatal services (a service not used by men). Whilst Africans do go to their GPs, this opportunity for earlier HIV diagnosis is often missed. There is a need to increase the range of occasions and locations where HIV testing is offered to Black African people. This may help to improve the extent to which knowing your HIV status becomes a routine, simple opportunity that is unhindered by accessibility issues such as transport costs, childcare and clinic opening hours.

1.2 Intervention Purpose

The HAUS study seeks to develop and test a model of distributing self-sampling kits (SSK) for HIV testing within general practice and community services to determine if this will increase HIV testing in African communities. Phase 1 of the study examined what the target population and service providers thought about different ways of achieving this. The following intervention is based on their direct input.

1.3 Intervention Process

The intervention will take place in Glasgow and London. The SSKs will be distributed by: Practice Nurses (PN) in GP clinics (Glasgow and London) and by Community Workers (CW) from community organisations providing HIV prevention as a part of their outreach (London only). These service providers will be trained and supported to opportunistically offer black Africans an HIV self-sampling kit using a scripted discussion within their standard service provision. The script provides a rationale for HIV testing and explains how the kit is to be used. All eligible black Africans (see section 3.2) engaging with the participating service will be given a brief description of the study and a brief demonstration of how to take the sample. They will then be asked if they would be willing to participate. If they agree informed consent will be obtained and participants will be asked to fill out a baseline questionnaire before being given the self-sampling kit. They will be asked to return their sample within two weeks using the stamped, addressed envelope provided with the kit. Figure 1 gives an overview of the intervention process.

The self-sampling kit being used is called TINY. There are three possible results.

1. Reactive – this indicates the participant may have HIV. A confirmatory test at a sexual health clinic needs to be arranged.
2. Non-Reactive – This indicates the participant does not have HIV.

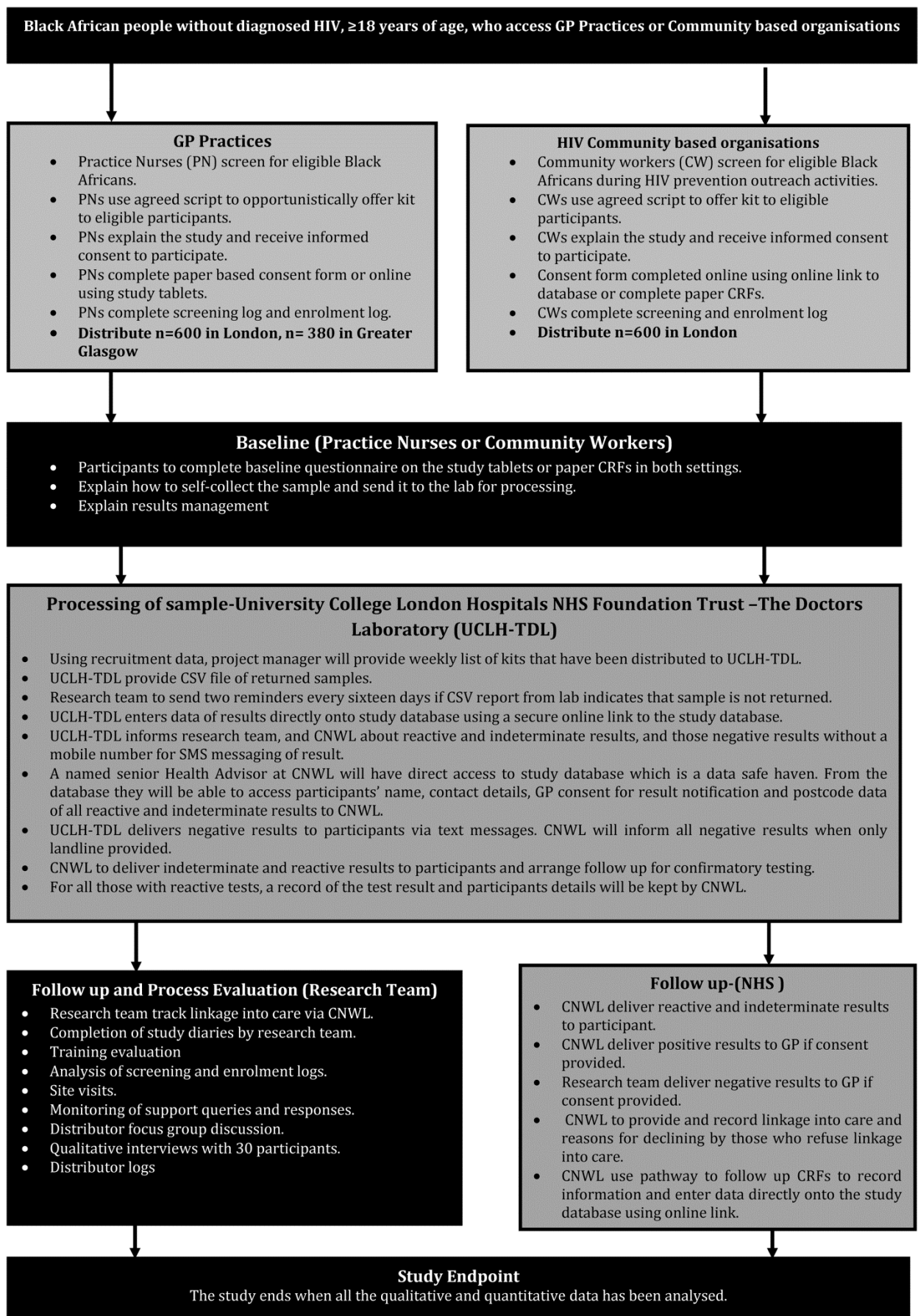
3. No-result/Indeterminate – This indicates the lab were unable to get any result from a particular test.

Negative results will be delivered directly to participants by TDL (the processing laboratory) working in collaboration with University College London Hospitals NHS Foundation Trust (UCLH) via text message. Central & North West London NHS Foundation Trust (CNWL) will deliver all results when only a landline has been provided. Management of reactive results will be provided by CNWL as part of their existing clinical system. Where a sample is reactive, the individual will be directly contacted by telephone to discuss the results, the implications, and to arrange confirmatory testing and linkage to care. Similarly, all participants who send samples that are not able to be processed will be informed by CNWL and offered a further self-sampling kit or assisted in accessing alternative testing options.

1.4 Training

In both Glasgow and London, the PN in GP clinics and CW from community organisations providing HIV prevention as a part of their outreach, who distribute the kits will be supported by a programme of training on the delivery of the intervention and research governance. This manual outlines intervention processes and procedures including (targeting, data collection, result management and linkage to care). This resource supports the training package, and both are designed to help the PN/CWs:

- identify and approach black Africans about the intervention
- recruit participants to the study and gain informed consent
- demonstrate how to take the sample
- facilitate collection of baseline data
- complete the screening and enrolment log



2 Who is Involved in the Study

2.1 Overview

This study is funded by the [National Institute for Health Research](#), UK. It is being led by researchers based at [University College London](#) (UCL), [London School of Hygiene & Tropical Medicine](#), [University of Glasgow](#), and [Glasgow Caledonian University](#). Dr Fiona Burns from UCL is responsible for the study and all the data. Ethical approval for Phase 1 of the study was obtained from UCL Research Ethics Committee (Project ID Number): 3321/001, [to be updated when ethical approval is granted *and approval for Phase 2 via....*]

2.2 Core members of the study team

[Fiona Burns](#) is a Senior Lecturer at the [UCL Centre for Sexual Health and HIV Research](#) and an Honorary Consultant at the Royal Free Hospital. **Fiona is the Principal Investigator in charge of the HAUS study.**

[Catherine Dodds](#) is a Lecturer with [Sigma Research](#) at [London School of Hygiene and Tropical Medicine](#). **Alongside Fiona, Catherine is the lead on the qualitative elements of this project.**

[Paul Flowers](#) is Chair of Sexual Health Psychology at the [Institute for Applied Health Research](#) / Psychology at [Glasgow Caledonian University](#).

[Lisa McDaid](#) is a Programme Leader at the [MRC/CSO Social and Public Health Sciences Unit](#) at [University of Glasgow](#).

[Maureen Seguin](#) is a Research Associate at the [UCL Centre for Sexual Health and HIV Research](#). **Maureen is the Project Manager for this study, and oversees the day to day running of the project.**

[Caroline Park](#) is a Research Assistant at the [MRC/CSO Social and Public Health Sciences Unit](#) at [University of Glasgow](#).

[Sonali Woyal](#) is a Research Associate at the UCL [Research Department of Infection and Population Health](#).

2.3 Extended members of the study team

[Jane Anderson](#) is a Consultant Physician at the [Centre for the Study of Sexual Health and HIV](#) at [Homerton University Hospital NHS Foundation Trust](#).

Jabulani Chwaula is Programme Manager for HIV Prevention England and is based at [BHA for Equality](#).

[Ibidun Fakoya](#) is an NIHR Doctoral Research Fellow at the [UCL Centre for Sexual Health and HIV Research](#).

[Nick Freemantle](#) is a Professor of Clinical Epidemiology and Biostatistics in the UCL [Research Department of Primary Care & Population Health](#) and the [PRIMENT Clinical Trials Unit](#).

[Rachael Hunter](#) is a Senior Research Associate at the UCL [Research Department of Primary Care & Population Health](#) and the [PRIMENT Clinical Trials Unit](#).

[Greta Rait](#) is a Senior Clinical Lecturer at the UCL [Research Department of Primary Care & Population Health](#) and the [PRIMENT Clinical Trials Unit](#).

[Memory Sachikonye](#) is the Coordinator of the [UK Community Advisory Board for HIV \(UK-CAB\)](#) and is based at [iBase](#).

[Surinder Singh](#) is a Senior Lecturer in General Practice at the UCL [Research Department of Primary Care & Population Health](#).

[Peter Weatherburn](#) is a Senior Lecturer in Sexual Health and HIV, and Director of [Sigma Research](#) at [London School of Hygiene and Tropical Medicine](#).

Esther Mugweni is a Research Associate at the [UCL Centre for Sexual Health and HIV Research](#). She was the Project Manager for this study, but is currently on maternity leave.

2.4 Other Organisations Involved

UCLH is the NHS Trust responsible for overseeing the clinical governance of this study. They will be responsible for testing all the samples that are collected during the trial. They are also responsible for delivering negative results to participants with mobile contact numbers. This will be done via text message. If a mobile number was not provided then details will be provided via a health advisor (see CNWL below).

Central and North West London NHS Foundation Trust (CNWL) will be responsible for the delivery of reactive and indeterminate results. This will be done through a senior Health Advisor. The process will be aligned with the current clinical practice. They will also be responsible for delivering negative results to those who only provide a landline telephone number.

3 Materials Required and Eligibility

This chapter contains details of the materials required to run the intervention as well as the inclusion and exclusion criteria for recruitment and participation purposes.

3.1 Materials Required for GP Intervention

The following equipment is required before delivering the intervention

- Tablet computer with online and offline access to screening and enrolment log, consent form and baseline questionnaire
- Paper copies of screening log, consent form and baseline questionnaire (for use when online services not available)
- Participant information sheets
- Lockable container for storage of self-sampling kits

- Pre-packaged, study labelled HIV self-sampling kits (includes sampling device, postage paid addressed return envelope, written instructions, acceptability questionnaire)
- Card listing reasons why people may decline to participate
- Self-sampling kits with written instructions for user
- Plain bag to put kit in (optional)
- Community-based organisation (CBO) referral information (for PNs to use where needed)

3.2 Materials Required for Community Based Organisation Intervention

- Tablet computer with access to screening log, consent form and baseline questionnaire
- Paper copies of screening log, consent form and baseline questionnaire (for use when online services not available)
- Participant information sheets
- Lockable container for storage of self-sampling kits
- Pre-packaged, study labelled HIV self-sampling kits (includes sampling device, postage paid addressed return envelope, written instructions, acceptability questionnaire)
- Card listing reasons why people may decline to participate
- Self-sampling kits with written instructions for user
- Plain bag to put kit in (optional)
- CBO referral information (for CWs to use where needed)

3.3 Eligibility criteria

Inclusion criteria:

To be recruited into the study, participants will need to be:

- Black African
- Without diagnosed HIV,
- 18 years of age or older
- Accessing GP practices or community based organisations that are taking part in the study.
- Able to provide informed consent.
- Able to read and understand English.

Exclusion criteria:

The following participants will be excluded from the study:

- Participants who do not provide a means of contact for result notification.
- Participants who are unable to provide informed consent.

4 Scripted Interaction

4.1 Aim

To introduce and recruit eligible candidates to the research study. To explain the benefits of participating and having an HIV test. To give a demonstration of how to take the sample and alleviate any concerns participants may have.

4.2 Target and Recruit

“We are currently involved in an important study that I wonder if you’d be interested in taking part in? We want to see if people will use HIV self-sampling kits. HIV treatments are so good now; that you can live a normal healthy life with HIV, and being on treatment also stops most people from passing on the infection. So we are trying to find new ways to offer testing as it’s the people who don’t know their HIV status who become unwell.

This study is looking at whether people from the Black African community would want to use these kits. It’s a great opportunity as most people don’t have access to them yet.

Testing is very easy. It’s all in this kit, which you take home to use when it is convenient to you. Once you’ve collected the sample you put it in the envelope provided and pop it in the post.

A few days later you are contacted by a NHS health clinic via your mobile phone with the results. Most people testing will be negative. A few people will have a test suggesting they have HIV (this is called a ‘reactive’ test) and we would have to check the result is correct.

It’s all completely private and confidential - no one, other than the clinic contacting you, will know your result unless you want them to. What do you think? Is this something that you may be willing to try?”

If answer = NO then go to **Section A**

If answer = YES then go to **Section B**

Section A

"That's absolutely fine. We would really like to understand why people do not want to participate in the study. On this card are some of the common reasons why people say no – "

(Hand participant card)

"Would you possibly be able to let me know if any of the numbers match with your own reason? And if so which numbers? Of course it is also ok if you do not want to give me a reason."

(Participant gives reason or declines to do so)

(If reason given then insert into participant screening and enrolment log)

CONTACT ENDS!

Section B

"First we need to determine if you're eligible for the study. Are you aged 18 or older and do you consider yourself Black African?"

(NOTE: If asked, the term 'Black African' includes anyone who identifies themselves as Black African, whether they are migrants from Africa, African descendants or African nationals. If asked why black Africans are being targeted refer to section 5.1)

If answer = NO then go to **Section B1**

If answer = YES then go to **Section B2**

Section B1 – Not eligible to participate

*“Thank you for taking the time to consider the study but you do not meet the eligibility criteria. If you would like to test for HIV then the easiest way would be to *.....”*

(NOTE: Answer varies according to options available e.g. standard blood test if in GP, referral to testing centre if in community)

CONTACT ENDS!

Section B2 – Eligible to participate

(Hand them the information sheet)

(Copy SSK Unique ID to the consent form)

(Hand them the consent form and ask them to read it and consent to the statements to participate in the study).

(Retrieve consent form from participant and check to make sure that all options marked as ‘essential’ have been consented to)

Check forms have been completed then continue to section 4.3

4.3 Baseline data

Participants who consent to be part of the study should then be asked to self-complete a short baseline questionnaire. The baseline questionnaire collects name, contact details (mobile or landline number), demographics (age, gender, country of birth) and details about prior HIV testing and sexuality. The baseline questionnaire is available in electronic and paper based formats. The mode used will depend on recruiter and user preference and whether internet access is available.

If using the online forms please ensure you enter the kit specific identification number before handing the tablet to the participant for completion.

If a paper based version is used, the data will need to be subsequently entered directly by the distributor onto the study database via a web link later that day.

Please reassure participants that the information is confidential and is needed to be able to provide their results (see anticipated questions section 6).

Section C – Baseline Data

(Fill out SSK number and hand participant the baseline questionnaire)

(Retrieve questionnaire from participant)

Check forms have been completed then continue to section 4.4

4.4 Introduce SSK

Section D – Introducing SSK

“This box contains the self-sampling kit. It has a study ID code on the top but that is just for our purposes. The code is unique to you though so please do not give the kit to someone else to use.”

“The kit contains a full set of simple instructions to guide you through the process of taking the sample and there is a link to an online video that shows someone taking the sample themselves. It is important that you follow the instructions carefully to ensure we get a good sample to test. Do you think you will be able to take the sample yourself?”

If answer = NO then try to identify and alleviate participants concerns (see section 5.3)

If answer = YES then go to Section D1

Section D1

“That’s great, here is your kit.”

(Hand participant the SSK and ask them if they would like a bag to carry it in)

(Tell participant they should get their results within 5 working days of the lab receiving the sample)

(Tell participant if they consented, they will receive a text reminder if the lab does not receive their sample within 2 weeks)

(Thank the participant for participating)

CONTACT ENDS!

Completed Forms

The following forms need to be completed during each encounter where a potential participant has been approached and recruited.

By participants:

1. Consent form
2. Baseline questionnaire

By distributors:

1. Participant screening and enrolment log
2. Weekly distributor log

5 Anticipated Questions

5.1 Targeting

The following is a list of questions that participants may ask. Answers have been provided to assist you in dealing with these as and when they arise.

Do I need to take part?

"No you do not need to take part if you do not wish to. Participating is entirely voluntary and you are free to withdraw at any stage without giving a reason and without your care being affected in any way. It is a great opportunity though, so please do consider it."

Can I take a test for my friend/partner too?

"Unfortunately we can't give you a kit for your friend as we need to gather details and consent from all the people who are taking part in the research study. You can however tell your friend to come and see us about it."

Are you only approaching African people? Why?

"Yes this study is only available to the African community. The National Institute for Health Research (NIHR) who is funding this study wants to increase HIV testing in African communities in particular because there are still lots of African people unaware of their HIV status who therefore cannot benefit from treatment or take steps to prevent passing it on. Around 1 in 20 African people in the UK have HIV and that is not the case for other ethnic groups. Around 1 in every 3 African people with HIV here does not know they are HIV positive."

5.2 Personal Details

Do you not already have my personal information? (PN only)

"Yes we do have personal information on you in the surgery but as this is for a specific research study, we need to ask you for information for the purposes of the study"

Why do I need to give my personal information?

“We require you to give personal information so that your sample can be identified at the lab and you can be contacted with your test result. “

Who will have access to my personal information?

“All kits are returned to the University College London Hospital NHS Foundation Trust, who will keep a confidential record of your test result. Central & North West London NHS Trust will manage all those with reactive results or samples that are unable to be processed so they will also keep a record of those results. They are a sexual health service and will not divulge any details to anyone else unless you provide explicit consent for this to occur. Any identifying information needed for research purposes will be held on a very secure database at UCL with access limited to a senior member of the research team. All identifying information will be destroyed as soon as possible. Otherwise all the information will be anonymised for research purposes. Even the laboratory processing your sample will not know your name, only your initials, date of birth and phone number.”

How will my contact details be used?

“Your contact details will be used by NHS staff to contact you with your test result. In the case of a reactive or indeterminate test result, the NHS sexual health service involved with this study will contact you to discuss your options and ensure all the appropriate next steps to determine if the test result is correct are undertaken.”

How will my contact details be stored?

“Your information will be stored on encrypted hard drives at University College London. These are located within extremely secure networks and no one outside the research or NHS team can use them. I will not have access to any of the details you put into the system today, or any of the information you give to the study team later on.”

I don't have a mobile number I can use

“What we can do is we can take a landline number and the sexual health team involved with this study can call you to give you your test results.”

Will you do any other testing on the sample such as DNA?

“No we will not carry out any form of testing on the sample you submit other than the HIV test”

What do you mean by 'black African'?

“The term 'black African' includes anyone who identifies themselves as black African, whether they are migrants from Africa, African descendants or African nationals.”

5.3 Taking the Sample

Will I be able to take the sample?

“Yes, the instructions are simple to follow and they have pictures to help you follow them. If you find that you have problems with this however there is also a link to an online video that shows someone taking the sample themselves. The video is available in English, French and Somali and offers a clear demonstration of what is involved in taking the test. Is there anything in particular that you think you might find difficult?”

I don't think I am qualified to take the sample?

“The kit has been designed so everyone and anyone can use it. The process is simple with no experience necessary, so don't worry. I am sure you can do it. If you find that the instructions are confusing there is also a link to an online video that shows someone taking the sample themselves. The video is available in different languages and offers a clear example of what taking a sample involves. You definitely can do it.

How long will it take from start to finish?

“It should take you about 5 minutes to take your sample, and you will receive the results within 5 working days after the lab receives your sample.”

Can you do it for me or help me with it?

“I cannot help you to do the test, but I can show you how it is done. In the kit there is also a link to an online video that shows someone taking the sample themselves”

5.4 Concerns over Blood Based Testing

Can you really test for HIV just using a small amount of blood?

“Yes, new improvements in testing technologies mean that we can use small amounts of blood to very accurately test for the presence of HIV contracted more than 4 weeks ago.

Is it safe to put a blood sample in the post?

“Yes, it is safe – that is why we are allowed to do it. You will need to follow the instructions but it's very simple. Once you have collected the sample you put a lid on the vial, place it in a plastic holder and them into the waterproof postage paid addressed flexi-envelope provided”

How accurate is the test?

“If your result is reactive then there is around a 90% chance that you have HIV. This is the reason that you are invited in for a confirmatory test if you have a reactive result.”

“The TINY vial is very reliable but will not always react if you were exposed to HIV very recently. If you think you may have been exposed to HIV less than 4 weeks ago, you may need to take another test or use another self-sampling kit after the 4 weeks have passed.”

I have a fear of needles and of blood, is there another test I can take that doesn't need blood?

“There is not another test that we can give you today. Some services do however offer tests based on saliva which usually you can order over the internet. Saliva tests are a little less reliable for recently acquired infection so may miss infection if acquired in the last 14 weeks.”

I have children in the house. Is it really safe to be potentially spilling my own blood in that environment?

“The way the kit is designed it is relatively simple to make your blood go into the vial rather than spill out. If some does spill then you should deal with it in the same way as you would if you had cut your finger”

Why are there so many lancets?

“There are multiple lancets as you may need to prick your finger more than once to extract enough blood to fill the vial, and in the interests of hygiene, we recommend that you use each lancet only once.

Is it safe to put the used lancets in the trash?

“Although the sharp point of the lancet retracts after use, we ask that you return the lancets with your sample in the envelope (rather than your rubbish bin). That way they can be disposed of as clinical waste”

If it is not safe to put used lancets in the trash is it really safe to mail them?

“Yes it is safe to return them in the mail”

How much blood do you need?

“You need around 40 drops of blood to fill the vial. Though this may sound like a lot you will most likely find it is easier to do than you would think”

Will the blood not get contaminated from running down my finger?

“There are swabs included in the kit for you to clean your finger before using the lancet to pierce the skin. If you use these then contamination can be prevented.

Will it be painful?

“With the finger prick you will feel a slight discomfort as the skin is pierced, this will only last for a fraction of a second though”

What is the gel inside the vial?

“The gel contains preservatives, which stabilize the sample for up to 21 days if temperatures are between 4° C and 37° C”

5.5 Filling out Questionnaire

I find it difficult to read in English

“You really need to be able to read English to participate in the study”

I don't know if I would have time to fill out a questionnaire

“The questionnaire is very short. There are only a few questions and it will take less than 5 minutes to complete it.”

5.6 Packaging

If you are handing these out to everyone then will they not be recognisable to others who have them?

“If you like we can provide you with a bag that you can put it in so that no one can see what you have”

I don't really feel comfortable carrying that out of here in my hand/it doesn't fit in my handbag/pocket

“We have a bag that you can put it in to carry home”

5.7 Sending the Sample

How do I send the sample back?

“When you have taken the sample and filled out the questionnaire you just pop it into the self-addressed envelope and pop it into the post. The postage has already been paid so there is no need for stamps. Alternatively you can bring the sealed envelope into us here and we can post it off to the lab for you. When do you think you would be able to have the sample and questionnaire completed and sent back?”

Who is the sample sent to?

“The sample is sent to The Doctors Laboratory, who are working for University College London Hospitals.”

What happens if the sample goes missing in the post?

“This is very unlikely to happen. If it does then you should let us know if you:

- a. Receive a reminder text to send in your sample (when you have already sent it)*
- b. Do not receive your results within an estimated 5 working days from when the lab receive your sample*

5.8 Results

How long will it take to get my results?

“You will receive your results within 5 working days of the lab's receipt of the sample.”

How will I get my results?

“You will receive a text message if your result is negative. If your test is reactive or if there is a problem with the sample meaning we are unable to test it for any reason then someone will contact you on the mobile number you provided.”

What if I don't receive my results back?

"If you do not receive your results back, you should contact the place that you picked up the SSK from and inform them that you have not yet received your test results, or contact the research team – the details on your information sheet."

What if my result is positive?

"If you do find out you are HIV positive then we have world class care available to you. You should know that people with HIV can live a full and healthy life with a life expectancy similar to that of those who do not have the virus. HIV treatment in the UK is free for absolutely everyone"

Who will have access to my results?

See 'Who will have access to my personal information' – section 6.2 above

6 Supplementary Information

6.1 Self-Sampling

The TINY collection device in conjunction with ROCHE Combi will be used for this study. The ROCHE Combi is a 4th generation assay, used for the detection of HIV p24 antigen and antibodies to HIV-1 (Groups M and O) and HIV-2. This means it is suitable for detecting recently acquired HIV. It can detect HIV that was caught more than 4 weeks ago and is CE marked. The ROCHE Combi has a sensitivity of 100% (lower 95% CI 99.8%) and a specificity of 99.63% (95% lower CI 99.42). This test requires collection of a few drops of blood (obtained by pricking a finger with the supplied lancet) in a small collection tube. The test enables the specimen to be transported to a lab, by post, in a vial that contains preservatives, which stabilize the sample for up to 21 days if temperatures are between 4° C and 37° C. Self-sampling negates the need for dedicated staff or special infrastructure for specimen collection. The kit can be used at a time and setting of the users' choice. Members of our group have previously used the same or similar tests to screen MSM for HIV in England and Scotland. They have also developed instruction sheets, which provide a step-by-step guide to using the device.

6.2 Process of Results Giving

For negative results, the lab which tests the sample will contact the participant directly by sending a text message to the mobile phone number the participant provided. If they only provide a landline number UCLH-TDL will contact a senior health advisor at CNWL who will assume responsibility for results notification as per clinic practice. The results will be distributed within five days of the lab receiving the sample

For reactive results, a health advisor from CNWL will contact participants directly and inform them of the result. The CNWL health advisor will inform them of the result and need for confirmatory testing. If consent is obtained from the participant they will arrange linkage into appropriate local services for confirmatory testing.

For samples that are unable to be processed, a health advisor from CNWL will contact the participant and inform them of the situation. They will request permission for the study team to send them another kit or for them to attend an alternative testing venue.

(For further information see the study protocol at www.haus.org.uk)

7 Contact Information

If you have any questions or queries about what is contained within this intervention manual then please contact a member of the research team using the details below.

Ms. Maureen Seguin Phone: 020 3108 2073 Email: m.seguin@ucl.ac.uk

Dr Fiona Burns Phone: 020 3108 2060 Email: f.burns@ucl.ac.uk

Appendix 7: Sample Data Form

The following information is needed to test your sample and send you the result. Please answer all the questions.

Date sample taken: / /

My initials:

My gender: Male Female

My date of birth: / /

My mobile number

Alternative landline number:

Please note that **all** the questions must be answered before we can test your sample and provide a result.

Once completed put this form into the free post return envelope along with your test.

Thank you.

STEP 1 TDL TINY™ SAMPLE COLLECTION



Sample collection instructions

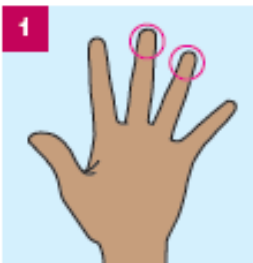
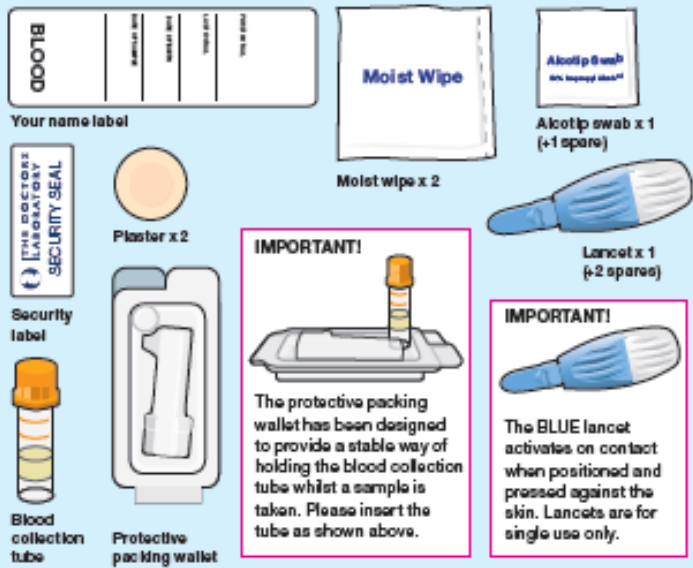
Please read these instructions first, slowly and carefully, the whole way through before attempting to collect your sample. A video showing how to collect your sample is available at www.haus.org.uk

Clearly complete the Name Label using a ball point pen with:

- Your First and Last Initial • Your Date of Birth • Date of Blood Collection

Do not affix the label to the blood collection tube until after collecting your sample. This is important as you will not be able to see how much blood you have collected if the label covers the sides of the tube.

Your sample collection pack contents



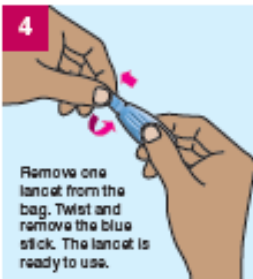
The best locations for collecting finger prick samples are from the 3rd or 4th finger of your non-dominant hand. This means if you are right handed, collect the sample from your left hand. Open your pack of lancets.



Wash your hands in warm soapy water. It is much easier to collect your sample if hands are warm. Dry them thoroughly with a clean, dry towel.



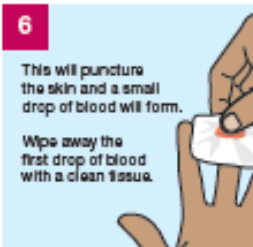
Using the Alcotip Swab clean the selected finger. Wipe dry with a clean tissue. Be sure your finger is completely dry as blood will not form a drop at the puncture site of a moist finger.



Remove one lancet from the bag. Twist and remove the blue stick. The lancet is ready to use.



Position the lancet against the end of your finger. The lancet will activate in one step only when positioned and pressed FIRMLY against the skin. Should you need to repeat the process to help obtain enough blood use one of the remaining lancets. Stand up rather than sit down when collecting your blood drops



This will puncture the skin and a small drop of blood will form. Wipe away the first drop of blood with a clean tissue.



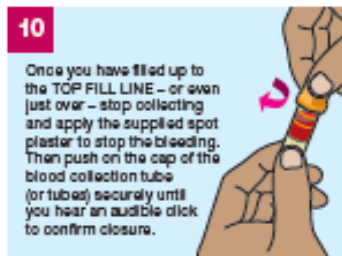
Holding your hand/arm downwards, firmly massage the side of your hand down to your finger to encourage blood flow.



Take your finger with the other hand and gently milk your hand and finger to help the blood drop into the blood collection tube as shown.



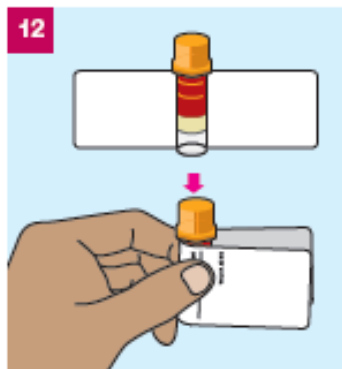
Fill the blood collection tube to the upper line on the side of the tube. NB: If you are unable to collect enough blood use the second lancet on another finger on the other hand. Alternatively, try wiping your finger you have been using with a dry tissue. Pause for 5-10 seconds and blood drops are likely to reform, and you can start collecting again.



Once you have filled up to the TOP FILL LINE – or even just over – stop collecting and apply the supplied spot plaster to stop the bleeding. Then push on the cap of the blood collection tube (or tubes) securely until you hear an audible click to confirm closure.



Once you have replaced the cap, gently invert the collection tube 5 to 10 times.



Make sure your tube(s) is labelled with your details using the label supplied in your pack. This is very important as unlabelled samples cannot be accepted.

Affix the label by placing the tube in the middle of the label and wrapping the label around the tube, as shown below.

Place the collection tube in the protective packing wallet provided.



Inside the self addressed, post paid mailer, please insert:

- the protective packing wallet containing the blood collection tube(s)
- used lancet(s)

Please run through the checklist below before returning samples.

CHECKLIST

Before you return your samples please tick off the contents of the white self addressed post-paid mailer.

- Completed Request form
- Blood collection tube(s) in the protective packing wallet
- Used lancets

You are now ready to seal the white self addressed post-paid mailer.

Please post your samples to The Doctors Laboratory as soon as possible from ANY Royal Mail post box in the UK. No stamp is required within the UK.

If you need assistance please contact The Doctors Laboratory on 020 7307 7373 or email samples@tdlpathology.com. If you wish to return your lancets please enclose with your samples.

PLEASE TURN OVER TO FIND OUT WHAT HAPPENS NEXT



The Doctors Laboratory
60 Whitfield Street, London W1T 4EU
Tel: 020 7307 7373 Fax: 020 7307 7374
E-mail: tdl@tdlpathology.com Website: www.tdlpathology.com

Once you are finished, all you need to do is put it into a postbox, and you will usually be contacted with your results within five working days.

If you are concerned because you have not heard back about your test result, please contact the research team – their contact details are on the information sheet you were provided when you were given the kit.

You will usually be contacted about your results through a text to your mobile phone, but if you do not have a mobile, or there is a problem with the sample, or if the test is reactive (meaning that you may have HIV), you will get a call from a health advisor who will advise you what to do next. If that is necessary, they will arrange for further testing and can put you into contact with local organisations that can provide you with any information and support you require. There is a lot they can do to give support and information to people in that situation, and people with HIV need to know that this is now a very manageable illness.

You should keep hold of your information sheet which has our contact details and your unique ID study number.

Appendix 9: Pathway to care outcome measures

1. SSK number	
2. Patient initials	
3. Patient DOB	<u>DD/MM/YYYY</u>

If sample indeterminate:

How was the participant informed of the result:

- . Phone
- . SMS
- . Other _____
- . Not informed of result – reason _____

Outcome:

Attended alternative site for HIV testing Yes No Don't know
Additional SSK sent Yes No SSK number:

If sample reactive:

How was the participant informed of the result:

- . Phone
- . SMS
- . Other _____
- . Not informed of result – reason _____

Did the Participant attend for confirmatory testing? Yes No Don't know
If yes when and where: _____

If no why not if known: _____

What was the confirmatory result: HIV positive HIV negative

If HIV positive, first CD4 count : _____

Appendix 10

Haus Study Researcher Diary

These diaries will remain entirely confidential within the core research team. In the main, these will be analysed by Peter Weatherburn and Catherine Dodds for the purposes of the process evaluation, but also be aware that they can be accessed by any member of the core team. We plan to monitor these entries monthly, and all core team members are asked to submit **AT LEAST ONE DIARY ENTRY PER MONTH starting from February 2016.**

1. **Researcher Initials:**
2. **Date:**
3. **Was there a particular issue that stimulated the entry? Or is this a routine entry?**
4. **What thoughts / reflections / successes / challenges would you like to record in this entry?**
5. **Is there someone inside / outside of the team that you should speak with about these issues, either for the immediate benefit of the study (in terms of problem-solving) or for you to gain support?**

Appendix 11: Haus Study Distributor Weekly Log

Name of individual distributor	
Organisation	
Location for today's distribution	
Date	

1. How many people did you recruit to Haus this week: _____

2a. How did you feel about recruiting people to the Haus study this week? (circle a face below)



2b. Why do you say that? _____

3. How confident do you now feel about targeting Black African people to take part in the Haus study?

- Very confident
- Quite confident
- Not sure
- Not really confident
- Not at all confident

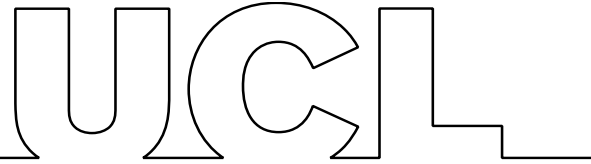
4. Do you use the techniques provided in the training sessions or study manual to encourage people to take part?

- Always
- Most of the time
- Some of the time
- Rarely use
- Never

5. How confident do you now feel when answering people's questions about the study?

- Very confident
- Quite confident
- Not sure
- Not really confident
- Not at all confident

6. Is there anything you would like to add about your experience of being a Haus distributor this week?



Appendix 12: Haus Study Semi-Structured Interview topic guide

SSK unique code _____

Interviewer initials _____

Date _____

Interview format: Phone Face to Face Online

PARTICIPANT CONSENT

Before we start I need to ensure that you understand the nature of the interview you are about to take part in and are happy to proceed.

This interview will involve me asking you questions about your experience of being approached to consider using the HIV self-sampling kit, and your decision about using it. We will also ask people who used the kit about their experience of using it. This interview should take around 30 minutes. Your participation is voluntary and you may stop the interview at any point or refuse to answer any question with which you are not comfortable.

I would like to audio-record the interview: this is because I am not able to write down everything you say quickly enough.

The recording will be kept strictly confidential and no one outside of the Haus study team will have access to it. When we are finished taking notes from the interview, the recording will be safely destroyed, so there will be no

record of your voice or any of your identifying details remaining. In any report or presentation that we write about this study, we may use some of your exact words, but we will do that in a way that makes sure no one could identify you.

- Do you have any questions about the interview?

Note any questions raised:

I would like to start the interview now which means turning on the recording is that ok? Yes No

I just need to ask you a few confirmation questions again so that we have an audio record of you saying that you are happy to go ahead based on what we have just discussed.

- We have just discussed what the interview is about, and how we will store the information you give us until it is destroyed. Are you fully aware what your participation involves?

Yes No

- Do you consent to the interview being digitally recorded?

Yes No

- Are you happy for us to get started?

Yes No

Section 1 – Kit distribution

- 1.1 Is being tested for HIV something that you had done or considered before you were asked to consider using this self-sampling kit?
[prompts: prior access to traditional HIV testing and associated benefits/challenges, personal considerations of risk]
- 1.2 Before you were approached to consider taking/using an HIV self-sampling kit, did you know that such kits were available?
[probes: prior thoughts about SSKs/change in thinking/immediate response when learning about them for the first time]
- 1.3 Can you think about the time you were offered this kit and let me know what do you recall about it?
[prompts: location, distributor characteristics, what was said]
- 1.4 How did you feel about being offered an HIV test because you are African?
Why/why not?
- 1.5 How did you feel about being offered an HIV test in [location]?
Why/why not?
- 1.6 Why did you agree to consider using the kit?
[prompts: relevance of distributor characteristics/information; personal reasons, convenience]

Section 2 – Kit Use and Sample return

- 2.1 Did you actually open the kit and attempt to use it?
- No - Why was that?
- Yes - Tell me how that went and what you thought of using the kit.
- 2.2 In the end, you did [OR] did not return the sample. Tell me a bit about why you made that decision.

[probes: confidence, privacy, kit characteristics, interest in knowing status and reasons why/why not]

2.3 **only ASK if sample was returned**

How did you feel about the way that your test results were communicated to you?

Section 3 – Implications of this approach

3.1 Would you be willing to use the same kind of HIV self-sampling kit in the future?

- Why/why not?
- Are there particular circumstances that would influence your decision? What are they?

3.2 What was your overall experience of using this kit to test for HIV? Please tell me what you liked, and what you think needs to be changed.

[prompts: consider this in relation to the discussion/the kit/the sample return/communicating the results/being targeted]

3.3 In your view, do you think other Black African people like you would like to use a kit like this to find out their HIV status?

[Probes: Why do you feel that way?

- Is that the same for everyone, or are there some for whom this is a better or worse option?]

3.4 Do you think there are other ways, and maybe even better ways to encourage more Black African people to test for HIV regularly?

3.5 Is there anything else you would like to say before we finish the interview?



UCL/UCLH Joint Research Office

Office Location:
1st Floor Maple House
149 Tottenham Court Road
London W1T 7DN

Postal Address:
UCL,
Gower Street
London WC1E 6BT

Email david.wilson@ucl.ac.uk : Tel No. 020 3447 5199
Web-sites: www.uclh.nhs.uk; www.ucl.ac.uk/jro

13/10/2015

Dr Fiona Burns
UCL Institute of Epidemiology and Health Care
Department of Infection & Population Health
Capper Street
London WC1E 6AU

Dear Dr Burns,

Chief Investigator: Dr Fiona Burns

Study/Trial Title: Feasibility and acceptability of home sampling kits to increase the uptake of HIV testing among black Africans in the United Kingdom: The Haus Study Phase II

Funder: NIHR HTA

UCL Project ID No. 15/0621

Re: Insurance for studies not involving a Clinical Trial of an Investigational Medicinal Product (non-CTIMP) sponsored by UCL

Thank you for completing the UCL Insurance Registration Form dated 6/10/2015. I am pleased to inform you that the above study, as described in the registration form, is now insured under UCL's policy. A copy of the current insurance summary (Verification of Insurance) is attached to this letter.

The policy provides for the legal liabilities (negligence) of UCL and its' employees or agents.

This confirmation letter, together with the attached summary, needs to be submitted to the Research Ethics Committee in support of question A76 for both your NHS REC and, where applicable, NHS R&D applications submitted via the Integrated Research Application System (IRAS).

.../Continued

Director Research Support Centre, Director R&D UCLH – Brian Williams
Managing Director Research Support Centre – Dr Nick McNally

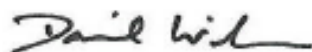


Page 2 / Continued

The UCL insurance policy is renewed annually, but studies included in the UCL insurance portfolio will be automatically rolled over into subsequent insurance period(s) until the study terminates. Indemnity and insurance arrangements for any participating sites will be detailed in individual Site Agreements.

Please keep a copy of this letter for your records. Feel free to contact me if you have any queries concerning the insurance cover.

Yours sincerely,

A handwritten signature in black ink that reads 'David Wilson'.

DAVID WILSON
Database & Information Officer



13th July 2015

TO WHOM IT MAY CONCERN

We, the undersigned Insurance Brokers hereby certify that we have place the following Insurance:

VERIFICATION OF INSURANCE

Unique Market

Reference: B1262 FI0153315

Type: Clinical Trials Insurance

Insured: University College London

Period: From: 01st August 2015
To: 31st July 2016 Both days inclusive at Local Standard Time.

Interest: This Policy will indemnify/cover the Insured in respect of their Legal Liabilities arising out of the Insured's activities and as more fully disclosed within the Policy Wording.

Limit of Indemnity: GBP 15,000,000 Any One Claim and GBP 15,000,000 in the Aggregate, including costs and expenses

Excess: GBP 2,500 Each and Every Claim, including costs and expenses

Territorial

Limits: Worldwide and as more fully described within the policy

Underwriter: 100.0000% Newline Syndicate 1218

This document is for information only and does not make the person or organisation to whom it is issued an additional Insured, nor does it modify in any manner the Contract of Insurance between the Insured and the Insurers. Any amendment, change or extension to such Contract can only be affected by specific endorsement attached thereto.

Should the above mentioned Contract of Insurance be cancelled, assigned or changed during the above policy period in such manner as to affect this document, no obligation to inform the holder of this document is accepted by the undersigned or by the Insurers. The information provided is correct at the date of signature.

Authorised Signatory
Gallagher London.



13th July 2015

TO WHOM IT MAY CONCERN

We, the undersigned Insurance Brokers hereby certify that we have place the following Insurance:

VERIFICATION OF INSURANCE

Unique Market Reference:

B1262FI0500915

Type:

Clinical Trials Insurance

Insured:

University College London

Cover and Retroactive cover is to include clinical trials having been, being, or to be undertaken by or on behalf of University College London, where the Medical Research Council Clinical Trials Unit, has been, is or shall be the sponsor of such trials and only covering the list of trials that have been supplied and seen by the underwriters.

Period:

From: 01st August 2015

To: 31st July 2016

Both days inclusive at Local Standard Time.

Interest:

This Policy will indemnify/cover the Insured in respect of their Legal Liabilities arising out of the Insured's activities and as more fully disclosed within the Policy Wording.

Limit of Indemnity:

GBP 15,000,000 Any One Claim and GBP 15,000,000 in the Aggregate, including costs and expenses

Excess:

GBP 2,500 Each and Every Claim, including costs and expenses

Underwriter:

100.0000%

Newline Syndicate 1218

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Authorised Signatory
Gallagher London.