HIV Testing at Family Planning Clinics in Mombasa County, Kenya: A Cluster-Randomized Trial comparing the Systems Analysis and Improvement Approach (SAIA) to Usual Procedures

March 2021 Protocol

NCT 02994355

[DATE]

UNIVERSITY OF WASHINGTON
[Company address]

INSTRUCTIONS

- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ◯. For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: HIV Testing at Family Planning Clinics in Mombasa County, Kenya: A Cluster-Randomized Trial comparing the Systems Analysis and Improvement Approach (SAIA) to Usual Procedures

1.1 Home institution. Identify the home institution of the lead researcher as listed on the IRB application. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **POLICY: Use of the UW IRB.***

University of Washington

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[X] **No**
[ ] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[X] **No**
[ ] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[X] **No**
[ ] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

Our overarching objective is to assess the effectiveness, costs, and budget impact of implementing this **systems analysis and improvement approach (SAIA)** to increase HIV testing in FP clinics in Mombasa County.

Our specific aims are as follows:

AIM 1: To conduct a cluster-randomized trial comparing the effect of the SAIA approach versus usual procedures on rates of HIV testing in first-time attendees at 12 intervention versus 12 control FP clinics in Mombasa County, Kenya.

HYP 1: After one year of study team support implementing SAIA vs. usual procedures, a higher proportion of first-time FP clinic attendees will be tested for HIV at intervention compared to control facilities

AIM 2: To determine whether the SAIA training results in a lasting effect, we will compare HIV testing rates for first-time FP clinic attendees in SAIA intervention versus control facilities after an additional year, during which FP clinics in the intervention arm will be encouraged to continue to use the SAIA tools with minimal support from the study team. The Mombasa County Ministry of Health will take ownership of implementation during this phase.

HYP 2: After an additional year with minimal support from the study team, there will continue to be significantly higher rates of HIV testing in first-time FP clinic attendees at intervention compared to control facilities.

AIM 3: To estimate the incremental cost and budget impact of applying SAIA versus standard of care. Using an activity-based approach, we will perform a costing analysis, estimating cost per new HIV diagnosis, both

during active support from the study team and after a period without active support. We will also estimate cost to scale up, and conduct a budget impact analysis from a Department of Health (DOH) perspective.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This is a cluster-randomized controlled trial with FP clinics as the unit of randomization.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
☐	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	2. Part of an institution, organization, or program's own internal operational monitoring.
X	3. Improve the quality of service provided by a specific institution, organization, or program.
X	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	5. Develop information about a drug or device through its prospective use and assignment to subjects, which will then be submitted to the Food and Drug Administration (FDA) in support of a marketing or research application for an investigational drug or device, or for changes to the purpose, population, or dose for an already-approved drug or device.
☐	6. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
X	7. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	8. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
☐	9. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
☐	10. Expanded access use of a drug or device not yet approved for this purpose

☐ 11. Use of a Humanitarian Use Device

☐ 12. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

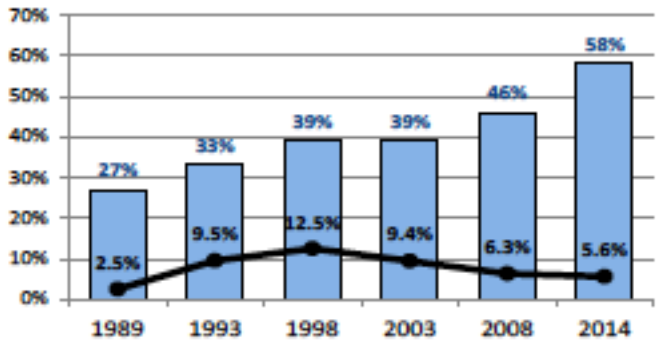
1. Many women in Africa remain unaware of their HIV status.

In sub-Saharan Africa, 60% of the ~23 million people living with HIV are women (11). Over half of HIV-positive individuals remain unaware of their status, making it impossible to link them to services (10). Likewise, when women without HIV infection are not tested, opportunities to link them to HIV prevention services are missed. Addressing this HIV testing gap is among the most fundamental needs in global HIV treatment and prevention.

2. Family planning services are common in many African countries.

Demographic and health surveys from numerous African countries show that a high proportion of women access FP services, and that use of modern contraceptive methods continues to increase (6-9). In Kenya, 53% of currently married women and 61% of sexually active unmarried women reported using a modern method of contraception (9). Figure 1 illustrates the striking increase in contraceptive use in married women in Kenya between 1989 and 2014. Adult HIV prevalence is superimposed on the same figure (18-23). This illustrates that a large proportion of Kenyan women, including many who are

Figure 1: Proportion of Married Women in Kenya using Modern Contraception (blue bars) and National HIV Prevalence in Kenya (black line) from 1989-2014



HIV-positive, could be reached through universal HIV testing in FP clinics.

Integration sexual and reproductive health (SRH) services including FP with HIV services has been recognized as a key strategy for increasing access, uptake, quality, efficiency, and cost-effectiveness (14, 24). Integration and linkage of programs was emphasized in the US Government Global Health Initiative Strategy of 2010 (25).

3. There are advantages to linking HIV testing and family planning services.

From an HIV-prevention perspective, there are numerous reasons to link HIV testing to FP services. First, FP clinics have access to a large proportion of sexually active women. Second, integrating HIV testing into FP clinics opens the gateway for women to access prevention and treatment services (10). HIV-negative women may benefit from prevention strategies such as couples counseling and testing (26), condom use (27), pre-exposure prophylaxis (28), and treatment of positive partners (29). Likewise, HIV-positive women can decrease their risk of transmission to sex partners by taking ART (29-31). A third reason to integrate HIV testing and FP services is the potential to reduce mother-to-child transmission of HIV by preventing unwanted pregnancies in HIV-positive women (32). On the other hand, many HIV-positive women will eventually desire additional children (33-42). Women with HIV, their partners, and their infants can benefit from knowing their status prior to conception (43).

4. WHO supports integration of sexual and reproductive health with HIV services.

In 2009, WHO reviewed evidence on linkages between SRH and HIV services (1), highlighting promoting and inhibiting factors that will be useful in planning future studies including this one (Figure 2). The SRH services (FP, maternal & child healthcare, gender based violence prevention and management, and STD prevention and management) were linked to HIV services including prevention, education, counseling, testing, prevention of mother-to-child transmission (PMTCT), clinical care, psychosocial, and other services. While differences in target audiences, provider time constraints, and structural barriers can be problematic for some linkages (44- 47), WHO and several

Figure 2. Factors Promoting or Inhibiting Effective Linkages between HIV and FP Services (1)

Promoting Factors	Inhibiting Factors
• Positive attitudes & good practices among providers & staff • Ongoing capacity building • Involvement of the community and government during planning and implementation • Simple, easily applied additional services which add no costs to existing services • Non-stigmatizing services • Male partner inclusion • Engagement of key populations	• Lack of commitment from stakeholders • Non-sustainable funding • Clinics understaffed/low morale/high turnover • Inadequate infrastructure, equipment, and commodities • Lack of male partner participation • Women not sufficiently empowered to make SRH decisions • Cultural and literacy issues • Adverse social events/domestic violence incidence • Stigma preventing clients from utilizing services

reviews have concluded that integration is beneficial and feasible (1, 12-14). Many reviews also conclude that more data on integration of SRH and HIV services are needed (12-14).

5. Provider-initiated testing and counseling is key to increasing HIV testing.

A recent report from Central Province, Kenya showed that following training on provider-initiated testing and counseling (PITC), the proportion of visits at which HIV testing was offered in FP clinics was higher in PITC clinics (35%) compared to clinics that continued to use a referral system for HIV testing (20%), $p<0.01$ (48). A separate study in Kenya found that integration of services was motivating for staff and distributed clinics' workload better (49). These findings are consistent with

those of a systematic review of PITC in low- and middle-income countries, which support PITC as an important intervention to increase HIV testing (50).

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

Dr. Sherr leads the SAIA Trial (R01 HD075057), which aims to improve PMTCT services in Kenya, Mozambique, and Cote d' Ivoire by applying the SAIA approach proposed in the present application. The methods have been published following peer-review (51). Briefly, the SAIA intervention is used chronologically and iteratively to optimize PMTCT across the cascade (Figure 3). First, an Excel-based tool is used to analyze the facility's PMTCT cascade (54), identifying steps where optimization would have the greatest impact on overall performance. Second, sequential process flow mapping is performed (Figure 4). The map guides step 3, in which healthcare workers identify, define, and implement workflow adaptations to eliminate bottlenecks. Step 4 involves monitoring the effect of the adaptations using routinely collected data. In step 5, additional iterations of the analysis and improvement cycle are implemented (Figure 5). To date, 17 of 18 intervention facilities have accepted the intervention, and report ownership of the process. Over a 6-month period, sites have implemented an average of six interventions; 81% of interventions show some improvement in relieving bottlenecks. We have identified five broad categories of interventions: service reorganization, expanding patient knowledge, improving communication, improving data, and introducing new interventions (norms, treatments, modalities, technologies. Several key lessons have been learned from the process to date:

• GET LEADERS ON BOARD: Support from leadership is essential, and it may take time to get buy in
• ENGAGE SUPPORT STAFF: Community health workers support and sustain implementation
• GO FOR LOW HANGING FRUIT: Interventions that improve facility adherence to existing DOH norms
• KEEP IT SIMPLE: Implement 1-2 interventions at a time
• PUSH SYSTEMS THINKING: Effective continuous quality improvement must include user-friendly systems tools for use by frontline healthcare workers and managers

Figure 3: Iterative Systems Analysis & Performance Improvement

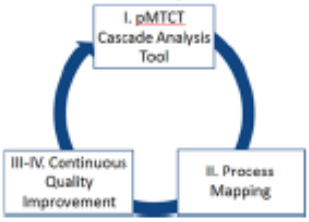


Figure 4: Sample of Initial Steps in Sequential Process Flow Map

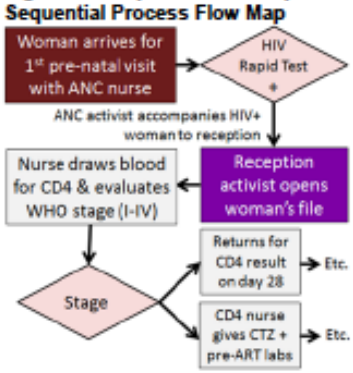
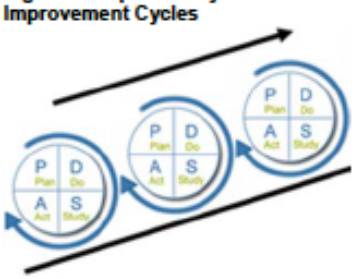


Figure 5: Repeat Analysis & Improvement Cycles



1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research	*ZIPLINE* SUPPLEMENT: Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	*ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
☐	**Multi-site study** (You are asking the UW IRB to review one or more sites in a multi-site study.)	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
☐	**Participant results sharing** Individual research results will be shared with subjects.	*ZIPLINE* SUPPLEMENT: Participant Results Sharing
X	None of the above	

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

The unit of study and eventual randomization unit are the family planning clinics themselves. In 2014, there were 194 FP clinics in Mombasa County. Forty-three were public, while 151 were private, but worked with the DOH to dispense FP products provided at no cost by the government. Clinics ranged

from dozens to hundreds of clients per month. In total, the county had 110,682 FP clients in 2014, of whom 38,418 were new (mean 21 new clients/clinic/month). About 10% of new visits were post-partum.

In addition to FP clinics, there will be in-depth interviews conducted with FP clinic managers. These will likely be adults>18 years of age and both male and female.

2.2 Inclusion and exclusion criteria. Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

Inclusion and Exclusion Criteria:

Clinics will be enrolled in the study though clinic managers and clinic staff will consent to participate in in-depth interviews. A set of family planning clinics will be enrolled with the goal of having a wide range of clinic sizes, degree of urbanity and performance level of the clinic. If clinics plan to be closed during the study period, they will be excluded. Additionally, if clinics are unwilling to be randomized or to participate in the SAIA intervention/approach then they will be excluded.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will you recruit or obtain data from individuals that you know to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

[X] **No**
[ ] **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. What will you do to reduce the chances of this?

iii. Describe what you will do to make sure that (a) your recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

[ ] **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

[X] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed or submitted.

Population	Worksheet
[ ] Children	WORKSHEET: Children
[ ] Children who are wards	WORKSHEET: Children
[ ] Fetuses in utero	WORKSHEET: Pregnant Women
[ ] Neonates of uncertain viability	WORKSHEET: Neonates
[ ] Non-viable neonates	WORKSHEET: Neonates
[ ] Pregnant women	WORKSHEET: Pregnant Women

"Children" are defined as individuals who have not attained the legal age for consent to treatments or procedures involved in the research and its specific setting. This will vary according to the location of the research (that is, for different states and countries).

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

N/A

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[X] **No**
[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

[X] **No**
[ ] **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.

[ ] **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

[X] **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research **For clinical trials: provide numbers for your site and for the study-wide total number*
Preliminary review of FP clinics	
Randomization of FP clinics	
In-depth interviews	

3 INTERNATIONAL RESEARCH SETTING

Answer the questions in this section ONLY if your research will occur at sites outside of the United States

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

Many women in Africa remain unaware of their HIV status. However, many women access family planning services. By conducting this research in Kenya, we hope to make an impact on the number of women who are tested for HIV. The National AIDS & STI Control Programme (NASCOP) has stated that women who access FP services should be tested for HIV though estimates suggest that this is not actually happening.

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

There should not be any cultural barriers to conducting this research. FP clinics that are approached will be introduced to the study through stakeholders meeting and a letter of introduction from the Mombasa County Ministry of Health.

3.3 Site-specific laws. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

If clinic staff are under 18 years of age, they will be allowed to participate only if they qualify as emancipated minors who are legally considered adults under Kenyan law (14 years or older and married or pregnant).

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

We have received ethical approval from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (ERC) prior to starting this research.

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Individual FP clinics will be approached after the sub-county Ministries of Health are aware of the study. A letter of introduction from the Mombasa County Ministry of Health will accompany study staff. Clinic managers will assent to the preliminary clinic review and then if selected to be randomized into the study.

Clinic managers and clinic staff will be approached by study staff to discuss participating in in-depth interviews. Individual health workers will be recruited confidentially at a convenient time in their work day. They will be reassured that they are free to decline to participate.

4.2 Recruitment materials.

a. What materials (if any) will you use to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

A letter will be presented to FP clinic managers upon arrival to their facility. This letter details that investigators from the Mombasa County Department of Health, the University of Nairobi, Kenyatta National Hospital and the University of Washington are conducting research to learn about HIV testing at Family Planning (FP) clinics. This research has been approved by the Kenyatta National Hospital, University of Nairobi Ethics and Research Committee and by the Department of Health, Mombasa County. The research will include an initial review of 60 Family Planning clinics. Following this review, there will be a randomized clinical trial of an implementation

science tool compared to usual procedures in 24 randomly selected FP clinics. This letter is signed by the Chief Officer, County Department of Health.

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

[X] **No**
[ ] **Yes** → If yes, describe the nature of the relationship.

4.4 Payment to participants. Describe any payment you will provide, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

N/A

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

N/A

4.6 Consent for recruiting and screening. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[X] **No** → If no, you must still answer question **4.7** below.
[ ] **Yes** → If yes, describe the consent process.

a. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for all of the **recruiting and screening procedures**?

[ ] **No** → If no, describe the information you will provide during the consent process and for which procedures.

[ ] **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

4.7 Data and specimens for recruiting and screening. For studies where you will obtain consent, describe any data and/or specimens (including any PHI) you will obtain for recruiting and screening (prior to obtaining consent) and whether you will retain it as part of the study data.

***Obtain** means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time.*

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

N/A

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY: Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*

Preliminary Performance Review

The initial step will include a performance review of 50 FP clinics, purposively sampled to include a range of large and small, public and private, urban, peri-urban, and rural facilities. We will use routinely reported data in the FP Registers to measure the proportion of new clients counselled and tested for HIV. These data will be used to assign a performance score to each clinic, as shown in Figure 6. This will also help to confirm that different clinics are using the same registers. If multiple registers are identified, then we will keep records of the different versions that exist and compare between registers when able.

Figure 6: Definitions & Calculation of Performance Score Using Data from FP Register

HIV Counseling	***Numerator:*** Number of new FP clients counselled about HIV testing in the past 3 months ***Denominator:*** Total number of new FP clients in the past 3 months	**Score 1**
HIV Testing	***Numerator:*** Number of eligible (not known HIV+) new FP clients tested for HIV in the past 3 months ***Denominator:*** Total number of eligible (not known HIV+) new FP clients in the past 3 months	**Score 2**
Overall Performance	***Score 1 X Score 2:*** The product of the two proportions will fall on a 0-100 distribution	**Score 3**

While HIV testing in new clients is our primary outcome, we feel that a performance score incorporating both counseling and testing may provide a better baseline measure of performance. Nonetheless, we will also consider the individual *HIV Counseling* and *HIV Testing* scores if they do not tend to track together, and will adapt our randomization accordingly. If too few clinics perform any HIV counseling or testing, we will choose alternative measures of performance in the FP Register, such as recording of client number, client type (new/revisit), age, telephone number, and village/landmark. The rationale for conducting this initial step in 50 clinics, rather than just the 24 needed for completion of the RCT, is to provide a larger sample to enter the restricted randomization process. Preliminary examination of these data will allow us to fine-tune our choice of variables on which to balance the study arms and to optimize the planned length of outcome evaluation periods to capture sufficient endpoints. If any clinics seem inappropriate for participation (e.g. planned closure or unmatchable outliers), they may be removed prior to the randomization.

Aim 1:
In the 12 intervention facilities, the study team will first work with FP clinic staff and managers to identify one or more sets of best practices, which will help to guide the subsequent iterative process improvement steps. A combination of quantitative, qualitative, observation, and flow-mapping data will be used for this purpose

Quantitative data: We will collect data on health system factors that could influence facility performance. We will develop a standardized reporting form, refining assessment items according to current implementation experience, but expect to cover domains including commodities, facility characteristics, human resources, information systems, management, and structure of linkage to HIV

care.

Qualitative data: We will carry out half-day direct continuous monitoring observations of FP service delivery at each intervention clinic to identify patient flow bottlenecks, assess wait times, and observe quality of staff interaction with patients. Research teams will conduct open-ended semi-structured individual in-depth interviews (IDIs) with clinic managers and staff from each clinic to identify key health system factors perceived by respondents to influence clinic performance. In-depth interviews will focus on organizational values and goals, senior management roles and engagement, staff presence and expertise, communication, coordination, problem solving, and training (58). Detailed observation and interview notes will be collected and compiled. We anticipate that we would notify staff of the observation. If a staff member did not want to be observed, we would allow them to opt out. This could mean either avoiding observation in their work area, or not observing within that clinic, depending on what was required to respect the staff member's request. Interviews will also be recorded to check accuracy, clarify, and refine the final interview notes. The IDI and observation notes will be analyzed using Atlas.ti software to identify key themes (59).

Sequential process flow mapping: Process mapping is an essential component of quality improvement in healthcare (51), allowing workers to identify key areas for intervention. To develop sequential process flow maps, trained research assistants will work with staff at each intervention clinic to generate an initial draft of the map on paper. The map will then be transferred to an electronic format using Microsoft Visio. The document produced in this process will be reviewed again with FP clinic staff to insure that it is an accurate representation of the processes and to fine tune the flow map as needed.

Analysis of Data from Detailed Performance Review of Intervention Clinics

We will evaluate the association between facilities' characteristics and performance scores, both overall and for the individual *HIV Counseling* and *HIV Testing* components (52). Results will be interpretable as showing that facility factor 'x' is associated with 'y' percent more women getting through counseling, testing, or both. With this small dataset, we are not focused on statistical significance. Instead, we will be interested in the magnitude of associations and triangulation with our qualitative data and observations. Qualitative data will be analyzed from the interview notes and recordings, using a rapid assessment approach to identify recurring themes. The quantitative data, qualitative data, and flow maps will be summarized in a report that highlights performance facilitators and barriers. We will then review the data with FP managers and staff to identify unique innovations and draft an intervention guide including best practices to guide the subsequent steps. Given variations between facility types, there may be more than one set of best practices.

Step 1: Understanding the cascade from FP clinic enrollment to HIV testing. The purpose of this step is to help clinic staff and managers to answer the questions, "What are we trying to accomplish?", and, "How will we know that a change is an improvement?" (53). Using readily available data from the FP Register, we will determine the number of new FP clients enrolled, counselled about HIV testing, and tested for HIV. To facilitate systems thinking, we will utilize a Microsoft Excel-based tool like the one that is currently being used in the *SAIA Trial*. While the present tool is not easily converted to a figure, an earlier and less detailed version used for studies in Mozambique highlights many of the key features of the cascade analysis tool (Figure 7) (55). Specifically, the tool demonstrates patient flow through the system, highlighting bottlenecks where patients are lost and calculating the potential increase in efficiency if loss were reduced or eliminated at each step, assuming that all other steps are held constant (55).

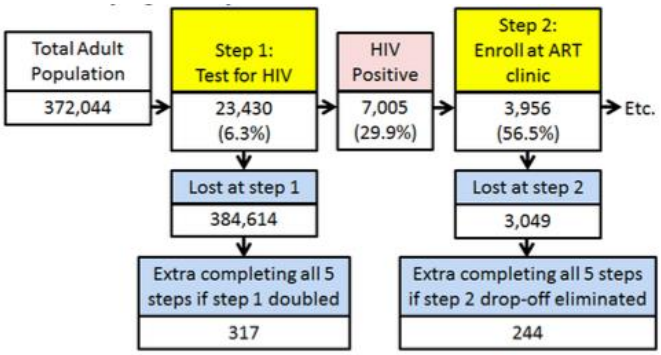


Figure 7. Example of Microsoft Excel-based analysis tool for identifying facility-level bottlenecks in the care cascade

Step 2: Use process mapping to identify modifiable bottlenecks. This step compels FP clinic staff and managers to address the question, "What change can we make that will result in improvement (53)?" Aided by the process map clinics will identify one or more processes to target for improvement.

Step 3: Define and implement workflow adaptations to eliminate modifiable bottlenecks. This step will involve development of a written implementation plan addressing the questions, "Who will be responsible for implementing the intervention?", "What activities will be initiated?" and "What materials/inputs are needed for the intervention?" (56). Small costs for materials/inputs can be covered from the grant budget and tracked for the costing and budget impact analysis. Interventions will be conceived by clinic staff and management with support from study staff using a combination of best practices from the intervention guide and context specific adaptations based on strengths and challenges at individual facilities.

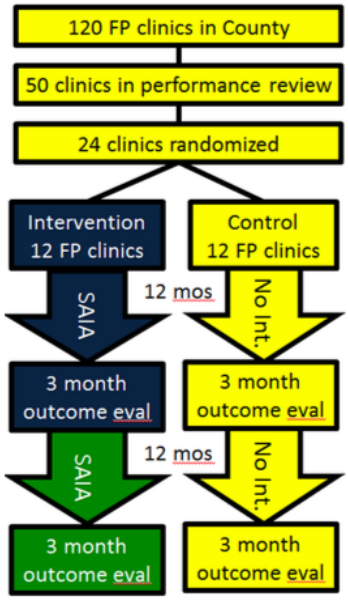
Step 4: Monitor change in performance. The goal of this step is for staff and managers to effectively use routinely collected data to understand the impact of workflow adaptations on the movement of patients through the system. Data from one to two months will be evaluated using the Excel-based tool introduced in *Step 1.* A graphic time-series display of key outcome data will be created to visually depict improvements.

Step 5: Repeat the analysis and improvement cycle (steps 1-4). This step reflects the concept that workflow quality improvement is a continuous and iterative process, with each new cycle of innovation, testing, and learning building on prior cycles (53). Multiple cycles will be completed over a period of 12 months.

At control clinics, we will collect the same information from the FP register as the intervention arm (contraceptive method, age, client type, HIV counselling, HIV tested and HIV status), periodically, but not more often than every three months. We do not want to collect these too frequently, as this observation alone might have some intervention impact on the control clinics (Hawthorne Effect).

Randomization:
Randomization will be performed by a statistician from our CFAR biometrics core, who does not have any other role in this study. We will use a restricted randomization that considers all possible combinations where the clusters are balanced on new client volume and performance score, then randomly selects one of these combinations as the randomization. This allows analysis of the data as if they were unmatched.

After randomization, clinics allocated to the control arm will receive no further training or support from the study team. The only study team involvement at control facilities following randomization will be outcome ascertainment. At intervention facilities, the study team will train FP clinic staff on the SAIA intervention and support them during the active intervention phase shown in blue in Figure 8. After a second year of observation with minimal support in the intervention arm and no support in the control arm, the study team will again ascertain outcomes. Ownership of the SAIA intervention will transition to the MOH team during year two of the trial.



To understand acceptability, feasibility, complexity, and appropriateness of SAIA as an implementation strategy, we will conduct exit interviews following the Aim 1 trial.

Aim 2

Minimal Intervention Period during the Second Year of the Trial and Transition of the SAIA intervention to MOH ownership

We would like to know if SAIA training can produce a lasting effect without long-term support from the study team. This seems plausible, and cost-effective, given the success of expanded HIV testing in the ANC setting (11). The study team will train FP clinic staff on SAIA intervention during the first year of the study and then provide minimal support during the second year of the study to assess for sustainability of this approach (Aim 2). During year two, ownership of the SAIA intervention will transition to the Mombasa County Ministry of Health.

Figure 8. Study

Aim 3

We will perform a costing analysis, estimating incremental cost per outcome (e.g. new HIV diagnosis). We will also estimate cost to scale up, and perform a budget impact analysis (BIA) from the Kenyan DOH perspective. Our analysis will be conducted from the programmatic/payer (DOH) perspective. We will estimate economic costs in this analysis, including actual financial outlays and costs of donated and volunteer time (Table 1).

Table 1. Costing characteristics

Perspective	**Programmatic perspective** (e.g, NASCOP or Mombasa County DOH perspective) to determine the incremental costs and net benefits to anticipate whether the SAIA intervention is feasible.
Cost estimates	Intervention costs will include costs associated with the SAIA intervention, including the increased costs and benefits of additional newly diagnosed HIV-positive women started and retained on ART.
Data collection	Cost data will be collected from the study budget, health facilities, published government information on labor costs, and health economics literature. These data will be used to complete intervention cost worksheets.
Primary outcomes	The incremental cost per new HIV-positive and HIV-negative individual identified
Discount rate	A discounting rate of 3% will be used, and varied from 0% to 5% in sensitivity analyses (66).
Time frame	Results will also be reported over a 1, 5, 10 and 15 year time frame.

Activity Based Micro-Costing Methods

We will estimate the incremental costs of implementing SAIA compared to standard procedures. Intervention costs will include costs associated with SAIA (start-up, personnel, transport, communication, consumables and overhead costs). Cost data will be collected from the study budget, clinic expense reports, published information on labor costs, and staff interviews. These data will be used to complete intervention cost worksheets at SAIA intervention and control facilities. Intervention clinic data will be collected during start-up, to capture the initial costs of program implementation, and again when the intervention is running at steady state. Costs will be categorized as fixed or variable. Variable costs indicate which costs could change (e.g. using free communication instead of standard telephone rates) and influence study estimates.

Time-and-Motion Studies

Time-and-motion studies will be conducted over a two-week period at each site while the intervention is running at full capacity. A mentee trained in this process will collect data on the time required to complete each step of the SAIA process. Observing multiple visits will allow estimation of the average time taken for each step, and any time taken for research purposes (e.g. consent or assent of clinic staff members) will be subtracted from the estimated time needed for the intervention. Multiple providers and clients will be observed to capture the range of time required for a successful SAIA intervention. We anticipate that we would notify staff of the observation. If a staff member did not want to be observed, we would allow them to opt out. This could mean either avoiding observation in their work area, or not observing within that clinic, depending on what was required to respect the staff member's request. Through staff interviews and accounting for time available for the SAIA intervention, the number of patients supported by a clinic will be estimated. Together, the micro-costing data and the time-and-motion studies will be used to estimate the average cost of new HIV-positive and HIV-negative diagnoses.

Budget Impact Analysis

For BIA, we will consider direct program costs. Direct medical costs will be measured using established micro- costing methods, described above, to ensure that measurements of DOH costs reflect the opportunity cost of the resources used in delivering services. Further, the "top-down" approach of expense report collection will be compared with the "bottom-up" micro-costing approach to triangulate

and refine our cost estimates.

Data Analysis for Costing and Budget Impact Analysis

To the extent possible, we will use guidelines to facilitate standardization of cost data collection and reporting and to increase the transparency and generalizability of our results. For all key inputs and outputs, we will follow standard practices (57), including the guidelines by the Panel of Cost-Effectiveness in Health and Medicine (58). We will report on all costs using a recommended discount rate of 3% per year, as well as an alternative 5% discount rate and undiscounted inputs. We will conduct sensitivity analyses around key cost inputs to account for the uncertainty in our results.

Disclaimer: Due to restrictions on human subject research as a result of the COVID-19 pandemic, most activities for Aim 2, which began in February 2020, were on hold between March and August 2020. Activities resumed in September 2020, but were interrupted again by a strike, in response to unpaid wages and lack of PPE in the context of the COVID-19 pandemic. This has led to a number of our FP clinics being unable to participate in the trial for portions of the original 12-month period described in the Aims and Study Procedures. As a result, Aim 2 data collection will be extended an additional 6 months, for a total of 18 months of data collection for Aim 2.

5.2 Data variables. Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

The primary outcome will be the proportion of eligible (not known HIV+) new FP clients who are tested for HIV during the evaluation periods at the end of 12 months of SAIA training and following an additional year in which intervention clinics are encouraged to continue to implement the SAIA intervention with minimal support from the study team. The secondary outcome will be the proportion of new FP clients who are counseled about HIV testing. When data are not filled, we will assume the counseling or testing has not been done. While we recognize that there are few variables available in implementation research datasets (e.g. clinic size, public/private, rural/urban), these variables will be collected for comparison of the randomization arms to assess balance across intervention groups.

Our primary analysis will follow the intent-to-treat principle. The proportion of eligible new FP clients tested for HIV and the proportion of new FP clients counselled about HIV testing will be compared in intervention versus control facilities using generalized estimating equations with a binary link, clustered by clinic. Because there will be more than a year between the first and second assessments, we anticipate that these will take place as separate analyses, as they are completed.

5.3 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

We are obtaining are data from: 1. FP registers and 2. In-depth interviews from FP clinic managers.

5.4 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: Describe which data are:

- Retrospective (i.e., exist at the time when you submit this application)
- Prospective (i.e., do not yet exist at the time when you submit this application)
- Both retrospective and prospective (for example, past and future school records)

This is both a prospective and retrospective study as we are obtaining data from clinics records in addition to subject interviews.

5.5 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
__Identifiable__ means that the identify of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

We will be abstracting data from FP registers that will have FP client names and contact information. We will be covering this prior to image capture.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

[ ] There will be no identifiers.

[ ] Identifiers or the key have been (or will have been) destroyed before you have access.

[ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

[ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you obtain any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

We will obtain names and signatures of clinic staff for in-depth interviews. These consent documents will be kept in a locked cabinet. In-depths interviews will be audio recorded. Audio recordings will be transcribed in Kiswahili, and then translated verbatim into English. Transcripts from these interviews will be de-identified.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data).

☐ You will store the identifiers with the data. Describe the data to which this applies:

☐ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

☒ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

Transcripts will be de-identified and kept separately from signed consent documents. Digital audio devices will be retained in possession of the interviewer until the digital audio content is transferred to an encrypted and password protected computer. In the

event that a device needs to be stored prior to transfer of the digital audio, the device would be stored in a locked cabinet, within a locked room, and separately from the stored informed consent form that includes the clients name.

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

N/A

5.6 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

[X] **No**
[ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

[ ] **No**
[ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.7 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral.

[X] **No** → If no, skip the rest of this question; go to question **5.8**
[ ] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

b. Is any of the PHI located in Washington State?

[ ] **No**
[ ] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific.*

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

☐ **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

Provide the following assurances by checking the boxes.

☐ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

☐ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will you obtain or generate genomic data (as defined at *https://gds.nih.gov/13faqs_gds.html*)?

☒ **No**
☐ **Yes** → If yes, answer the question below.

a. Is this research funded by NIH through a grant or contract application submitted to NIH on or after January 25, 2015?

☐ **No**
☐ **Yes** → If yes, you must comply with the NIH Genomic Data Sharing policy. Complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.9 Data and specimen sharing/banking. Do you plan to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **NO** if your only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the NIH dbGaP database, the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

☒ **No**
☐ **Yes** → If yes, answer all of the questions below.

a. Describe what will be stored, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

b. Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

c. Who will oversee and/or manage the sharing?.

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

e. Consent. Will you obtain consent now from subjects for the banking and/or future sharing?

☐ **No**
☐ **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 6.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from banking or sharing?

☐ **No**
☐ **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

g. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data. Do not attach your template agreement forms; the IRB neither reviews nor approves them

☐ **Confirmed**

5.10 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

We anticipate conducting the exit interviews with FP clinic staff that we have been working with throughout the randomized clinical trial (and whom we interviewed previously for HIV counseling and testing practices). Study staff will text or call FP clinic staff and see if they are available to spend approximately 1 hour with our staff to answer some questions about SAIA. Written informed consent will be obtained.

In the event that social distancing prevents participants from signing the written informed consent document, the consent process will be over the phone with study staff reading the consent document.

5.11 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[X] **No**
[ ] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

5.12 Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[X] **No**
[ ] **Yes** → If yes, describe the alternatives.

5.13 Upload to the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instructions for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

Minor changes may be made to the *Key Informant Interview Guide for Family Planning Clinic Staff* without submitting the materials for IRB review as long as the changes are within the scope and range of the current topics.

The exit interview guide includes questions about acceptability, appropriateness, feasibility, and complexity of SAIA. The draft of the interview guide has been uploaded to Zipline.

5.14 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State. See the **WORKSHEET: Children** for details.
- The generic age of consent may be different in other states, and in other countries.

[X] **No** → If no, go to Section 8.

[ ] **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

[ ] **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

☐ All of your research procedures	→ Go to question **6.2b.**
☐ None of your research procedures	→ Use the table below to provide your justification, and skip question 6.2b.
☐ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written parental permission.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission	Reason why you will not obtain parental permission	Will you inform them about the research?[2] YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will you obtain assent for:

☐ All of your research procedures and child groups	→ Go to question **7.2.**
☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then skip to question 7.5.
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which you will not obtain assent.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why you will not obtain assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

7.3 Dissent or resistance. Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

7.4 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then go to question 7.4.a.
☐ All of your research procedures and child groups	→ Go to question **7.4.a**, do not complete the table
☐ Some of your research procedures and/or child groups	→ Complete the table below and then to go question 7.4.a

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented	Reason why you will not document assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.5 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe your plans (if any) to re-obtain assent from children.

b. Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.6 Other regulatory requirements. (This is for your information only; no answer or response is required.)
Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.
PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.

WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process.
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which your answers in this section apply.

[X] Adult subjects

[ ] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.6. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which you will not obtain consent?

[ ] **No**

[X] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why you will not obtain consent	Will you provide subjects with info about the research after they finish? YES	NO
FP clinic	Preliminary Clinic Review	Clinic manager assent	[X]	[ ]
FP clients	FP data register	We will not have direct access to the FP clients and will be obscuring names of clients in image capture.	[ ]	[X]
FP clinic	Randomized trial	Clinic manager assent for participation	[X]	[ ]
			[ ]	[ ]
			[ ]	[ ]

Table footnotes

1. *If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names).*
- *Whether/how you will provide an opportunity for questions*
- *How you will provide an adequate opportunity for the subjects to consider all options*

Assent of participation of FP clinics: Letters of introduction from Mombasa County will be sent to individual clinics. Following this**,** clinic managers will be approached and asked for voluntary participation in the initial performance evaluation of the clinic. They will also be advised that they may be asked to continue to participate in the randomized controlled trial, and that trial participation could include assignment to either the intervention or control arm. The study will be explained in detail. After answering any questions, we will ask the manager to provide verbal assent for participation of the clinic and staff.

Individual FP clinic staff: Study staff will obtain informed consent for participation in in-depth interviews. They will be reassured that they are free to decline to participate without penalty. The consent process will follow the Standard Operating Procedure that is in place for all of our research activities in Mombasa (see Appendix). This consent process includes the following procedures:

- Ensure that the consent process is taking place in a private area.
- Use the informed consent checklist as a guide throughout the consent process and enter the time at the beginning of the sheet.
- Give the consent form for the client (FP clinic staff member) to read in their language of choice (English or Kiswahili) and allow enough time for the staff member to read the consent form.
- After the potential participant reads the consent/has it read to her, review the key points.
- Ask the potential participant if they have any questions and discuss any questions or concerns.
- Clarify any misunderstanding and determine eligibility.
- Once eligibility is determined the counselor can proceed with the consent process.
- Sign the informed consent checklist and retain if the staff member enrolls
- The potential participant should sign and date first and must write her/his own name. The person obtaining consent signs last.

Potential participants must demonstrate their understanding of key concepts about the informed consent before signing. Specific questions used to assess understanding may include items such as:

1. Please describe what your role will be in this research study?

2. Is participation in these interviews voluntary?

3. If you do not participate, will this reflect negatively in your work evaluations or job status?

The consent form will include the possibility of negative consequences regarding employment if staff members are identified as providing negative information about the workplace. We will also explain how we plan to keep these data confidential.

FP clinic clients: We are requesting a waiver of consent for the FP clinic clients, as we will only be abstracting information that will be de-identified.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

Consents will be written in both English and Kiswahili with study staff performing the consent process being fluent in both English and Kiswahili. In order to assess comprehension of potential participants for the in-depth interview, we will ask similar questions as follows:

1. Please describe what your role will be in this research study?

2. Is participation in these interviews voluntary?

3. If you do or do not participate, will this reflect negatively in your work evaluations or job status?

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

[X] **No**

[ ] **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

FP clinics will have the opportunity to withdraw the study at any time.

8.3 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.6.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Are you obtaining written documentation of consent for:

☐ None of your research procedures	→ Use the table below to provide your justification then go to question **8.4.**
☐ All of your research procedures	→ Do not complete the table; go to question **8.3.b.**
☒ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will you provide them with a written statement describing the research (optional)? YES	NO
FP clinic	Preliminary clinic review assent by clinic manager	☐	☐
FP clients	Data abstraction from FP register with client names removed	☐	☐
FP clinic	Randomized trial with assent by clinic manager	☐	☐
FP clinic staff	Exit in-depth interviews during COVID19 social distancing guidelines	☐	☐
		☐	☐

Table footnotes

1. *If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.*

8.4 Non-English-speaking or -reading adult subjects. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☐ **No**

[X] **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

Consent documents will be translated from English into Kiswahili and then back-translated to English to confirm consistency in language and appropriate cultural context.

a. Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

Study staff performing the semi-structured interviews and in-depth interviews will be fluent in both English and Kiswahili and consent documents will be in both languages.

All study staff are fluent in English and Kiswahili, so there is no interpretation required between staff and participants. In the course of a study that involves trained health professionals, we do not expect to identify individuals in coastal Kenya who do not speak one or both of these languages fluently.

b. Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

Consent documents will be translated from English into Kiswahili and then back-translated to English to confirm consistency in language and appropriate cultural context.

8.5 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person; excluding individuals who cannot read and understand the consent form.

Consent documents will be translated from English into Kiswahili and then back-translated to English to confirm consistency in language and appropriate cultural context.

8.6 Deception. Will you deliberately withhold information or provide false information to any of the subjects?

[X] **No**

[ ] **Yes** → If yes, describe what information and why.

Example: you may wish to deceive subjects about the purpose of the study.

a. Will you debrief the subjects later? (Note: this is not required.)

☐ **No**
☐ **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

8.7 Cognitively impaired adults, and other adults unable to consent.

a. **Cognitively impaired adults and other adults unable to consent**. Do you plan to include such individuals in your research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

☒ **No** → If no, go to question **8.8**.
☐ **Yes** → If yes, answer the following questions.

a.1. Rationale. Provide your rationale for including this population in your research.

a.2. Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will re-assess decision-making capacity and consent during that time.

a.3. Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **SOP: Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

a.4. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

a.5. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.8 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps you will take, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

All procedures will be explained to subjects prior to enrollment in the study and all conversations and will be conducted individually in a private setting. All hard copies of research data will be kept in a secure locked area accessible only to study staff requiring access to this information for research purposes. Computerized databases will be maintained on password protected computers using encryption software accessible only to authorized research personnel.

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[X] **No**
[ ] **Yes** → If yes, will you obtain subject consent for this use?
  [ ] **Yes**
  [ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[X] **No**
[ ] **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

9.4 Retention of identifiers and data. Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left black for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/retentionschedules/gs/general/uwgsResearch#R

See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***http://www.uwmedicine.org/about/Documents/UWMRRS-1.5.pdf***

[ ] **Confirm**

9.5 Certificates of Confidentiality. Do you have or, are you planning to obtain, a federal Certificate of Confidentiality for your research data?

[X] **No**
[ ] **Yes**

9.6 Data and specimen security protections. Identify your data classifications and the security protections you will provide, referring to the **ZIPLINE GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels.

Observation data from FP clinics will use clinic roles, instead of staff names. All observation notes and flow mapping will be stored on a password-protected computer and encrypted using Bitlocker or similar encryption software. Data that have not been decrypted appear as blank files.

Health worker interviews will be recorded, and detailed field notes will be collected by the interviewer. Interview data will be stored on a password-protected computer and encrypted. Interview recordings will be destroyed five years after completion of the research. Digital audio devices will be retained in possession of the interviewer until the digital audio content is transferred to an encrypted and password protected computer. In the event that a device needs to be stored prior to transfer of the digital audio, the device would be stored in a locked cabinet, within a locked room, and separately from the stored informed consent form that includes the clients' name.

Data collected on clinic clients will be abstracted from routine health service records, and will not include any individual patient identifying information. These data will also be stored on a password protected computer and encrypted. We will physically cover name and contact information using an opaque material (e.g. cardboard strips) prior to scanning, so that digital records will not have any identifiable information.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider physical, psychological, social, legal, and economic risks, including risks to financial standing, employability, insurability, educational advancement or reputation.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

FP clinics: Entire FP clinics that participate in the observation period and/or in the randomized controlled trial are not expected to be at risk for injury or side effects. However, we acknowledge the potential for stress or discomfort during the observation period if this identifies individuals as performing poorly or highlighting negative aspects of the workplace. Steps will be taken to mitigate this risk as detailed in response to question 2.

Individual staff members: No adverse effects would be expected to result directly from the semi-structured interviews or observation of clinic procedures. However, there is potential for negative consequences regarding employment for staff if they are identified as performing poorly or providing negative information about the workplace. This could take the form of harassment, transfer, lack of promotion, dismissal, etc. Staff in smaller facilities might be particularly at risk for inadvertent

disclosure if the content of their interviews identified them as being in a particular position. Several steps will be taken to mitigate this risk in response to question 2.

FP clinic clients: For patients accessing care through FP clinics, the risks associated with seeking family planning services will not be different from the risks associated with seeking these services in the absence of the research. However, there is the potential for a loss of privacy by data abstraction from health records/register. Steps to mitigate this risk are detailed in response to question 2.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[X] **No** → If no go to question 10.3
[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what you will do if a subject (or a subject's partner) becomes pregnant

For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?

10.3 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[X] **No**
[ ] **Yes** → If yes, identify the procedures.

10.4 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[X] **No**

☐ **Yes** → If yes, check all the boxes that apply.

- ☐ Administration of any drug for research purposes
- ☐ Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- ☐ Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- ☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- ☐ Administration of a radio-isotope for research purposes**
- ☐ Implantation of an experimental device
- ☐ Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

*** If you checked the box about radio-isotopes: you are responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.5 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for your research, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol, use the text box below to name the document that has the DSMP.

N/A

10.6 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.7 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

N/A

10.8 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

FP clinics: All clinics that could be randomized will have a performance evaluation of HIV testing procedures completed. This evaluation alone is useful quality assurance information for the clinic. Individual clinics and managers could then act independently of the intervention study to make changes to procedures to increase HIV testing.

Individual Staff Members: Participation in semi-structured interviews will provide a forum for staff members to provide confidential feedback on how the clinic runs and any problems or issues that are commonly encountered in their work. This information, in an aggregated form, can then be reported back to other clinic staff and managers. In this way, participating in the interviews may increase clinic organization and flow, improving work satisfaction for individual staff members.

Clinics in the intervention arm of the trial will have the benefit of in-depth review of procedures and application of the SAIA intervention to improve rates of HIV testing. This process could also improve job satisfaction for individual staff members and could benefit clinic attendees.

FP clinic clients: Performance evaluation of clinics could lead to improved clinic function and increase in HIV testing in clinic clients.

10.9 Individual subjects findings.

a. Is it likely that your research will unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

[X] **No**
[ ] **Yes** → If yes, explain whether and how you would share the information with the subject.

b. Do you plan to routinely share the individual results of your study procedures with the subjects – such as genetic test results, laboratory tests, etc.?

[X] **No**
[ ] **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

10.10 Commercial products or patents. If a commercial product or patent could result from this study, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined:

N/A

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

11.2 Costs to subjects. Describe any research-related costs for which subjects may be responsible (e.g., CT scan required for research eligibility screening; co-pays; cost of a device; travel and parking expenses that will not be reimbursed).

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

N/A

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

The study team in its entirety will be trained for each step of the process using both lecture-based training, practice with CRFs, training on study specific procedures. This training will be repeated annually or if sooner if there are any changes.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	

☐	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
☐ RDRC	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

13.3 Financial Conflict of Interest. Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

☒ **No**

☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.