JHSPH IRB Research Plan for New Data Collection

PI:	Dr. Anthony Gichangi, Jhpiego, Kenya
Co-investigators in Kenya:	Dr. Mildred Mudany, Jhpiego/Kenya Dr. Stephen Mutwiwa, Jhpiego/Kenya Ms. Rosemary Njogu, Jhpiego/Kenya Jonesmus Wambua, Jhpiego/Kenya
Co-Investigators in USA:	Dr. Jeff Korte, Medical University of South Carolina (MUSC) Dr. Eva Bazant, Jhpiego/Baltimore

Study Title: Increasing HIV Testing among Male Partners of ANC Clients: a Randomized Study in Kenya

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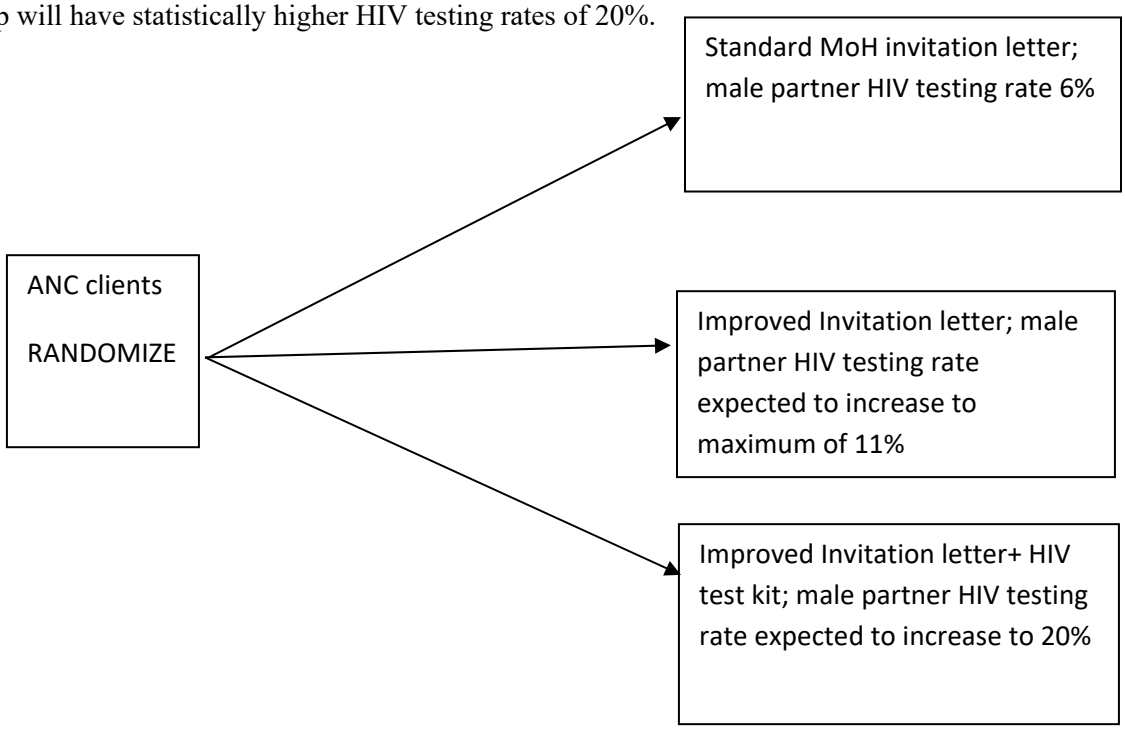
I. Aims of the Study: Describe the aims/objectives of the research and/or the project's research questions or hypotheses.

Primary research question: Can provision of oral HIV self-test kit and improved male partner invitation letter to ANC client increase the male partner HIV testing rates compared to provision standard MoH invitation letter or improved invitation letter with information on HIV?

Primary hypotheses: We hypothesize that male partners of women in the standard of care group will have HIV testing rates of 6%, that male partners in the improved invitation letter group will have HIV testing rates statistically similar to the first group (HIV testing rate not greater than 11%), and that male partners in the oral HIV self-testing intervention group will have statistically higher HIV testing rates of 20%.



Note 1: Standard MoH letter is a letter provided to ANC client inviting the male client to come with the partner to ANC for health discussions. The letter is not specific to HIV testing (**see 3ie standard MoH letter.pdf**).
Note 2: We propose to improve the content of the MoH letter to include some information about importance of HIV testing, couple discordance, and mother to child transmission (**see 3ie improved invitation letter.docx**).

Secondary research questions

1. What are barriers and drivers of HIV testing among male partners of ANC clients in central and eastern province in Kenya?
2. What are the acceptance rates for couple testing and disclosure of HIV status?
3. What are the rates of confirmatory testing among clients who self-test for HIV at home?
4. How long does it take for a partner of ANC client to take an HIV test after provision of an oral HIV test kit?

II. Background and Rationale: Explain why this study is being done. Summarize briefly what is already known about the issue and reference previously published research, if relevant.

HIV prevalence

In Kenya, HIV prevalence is **5.6%** among persons aged 15-64 years, with women having higher rates than men (6.9% vs. 4.4%) (KIAS, 2012). Up to **6.5%** of Kenya's pregnant women are living with HIV/AIDS. The HIV incidence rate of 0.5% translates to an estimated 106,000 new infections in 2012. Annually, 38,000 to 42,000 infants become HIV infected through maternal-to-child transmission (MTCT).[1] Overall, **4.8%** of all married or cohabitating couples are **sero-discordant** (one partner is HIV-positive while the other is HIV-negative). Among HIV-negative pregnant women, 1.3% report having a partner who is HIV-positive. Many (42.2%) pregnant women do not know their partner's status.[2] Among all women and men in Kenya, women were more likely to have ever been tested for HIV than men (80% vs 63%).[3] It remains critical for men and women to understand the importance of HIV testing even if their partner is negative in order to eliminate new pediatric and adult HIV infections.

Prevention of Mother to Child Transmission and Antenatal Care HIV testing

In Kenya, antenatal (ANC) clinics have the potential to be one of the key entry points to HIV testing and counseling (HTC) for not only pregnant women, but also their partners. Nearly all (95.4%) of Kenyan pregnant women ages 15–54 years went to at least one ANC visit in 2012, due to it being part of national HIV guidelines and quality of care standards. In Kenya, a **facility-based rapid diagnostic HIV test** is offered at no cost to every client who comes to the ANC clinic as part of the national PMTCT program. Of those who went to ANC at least once, **94.4%** accepted HIV testing and counseling in 2012.[4,5,6] PMTCT, when offered as part of routine antenatal care for pregnant women, can offer important HTC services, linkages to care and treatment if needed, and help prevent infant exposure to HIV during pregnancy, delivery and breastfeeding. Elimination of MTCT (EMTCT) is a priority for the Government of Kenya.

Male partner testing

Testing among **male partners of ANC clients**, however, is low. Only **6%** of *partners* of ANC clients in Eastern and Central provinces accept HIV testing, similar to the national rate of 5%[7] [8], and this has not increased over many years. Globally, male involvement is a critical success factor in EMTCT (Morfaw et al, 2013), and partner testing plays a key role. **Male partner testing with disclosure of** results allows couples to make informed decisions about prevention. It also enables PLHIV to access HIV clinical care including antiretroviral therapy (ART) if eligible, preserving their own health and reducing the likelihood of onward transmission. Male involvement in PMTCT improves adherence and retention in care and is associated with lower MTCT rates. Partner testing is equally important for women who test negative at their first ANC visit. There are high rates of **HIV acquisition among pregnant** and postpartum women as studies have shown from Western Kenya[9], Botswana and Rakai, Uganda.[10] Women who seroconvert during pregnancy or breastfeeding are at high risk to transmit the virus to their fetus or infant due to the high viral load associated with acute HIV infection.

Barriers to male partner testing at ANC clinics include cultural and social issues, perceptions, myths and misconceptions, and gender barriers. For example, the Cochrane review (Morfaw et al, 2013) noted the strong perception among sub-Saharan populations that ANC is an activity limited to women. The review also highlighted as barriers the limited awareness of discordant HIV statuses within couples, a fear of domestic violence or abandonment/divorce among female respondents, and a general lack of communication among couples. In a study in Nairobi, Kenya, the offer of voluntary HIV counseling and testing services to men at ANC resulted in 16% of nearly 2000 ANC clients returning with

their male partners. These partners were nearly all married and employed, but few (14%) had received any prior HIV testing (Katz et al, 2009).[11]

Current Practice in Kenya ANC program:
Kenya ANC program strives to encourage HIV testing in both ANC client and their male partners. As a standard practice, when a woman visits ANC clinic for the first time, she is taken through the standard clinical and laboratory examinations. At this stage the woman is then issues with a mother-child booklet which will be use to collect ANC and post-Natal information. After these examinations women are then offered a health talk session on nutrition, hygiene, general health issues, and HIV/AIDS. Thereafter, women are offered pre-testing (HIV) counseling after which they are offered a HIV test. According to the Kenya AIDS Indicator survey over 99% of the women who attend ANC do accept to take a HIV test. Post-test (HIV) counseling is then conducted depending on the results of the HIV test. After the HIV counseling and testing woman is then informed about the importance of having their partner tested for HIV on the baby's health and they are encourage to bring their partner with them in the next ANC clinic visit. Programmatic data indicates that only about 5% of men come with their partner for HIV testing. To improve on the male involvement, the ministry of health has developed a small letter which they request the man to come to the health facility to discuss health of his family. This letter is given to the woman to present it to her partner. Despite of these efforts male partner testing still remains low.

One limitation of the ministry of health letter is that it does not mention the need for HIV testing of the partner, nor does the letter contain important and potentially motivating information such as the proportion of married individuals who are HIV-positive but have an HIV-negative partner in Kenya (45%).

HIV Self-testing
The proposed intervention addresses the **barriers and facilitators** to increasing partner testing through the PMTCT platform by including the option to **self-test for HIV at home**, or another private location. Sabapathy et al (2012), in a systematic review of 21 studies from 5 Sub-Saharan African countries including Kenya, found high acceptability for home-based HIV testing (58% to 100% across the studies, pooled 83%), and men were as likely as women to accept home testing.[xii] In the KAIS 2012 report, 71% of Kenyans indicated a **willingness to use an HIV self-test kit** (74.1% of males and 67.3% of females).[xiii]

The Kenyan MOH recently approved the use of **HIV oral self-tests** for the general population in accordance with agreed-upon guidelines.[xiv] The current recommendation for self-tests in Kenya is to utilize the self-test as an initial screening. If the client tests negative, then he or she should consider re-testing after 4–12 weeks in case they were in the three-month window period. If the client tests positive, then he/she should go to the health facility for a confirmatory test.

Given the high rate of discordance among married couples in Kenya, the low rates of acceptance of male partner testing at ANC clinics, and the high health facility contact with many pregnant women during their pregnancies and delivery (approximately 73% of women in the project areas deliver in a health facility), the ANC platform provides a unique opportunity to offer the HIV oral self-test kit as an innovative way to increase the rate of testing for male partners of pregnant women without requiring men to come to the health facility for their initial HIV test. By increasing male partner testing, and thus involvement in PMTCT, there is a potential to reduce MTCT and other new infections among adults, which could have been affected by not knowing one's HIV status.

III. Study Design

A. Provide an overview of your **study design** and **methods**.

Background on Study's Program Platform (Aphiaplus Kamili program)
The study will be conducted in 14 high-volume health facilities selected from the Jhpiego led US Agency for International Development (USAID) program called APHIA*plus* KAMILI (A+K) operating in funded in Eastern and Central provinces in Kenya. The program goal is to increase the availability of high-quality health services, including HIV, tuberculosis (TB), reproductive health/family planning (RH/FP) services, and prevention and mitigation of Gender Based Violence (GBV) at the community and facility levels, including increasing the number of pregnant women who receive PMTCT

services, including HIV testing and counseling. This study will leverage existing program platform and relationships with the MOH at the national and county levels to achieve its objectives.

Study design: Women attending the first ANC visit of the current pregnancy will be randomized to one of three study groups (Randomized study at individual level)

Overview of methods:
The study is made of quantitative and qualitative components

I. Quantitative component:

This study will occur in 14 facilities in Central and Eastern regions in Kenya. In each site, first-ANC clients (HIV-negative or HIV-positive) will be screened for eligibility and, upon consent, individually randomized to one of three study groups:

1. **Study Group 1:** Women randomized into this group will be provided the standard ANC care which includes HIV counseling and testing, and the standard Ministry of Health letter inviting their partners to come to ANC clinic to discuss the health of their family (see 3ie Standard MoH letter.pdf)

2. **Study group 2:** Women randomized to this group will be provided with standard ANC care, HIV testing and counseling and an improved letter which will be male-friendly in the design, specific about the visit (i.e. to have HIV test), and with some messaging on the discordancy and transmission from mother to child (see 3ie improved invitation letter.docx).

3. **Study Group 3:** Women randomized into this group will receive the standard ANC care including HIV counseling and testing and the improved letter which is provided to women in group 2. In addition, women will be provided with two HIV oral self-test kits to take home and test with the partner. In addition, women will be provided with information on how the HIV test kit works, how to approach the partner, and what to do after testing.

The design rationale:

To implement the intervention in this study i.e. use of HIV oral self-test kit it is important and ethical to provide the participant in the intervention arm with information education, and communication (IEC) materials that will enable to understand the importance of HIV testing and especially the implications when the partner is pregnant. These material materials will be helpful for the woman pass communication to the man since the message will be coming from the health facility. This we hope will generate interest in the man to proceed and receive a HIV test at whatever source (at the clinic, VCT centers, or use the oral HIV self-test kit). To be more practical and for scalability into a national program, we have packaged this information in the already existing MoH letter so that we can give the woman a two-page card with standard information on one page and additional information on HIV on the other page (we have called this the improved invitation letter). However, the improvement in the letter may have some effect on the decision for the man to go and test for HIV; therefore, to tease out the effect of the improved letter, we propose to have a study arm which is provided with the improved letter only. Our hypothesis is that the improvement in the letter will not have a statistically significant effect compared to the normal standard letter; however, the improved letter combined with the oral self-test kit will have a significant effect on HIV testing. The rationale for this hypothesis is that in Kenya, especially in the communities where we will conduct the study, men do not take an HIV test if requested to by Health Care Providers or HIV counselors (this has been documented anecdotally by the Principal Investigator who was a co-investigator in the recently concluded Kenya AIDS Indicator survey during the field visit).

II. Qualitative component

Qualitative data collected at the end of the project will investigate the drivers and barriers to HIV testing among the male partners, and will help explain quantitative results in the theory of change.

B. Provide a **sample size and a justification** as to how you arrived at that number. If you use screening procedures to arrive at a final sample a table may be helpful.

Quantitative component:
The sample size calculation is calculated for comparing Group 1 vs Group 2, and Group 2 vs Group 3. We do not perform sample size calculation for Group 1 vs Group 3 as it is expected that the difference between the two groups will always be larger than any other comparison. In all sample size calculations, we assume 5% level of significance and 80% minimum power.

- Group 1 vs group 2 sample sizes are calculated based on an *equivalence test*. We assume that 5% will be the limit of equivalence, i.e., any difference exceeding 5% will make the two groups not equivalent. If there will be no difference between Group 1 and Group 2, then 950 (475 per group) ANC clients will be required to be 80% sure that the limits of a two-sided 95% confidence interval will exclude a difference between the two groups of more than 5%.[xv]

- Group 2 vs Group 3 sample sizes are calculated based on a *superiority test.* We assume that Group 3 will have an uptake of partner HIV testing of 20%, while Group 2 will reach at least 11% (the upper limit of equivalence). Based on these, 500 (250 per am) ANC clients will be required to have an 80% chance of detecting, with significance at the 5% level, an increase in the partner HIV testing measure from 11% in Group 2 to 20% in Group 3.[xvi]

- To achieve balance among the study groups, we will recruit an equal number of participants in all groups. Since a higher sample size is required for the equivalence test than for the superiority test, there will be greater statistical power to evaluate a possibly superior HIV testing rate in Group 3 compared to Groups 1 or 2. In addition, the increased sample size will allow comparable statistical power in each group to evaluate heterogeneity of effects (i.e., effect modification).

Therefore, each of the three groups will have 475 enrolled and consented ANC clients. This sample will be **1,425 enrolled participants** (ANC clients). We will also do a survey (in person) with the male partners three months after randomization, so that is up to **1425 male partners**. The grand total is 2850 male and female participants for the study.

Qualitative Component:
Focus group discussion (up to 8 women each) will be carried out with younger and older women, and among HIV negative and HIV positive women, and they will be mixed in terms of whether their partner tested or not. We will do this in 4 of the 8 Counties, selected to represent various cultural groups and regions. The focus group discussions will be carried out only in the study group which received oral HIV self-test kit.

Table 1. Number of Focus Groups with ANC clients, by relevant characteristics and County (a)

	County 1	County 2	County 3	County 4
Younger Women (<25)				
HIV negative	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)
HIV positive	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)
Older Women (25+)				
HIV negative	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)
HIV positive	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)	1 group (8 pax)

(a) In each group, we will invite women whose partner tested and women whose partners did not, as we think this can be discussed without being too sensitive

As shown in table, we will conduct 16 groups with 8 women each, for a total of 128 women focus group participants. Qualitative participants will be selected from the pool above (the 1425 ANC client participants) so these are not additional participants that will need to be recruited.

IV. Participants

Describe the study participants and the population from which they will be drawn.

Inclusion criteria for women	1. First ANC visit in this pregnancy 2. Age 18+
Exclusion criteria women	1. No current male partner / does not have at least weekly contact with partner 2. Woman reports that her partner is HIV positive. 3. Woman reports that her partner has tested within last three months ` 4. Woman is concerned for her safety or feels at risk of GBV if she asks her partner to self-test, or woman currently does not feel safe at home to encourage HIV testing (see the GBV screening tool)
Inclusion Criteria for men	1. Male partner of the ANC client enrolled into the study 2. Has personal contact with the woman at least once per week 3. Cognitive abilities to respond to the survey questions
Exclusion Criteria for Men	1. Un-willing to participate in the study. 2. Woman does not approve inviting him to participate

V. Study Procedures

In this section, provide details of your procedures, particularly as they relate to human subjects. If your study will develop in phases, address each item below by phase.

A. **Recruitment Process:**

1. Describe how you will **identify, approach, and inform** potential participants about your study. Include details about **who** will perform these activities and what their **qualifications** are.

Participants#1: ANC clients

ANC clients will be identified at the time they come for registration for the first ANC visit to receive the mother-child booklet (MNCH booklet) by the study nurse (Research assistant). The study nurse will approach the ANC client (expectant mother) after the registration and will inform the mother about the ongoing study to increase the male partner HIV testing at the ANC clinics. If the ANC client agrees to participate in the study, the study nurse will screen the client for eligibility and enroll into the study if eligible.

Qualifications of study nurse: In each of 14 sites, we will place a 'study nurse' who will trained in the study procedures, have at least diploma, and be available for 6 months and comfortable with data collection on tablet computers. Prior experience with HIV testing or counseling will be preferred in hiring.

Participants#2: Women for qualitative focus group at end

A subset of enrolled participants will be selected and invited at the end of the study to participate in a focus group. The ANC client will be notified of this possibility at the first consent (for the whole study). At the end of the study, we will contact the ANC client by phone to invite for a focus group discussions.

Participants#3: Men's survey

If the woman approves inviting the male partner to participate in the study (whether she contacts him on our behalf, or whether we recruit him directly), we will invite him to complete an in-person survey, which will occur 3 months from the date that each ANC client enrolled, or sooner if HIV testing has been completed. During the recruitment of the ANC client, we will explain that we'd like to talk to the male partner regarding HIV testing in general. If she is willing to let us contact her partner, we will ask the woman whether she would prefer to let us know when we should

come to talk to her partner, or whether she would prefer us to contact him directly. In addition, we will ask the woman whether we may approach the male partner if he accompanies her to the clinic. If she would like us to contact him directly, we will ask for her partner's telephone number or direction to their residence. The study nurse will then call the man and with the help of the community health worker the study nurse will locate the man's residence, recruit go through consent, and conduct the survey. Alternatively, if the male partner accompanies the ANC client to the follow up ANC appointments or the birth at the clinic, study nurse will approach him and recruit him.

When the research nurse contacts the man to recruit him to the study, the study nurse will explain to the man that he has a choice to meet with the research nurse in a place of his choice, not necessarily the home, in order to undertake the interview. If this is the case the research nurse will organize and ensure that the place for the meeting is quiet and confidential as required.

1. Address any **privacy issues** associated with recruitment. If recruitment itself may put potential participants at risk (if study topic is sensitive, or study population may be stigmatized), explain how you will minimize these risks.

Participants#1: ANC Client
Privacy will be ensured by requesting information in a space in the clinic that allows for audio and visual privacy. This may be near the triage station for ANC clients or at a study tent near the ANC clinic.

Participants#2: Women for qualitative focus group
Recruitment will be done on phone.

Participants#3: Men's survey
The study nurse will discuss with the ANC client whether we may contact the male partner, and if so how she would prefer that we do this (as outlined above). If we contact the partner, we will obtain the male partner's telephone numbers from the ANC client and with help of a trained community health worker will find the man's residence in the community. The recruitment discussion will be done in a discreet way and in a private space.

B. **Consent Process**:

1. Describe the following details about obtaining informed consent from study participants. If a screening process precedes study enrollment, also describe the consent for screening.
   - **Who** will obtain informed consent, and their qualifications

Participants#1: ANC Client
For first ANC clients who are eligible for the study, the study nurse will obtain consent from ANC client. Clients will be told that the study is a randomized controlled trial about HIV testing among male partners, and that information and support about male partner testing may be given to each participant. Only women in Group 3 will be told about the self-test kits. Then the study nurse will also collect baseline demographic data (see section C).

Participants#2: Women for qualitative focus group at end
A purposive sample of enrolled participants will be contacted to participate in a focus group (either on telephone or in person at a follow up ANC visit). If the woman is interested, the study nurse (or a trained qualitative interviewer) will obtain consent for the woman to participate in the focus group.

Participants#3: Men's survey
When the study nurse meets with the man, he/she will introduce the study to the man and emphasize that we are asking the man to answer questions about HIV testing, and not asking the man to test or offering him to test at that moment.

   - **How, where, and when** the consent discussion(s) will occur

Participants#1: ANC Client
Study nurse will obtain informed consent in private space in clinic, immediately after determining eligibility.

Participants#2: Women for qualitative focus group at end
When the woman comes to the clinic or the specified location for the focus group, the qualitative interviewer will obtain informed consent in a private space.

Participants#3: Men's survey
When the man is recruited either at the clinic (if he came accompanying the ANC client) or at his home, the study nurse will obtain consent prior to doing the survey.

- The process you will use to determine whether a potential participant meets **eligibility criteria**

See Recruitment.

- Whether you will obtain a **signature** from the participant or will use an **oral** consent process

Participants#1: Women at enrollment
We are interacting with women at several points in time and collecting and keeping identifiers during the study. So we will request a *written* signature or thumbprint for informed consent.

Participants#2: Women for qualitative focus group at end
Women agreeing to participate in the focus group will be asked for *oral* consent.

Participants#3: Men survey
Male partner agreeing the survey will be asked for *oral* consent since it is a one-time survey

2. Identify the countries where the research will take place, and the languages that will be used for the consent process.

Country	Consent Document(s) (adult consent, parental permission, youth assent, etc.)	Languages
Kenya	Consent1 for ANC client – Enrollment and Quantitative data collection	English, Kiswahili
	Consent2 for Woman – for Focus group	English, Kiswahili
	Consent3 for Men – Endline Survey	English, Kiswahili

C. **Study Implementation**:

1. Describe the **procedures that participants will undergo**. If complex, insert a table below to help the reviewer navigate.

After recruitment and informed consent is completed (See section 5A and 5B), the procedures are as follows.

Participants#1: ANC Client
- After obtaining informed consent, study nurse uses the randomizer on a computer to obtain the study group designation of 1, 2, 3 to which the participant will be assigned. (study-related)
- Study nurse puts a sticker on the ANC client's booklet: 1=yellow. 2=green. 3=blue. (study)
- Study nurse collects name, telephone number, and does baseline questionnaire with woman. (study)

- ANC client goes to ANC Nurse for routine counseling and receives her HIV test result. (routine care)
- Depending on the client's sticker color on MNCH booklet, study nurse gives relevant info and items based on the study group designation. (study)
    - For women in group 1 (yellow): ANC nurse gives the MOH letter (standard letter does not mention HIV testing but is an "Invitation to Reproductive Health Services" inviting the male partner to come to the clinic for a discussion of the family's health. Each woman is alerted that she will receive, over SMS, requests for info on whether the male partner tested. (routine care, study-related SMS)
    - For women in group 2 (green): ANC nurse gives an improved MOH letter that will be developed by this study (describes the benefits to the family and the man's own health when both partners are tested for HIV, will mention the possibility of sero-discordance) and will invite the partner to return to the clinic for standard HIV testing. Each woman is alerted that she will receive, over SMS, requests for info on whether the male partner tested. (study-related)
    - For women in group 3 (blue): ANC nurse gives the improved MOH letter + 2 self-test kits + instructions for use of kits at home and IEC materials in Kiswahili. ANC nurse also gives more counseling related to a) negotiation on use of the self-test at home and partner communication and b) alerting client that she will receive, over SMS, requests for info on whether partner tested. (study)

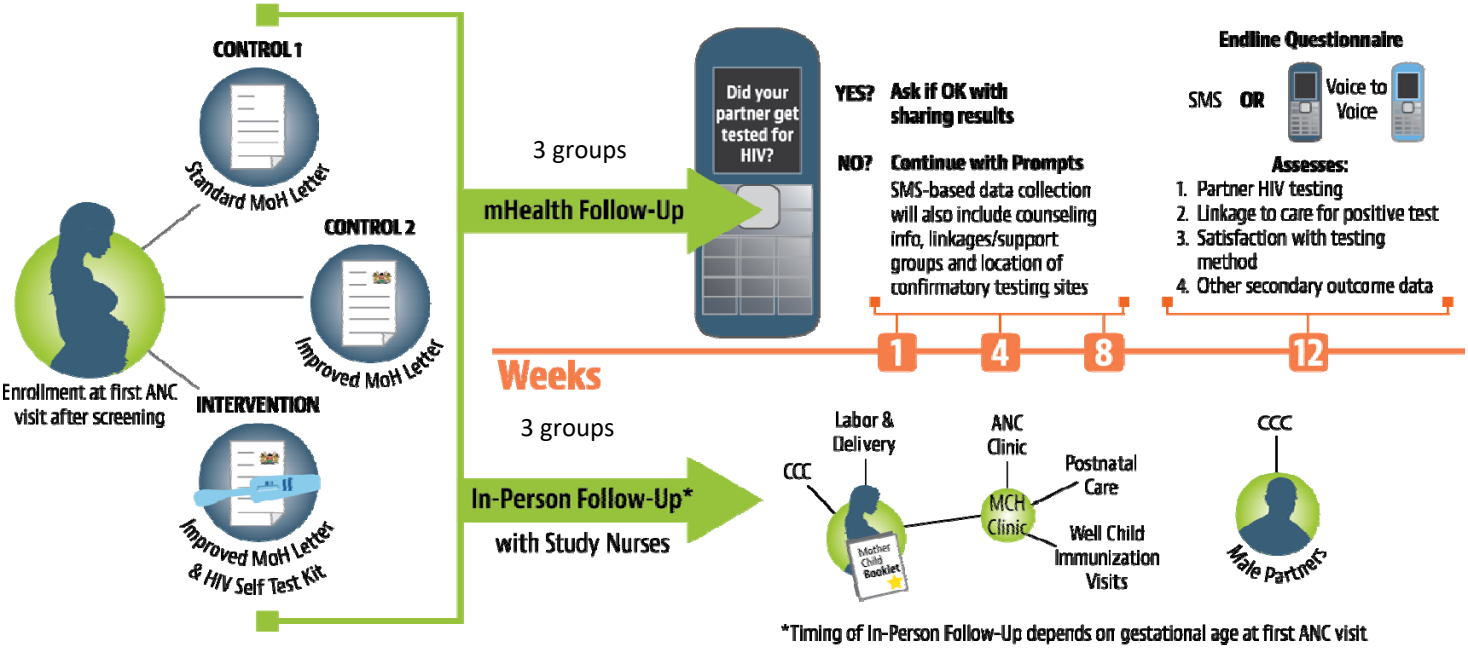
- If the woman tests HIV positive, she is given information on Mentor Mothers and community groups to help people living with HIV. (routine)
- Woman is given a resource card if she has questions in the future related to HIV testing (information on where to get a confirmation test). She is also given a resource card related to groups helping survivors of gender-based violence. (study)
- Woman schedules next ANC clinic visit and leaves. (routine)

Follow up with Participants

Participants in all three groups will receive **SMS messages** at: 1, 4, 8 and 12 weeks after their enrollment ANC visit. The SMS will ask for information on HIV testing, i.e. Whether her partner has used the self-test or got HIV-tested at clinic, and on what date this occurred. If the woman does not agree to receive the SMS messages, we will collect the follow-up data through a telephone or personal interview as preferred by the participant.

The woman may return to the clinic for one of several types of visits: return ANC clinic visit, labor and delivery, postnatal care, or well-child immunization visit. When the client returns, all facility-staff will be notified that the provider should look at the sticker color on her patient booklet. The provider will **ask the woman** if her partner tested for HIV, whether it was through the self-test or at a clinic, and the approximate date. This information will be given to the study nurse to add this info to the database. (All providers will have been sensitized to the goals of the study.)

After the woman has reported that her partner tested for HIV, or if she believes her partner has not tested at least 3 months after her initial study enrollment date, when the woman comes for ANC clinic visit, labor and delivery or for postnatal care, then she will be asked to do the **endline survey** (structured oral interview survey led by study nurse).



Data Sources and Variables

Study nurses (at each site) will collect all survey data at the facilities.

Qualitative interviewers will be hired to facilitate the focus groups.

Participants#1: ANC clients
Baseline socio-demographic questions, Reproductive health questions (parity, gestational period, number of children e.t.c.), HIV information (knowledge of status, knowledge of partner status, last test e.t.c.).

SMS data collection at intervals of 1 week, 4, 8, 12 weeks: did the male partner test? With self-test? Serial number? Or at clinic? Date of testing?

Endline survey: Confirmation of: HIV testing (did the male partner test, did they test together, did he disclose the results), linkage to care among positive, location of they did HIV test, satisfaction with testing.

Participants#2: ANC clients for qualitative focus group
What happened to the test kit, how was it handled?
How did woman feel taking it home?
How did she introduce it to male partner, what was the communication, negotiation, what was the initial reaction, how long after taking it home was the test done, what factors influenced the self-test being done or not, where was it kept
What was the reaction of any other family members? How did they handle privacy concerns within the family?
What did women think of the MOH letter or the improved letter? How did her partner react to it?
Was it easy to use at home? How was it stored until used? Did partner use it by himself or did they test together?
Did he share his test result? What was the reaction to the results? What was the interaction, communication? Any social harms? What would women recommend be done differently?

Field guide will assess the presence of specific barriers and whether self-testing helped to remove each barrier, including privacy concerns, fear of test results and lack of social support. Study staff will assess self-efficacy for

self-testing and how it compares to clinic-based testing. The project will carefully investigate how self-testing is related to secondary outcomes of interest, including risk of GBV, other social harms and appropriate linkage to care for confirmatory testing and evaluation for ART. The project will utilize qualitative data to investigate proposed causal and mechanistic links between self-testing availability and improved testing rates/linkage to care, as shown in the Theory of Change diagram.

Participants#3: Men survey
Socio-demographic questions, HIV testing history, and sexual behaviors
SMS: did the male partner test? With self-test? Serial number? Or at clinic? Date of testing?
What factors helped man in decision to test or not test?

If partner was positive, did he get enrolled in care?

Open ended questions:
What did men think of the MOH letter or the improved letter? What can help men test for HIV regularly? What can help men with concerns re HIV? What are ways men can test as part of HIV prevention? Where would men like to test? How? What support or individuals can help? What aspects of the environment can help men test? Would men self-test if they got them in the future?

2. Describe the **number and type** of study visits and/or **contacts** between the study team and the participant, **how long** they will last, and **where/how** they will take place.

Participants#1: ANC Clients
Participant will be enrolled at the clinic at first ANC visit and respond to a questionnaire. (10 minutes informed consent, 15 minutes questionnaire. Only study group 3 will receive counseling on partner self-testing at home (10 min).
At return ANC visit, ANC client will ask ANC client if her partner self-tested. This will also occur if the woman returns for Labor and delivery, postnatal care or well-child immunizations (5 min each).

SMS (up to three of them) will ask ANC client to inform study team whether and when the partner tested for HIV. (5 min each of 4 time points)

At least 12 weeks following enrollment, an endline questionnaire will be done in person at the clinic or at home (40 min).

Participants#2: Women for qualitative focus group
Women coming for the focus group will come only once, for 1.5 hours. This may take place at the clinic or at a central location with private space.

Participants#3: Men survey
Men participating in the survey at home or at the clinic if he accompanies his wife will participate once, for not more than one hour.

3. Describe the **expected duration** of the study from the perspective of the individual participant and duration overall.

ANC clients who enroll will participate for no more than 4 months. Men who participate in the survey will do so once for less than 1 hour.

4. Provide a brief **data analysis plan** and a description of **variables** to be derived.

The primary analysis will be conducted using the intention-to-treat (ITT) analysis: clients' data will be analyzed based on the groups to which they were randomized, as opposed to the actual intervention they received. The primary outcome will be whether the woman reports that her primary partner had tested for HIV within the three months of follow-up after the first ANC visit. (We will attempt to confirm this information through in-person follow up with the woman and separately with the man.)

Our primary comparison will be between group 2 and group 3 will be done using two-sided chi-square test of the association of study group and proportion of males who self-tested. The effect of the intervention will be quantified using the difference in proportion and will be reported with the associated 95% confidence intervals for the difference. Secondary comparison between group 1 and group 2 will be carried out using a two sided chi-square test. All comparisons will be adjusted for multiple and an alpha of 0.025 will be used for all comparisons.

Secondary analysis will be conducted using a multivariable logistic regression modeling the probability of having the male partner receiving a HIV test during the three months of follow-up, controlling for socio-demographic information and other characteristics.

The time to HIV test will be another important secondary outcome that will be considered in the evaluation, which will be measured as time from randomization to the time the partner was reported testing for HIV. The time to HIV test will be modeled using the Poisson model to compare which intervention group leads to a quicker uptake of HIV testing and determine which other factors influence the speedy uptake of the HIV test.

In the analysis, the project will control for study site as a fixed effect in the multivariable models.

Subgroup Analysis

As described above, study staff will evaluate subgroup analyses to investigate heterogeneity of effects (i.e., effect modification) by important factors including the woman's HIV status, marital status, age, socioeconomic status, availability of CHWs and social support systems, and other factors. Subgroup analyses will inform public health policy stemming from the study results, and will clarify populations in which the provision of home-based self-testing may have the greatest benefit.

Qualitative analysis

In qualitative analyses, the project will examine results of focus groups to address components of the Theory of Change (appendix).

Following each audio recording, the moderator will type up notes and do the transcription from listening to the audio recording (or an official transcriber familiar with Swahili and English will be hired for this). The transcription will be checked or a portion of them will be checked by persons listening to the audio file and reviewing the transcription. Transcriptions will be in English unless the qualitative analysts all know Swahili. Analysis will be on-going and does not need to wait until all qualitative data is obtained. Coding of textual passages will be done in Atlas-ti or other similar qualitative data analysis software. 2 to 3 qualitative data analysts will have training and experience in coding of textual information on health topics. The first step will be coding the transcript using the field guide a priori questions. The second review of each transcript will be to identify codes that emerge from the data and then applying those codes consistently. We will look for groupings of codes and label these, and write a analytic memos for each main code. We will look for discrepancies and divergent opinions, especially among women of different characteristics such as age and occupation, as well as convergent opinions and consistencies. The qualitative analysts will do the coding using the same codes or discuss frequently the codes to understand how they are using the codes and ensure that the codes are being applied consistently, but also allowing for the analysts to propose new codes. The next step will be to write up the findings in an organized framework, drawing on existing frameworks in the literature, and seeing what new relationships of phenomena emerge from the data. This process will follow the Framework analysis approach to qualitative analysis proposed by Jane Ritchie et al (2013).

5. Describe whether you are collecting or storing **personal identifiers**, and if yes, **why** you need them, and **when and how you plan to dispose** of them. Signatures on consent forms are considered to be identifiers.

We will collect personal identifiers at study enrollment to allow adequate follow-up of participants throughout the study period. We will require the names, telephone numbers, and home addresses of study participants to ensure minimum loss to attrition during the follow-up period. After data collection is complete and there is no further need for personal identifiers, we will transform the data into a de-identified format and delete the personal identifiers within three months.

6. Answer the following **if they are relevant to your study design**:

a. If the **study has different arms**, explain the process for assigning participants (intervention/control, case/control), including the sequence and timing of the **assignment**.

After informed consent is obtained, enrolled participants are randomized to one of three study groups. Individual-level randomization will be accomplished for each woman through the central computer-based data system. All study databases will be set up in REDCap (Research Electronic Data Capture) at Jhpiego Nairobi, allowing online entry of questionnaire, clinical, and laboratory data without storing any data on the laptop. The REDCap system is an institutionally implemented research service initiated by the South Carolina Clinical and Translational Research Institute (SCTR). It allows researchers to set up secure databases, with data entry accessible over the internet. All data will be stored on a secure Jhpiego Kenya server and accessible only by the study personnel with password protection. Server data is backed up weekly.

e. If you will perform **standard diagnostic tests**, clarify whether the tests are validated, and if so, how (e.g., CLIA certification in US clinical labs.) Explain the **failure rate** and under what circumstances you will **repeat a test**. Clarify your plans for reporting test results to participants or to their families or clinicians. Address returning unanticipated incidental findings to study participants.

OraQuick test kits are FDA-approved and approved for use in Kenya. Each kit costs approximately USD $9.
We will stamp a unique serial number on the back of the packaging (left) and swab (bottom right).
This study will only involve testing being performed by the participants; therefore, we will not have any reason to provide any study results to the study participants. However, the aggregate results of statistical analyses will be made public.

f. If your study involves medical, pharmaceutical or other therapeutic **intervention**, provide the following information:

- Will the study staff be **blind** to participant intervention status?

Lack of blinding in this study may be an issue. Study staff will not be blinded to knowing the study group to which each participant is randomized. Participants will know what they are offered. However, we will not be explaining to them that they are in a particular group and what each group will get.
The situation could lead to a tendency for study staff to more aggressively follow up women in one of the study groups regarding partner testing or another study outcome. Similarly, women in one group (e.g., Group 3 with home-based testing) may feel social desirability bias to report that the partner tested (main outcome is self-reported). To mitigate these threats to validity, investigators will stress to study staff the importance of unbiased follow-up and equal outcome assessment in all groups. In addition, study staff will emphasize to participants the importance of answering all questions honestly. To reduce social desirability bias, study staff will also express (e.g., before asking whether her partner tested) that they understand that the woman's partner may not have tested for HIV. Finally, much of the data collection during follow-up will be automated, with SMS messages being sent to all participants from our central system at one week, 4, 8, and 12 weeks follow-up time.

- Will participants receive **standard care or have current therapy stopped**?

All clients will receive the standard of care for antenatal care in the health facility and this will not change in the study. We are randomizing women to 3 means of encouraging male partner HIV testing.

- Will you use a **placebo or non-treatment group**, and is that justifiable?

The ANC client participants randomized to the control group in this study will receive the standard of care for partner testing, which a MOH letter is asking the man to come to the clinic. We do not yet know the effects of offering self-tests to the ANC client on partner HIV testing so a control group is justifiable.

- Explain when you may **remove a participant** from the study.

We will not remove a participant once she has consented and enrolled. The exception is if the woman decides later to 'withdraw' or stop her participation for any reason, she can return the kits if she is in group 3 but we will not require this. If study RA is concerned about the ANC client's relationship with the male partner, this will be determined at screening. If this occurs later on, then study RA or other A+K staff will discuss with the participant her options and she will always be able to withdraw.

- What happens to participants on **study intervention when the study ends**?

There will be no further engagement or action of the study participants with the research once the study has ended.

- Describe the process for **referring participants to care** outside the study, if needed.

Participants will receive normal ANC care and if they need referral as part of that care, this will be provided according to established mechanisms and will not be affected by the study. If a woman moves out of the study area or has a antenatal, delivery or postnatal complication that prevents study RAs from following up with her, then she will be considered lost to follow up. Furthermore, study participants (women, as well as their partners if consented into the study) testing positive for HIV will receive SMS messages, counseling, and/or other information providing them with recommendation for clinical confirmation, evaluation, and linkage to care.

VI. Data Custody, Security, and Confidentiality Protections

The sections below describe types of data sources and how they will be protected. For the type(s) of data you will have, put an "X" in the appropriate box to the left of the section that best describes how you will minimize the risk of a breach of confidentiality for your study. Note, as appropriate, how you will record/store data. These descriptions represent MINIMAL measures; you may add more stringent protections and other relevant information in B.

A. Data Storage

1. Hard Copies of Data Collection Forms.	
x	This activity will not involve receiving and/or accessing hard copies of data
	Data collection forms RECORD NO PERSONAL IDENTIFIERS connecting study participants, and there are no codes providing a link. Data are anonymous.
X	Data collection forms INCLUDE IDENTIFIERS. The forms are locked in a secure cabinet or room with limited access by authorized individuals. Forms will be kept in study team's possession during transport and will not be left unattended in a vehicle. When possible, de-identified copies will be used for coding and analysis.
	Data collection forms ARE CODED with study participants' random study ID numbers. Codes/links between study IDs and identifiers are stored securely in a separate place (locked storage cabinet or secure electronic database.) A master file will have unique study id, woman's name, telephone number, date of ANC visit and study enrollment, study arm, and basic demographic info, also residence in case in-person follow up by CWH is used. Later on through SMS we will ask if her partner did self-test. There will be multiple SMS follow ups. At end, there will be an in-person or telephone follow-up questionnaire with the woman.
	Other:
2. Electronic Data	
	The data do not contain personally identifiable information
X	These data are stored on a secure server protected by limited access and strong password systems. Data are coded when possible. Portable electronic devices will not contain identifiable information unless encrypted.
	Other:
3. Other Identifiable Data Storage, Retention, and Destruction (Audiotapes, videotapes, photographs, etc.) will be retained and stored securely (locked in cabinet or room) until:	
	Transcription is complete, then will be destroyed.
	Analysis is complete, then will be destroyed.
X	Study is complete and file is closed.
	Indefinitely. Provide justification for indefinite retention:
4. Existing Biospecimens to be used in this study: **N/A**	

B. Certificate of Confidentiality **N/A**

C. **Data Security and Sharing**

PIs have the responsibility for responsible stewardship of data and protecting data confidentiality. This responsibility includes protecting **physical custody of the data, storage and sharing** with appropriate **data use agreements** that contain the appropriate security provisions. Describe any additional plans beyond those identified in the table that you have for storing and sharing the study data and/or materials, and how responsibility for the data will be managed. Include the following details:

1. **Where** will the study data be stored?

Data will be stored in a secure online database, password protected, behind an internet firewall. Authorized study staff will enter data encrypted over a secure internet connection. Only authorized study staff will have access to data. Any paper records will be stored in a locked cabinet at Jhpiego Kenya office and only the PI will have access to this cabinet.

2. **Who controls** access to the data?

The study PI, Dr. Anthony Gichangi, will control access to the data.

3. Will data be shared only if **de-identified**?
   Yes. No personal identifiers will be shared. Datasets sent to MUSC will include the coded study identification number but will not contain any personal identifiers.
4. What additional (if any) **security controls** will be in place?

N/A

VII. Risks of the Study

A. Describe the risks, discomforts, and inconveniences associated with the study and its procedures, including **physical, psychological, emotional, social, legal, or economic risks**, and the risk of a breach of confidentiality. These risks should be described in the consent documents.

The only intervention in this study is for the woman to give a self-test kit for HIV to her partner at home. It is suggested that the couple do the testing together at home or it may be at different times. The woman should know her HIV status after the ANC visit. She may or may not know the man's status. He may or may not know his own status. The woman may experience anxiety and worry in how she will present the test to her partner, how he would react, and even what to do after he learns his result, and how he would treat her. So there is a possibility of psychological and emotional anxiety or harm, and physical harm from partner. There is also the possibility that the partner would also abandon his female partner if he or she is positive and this may have economic consequences for the woman. There are situations of sero-concordance. One possibility is he was negative, he may think, why is my female partner positive when I am not?

There is the risk of breach of confidentiality at various levels. We will conduct comprehensive training in confidentiality and appropriate research/clinical standards for study staff before the study begins, and reinforce this training throughout the study. Nevertheless, it is possible that a member of the study or facility staff may allow a breach of confidentiality. If the study participants were talking amongst themselves, there may also be sharing of information about home-testing. Couples may also not keep information about themselves or others confidential.

B. Describe the **anticipated frequency and severity of the harms** associated with the risks identified above; for example, if you are performing "x" test/assessment, or dispensing "y" drug, how often do you expect an **"anticipated" adverse** reaction to occur in a study participant, and how severe do you expect that reaction to be?

We do not anticipate any breach of confidentiality on our part. Any breach of confidentiality will be met with counseling and support provided by the study and clinical staff. In addition, any study staff responsible for a breach of confidentiality will be disciplined appropriately, up to and possibly including termination of employment.

Participants#1: ANC client

ANC client who participates in the study group 3 have elevated risks of gender based violence as they have to bring the test kits to the man and explain the purpose of the test kit. The may be perceived as a sign of mistrust and unfaithfulness leading to GBV.

Participants#2: Women for qualitative focus group

By the nature of the focus group structure, women participating in the qualitative focus groups will open themselves to a certain loss of confidentiality within the focus group. We will emphasize that discussions occurring in the context of the focus group are confidential within the group, and should not be shared outside the group without the woman's explicit consent. We do not anticipate any problems arising from breaches of confidentiality following focus group discussions.

Participants#3: Men's survey

Very minimal risk, loss of confidentiality if they provide data to the study

C. Describe **steps to be taken to minimize/mitigate risks**. Include a description of your efforts to **arrange for care or referral** for participants who may need it.

Participants#1: ANC client

ANC clients are likely to experience risks of gender based violence as they present the kits to the man. The following steps will be taken to minimize the risk of gender based violence

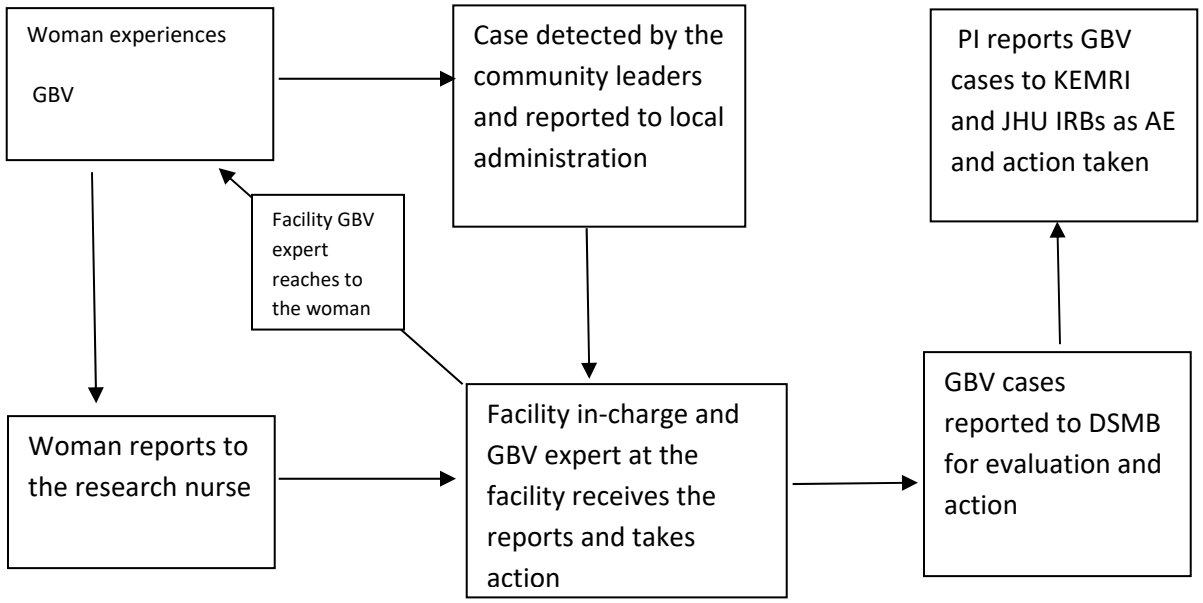
The following measures will be put into place to mitigate against the risks of gender based violence (GBV) among women who will participate in the study.

- The study teams will be working closely with the APHIAplus Kamili technical teams for the study implementation. Aphiaplus Kamili implements the GBV program and has GBV trained health care providers in each health facility. Most of the community health workers have been sensitized on GBV prevention and response and are able to support any clients they may encounter in the community who may be facing GBV. Pregnant women who may face GBV can also access services in the facilities that we support GBV services.

- All women participants who will recruited at the facility will be screened for the history of GBV or if they are potential for the GBV. Those participants who will be found to be at risk of GBV will be excluded from the study. The study nurses will be provided additional training by the Aphia plus Kamili GBV specialist.
- Women will be provided with information and orientation on how to avoid the GBV. For example how and when to approach the man, presentation of the HIV self-test kit, information on the importance of HIV testing and counseling especially for the pregnant women and their partners e.g.. This information will be provided by the study nurse with the support of mentor mothers.
- The ANC client who will be enrolled will be provided with the telephone number of the study nurse and the facility in charge so that they can call in case of incidence of GBV. The client will also be provided with national GBV hotline.
- Whenever the client has reported an incidence of GBV they will be provided with supportive information as to where they can report the incidence. The client will be counseled and referred to trauma counseling services.
- The project will engage the local authority (chiefs and village elders) to sensitize the community about the study and watch out for cases of GBV within their community and report such cases to the health facility

- Cases of GBV will be closely monitored by the facility in-charge. If in a site, there are 15 severe cases of social harm (confirmed) out of 100 enrolled participants, the study will be stopped at that site.

- **Schematic representation of the process of identifying and mitigating GBV.**



Actions taken by in case of GBV

Type of GBV	Specific Details	Action to be taken
Physical Violence	1. Physical bruising and injuries- evidence of bruising, slapping, hitting 2. Noted fear – when accessing health care 3. Threats of violence 4. Kicked out of home	1. Provide Clinical management 2. Provide Trauma counselling 3. Report to the police 4. Refer for Multisectoral intervention- Intervention by the Gender department, CBOs, Judiciary, Women groups
Sexual Violence	1. Evidence of rape/sexual assault, witnesses on the act in case of attempted violence 2. Forced prostitution 3. Sexual Exploitation	1. Provide Clinical Management 2. Provide Trauma counselling 3. Report to the police 4. Refer for Multispectral interventions- Intervention by Gender departments, Judiciary, CBOs, Paralegal, Ministry of Education, Children department
Emotional Violence	1. Shouted at and insulted/Use of abusive language 2. Delay in seeking treatment of infections/injuries due to threats. 3. Depression 4. Suicidal attempts	1. Provide Clinical Management 2. Provide Trauma counselling 3. Report to the police 4. Refer for Multispectral interventions- Intervention by Gender departments, Judiciary, CBOs, Paralegal, Ministry of Education, Child

		department
Economic Violence	**1. Child Labour- forcing children to work** **2. Malnutrition-due to unavailability of food** **3. Child neglect-due to unavailability of the basic needs** **4. Maternal Mortality-poor access to health care for hospital delivery** **5. Child Mortality-**	**1. Provide Trauma counselling** **2. Refer for Intervention by Gender departments, economic empowerment, CBOs, Paralegal, Ministry of Education, Children department**
Traditional/Cultural Violence	**1. Threats of Wife inheritance or polygamy** **2. Death- due to community punishments** **3. FGM- may lead to complications in labour** **4. Poor access to health care- due to the traditional beliefs**	**1. Provide Trauma counselling** **2. Report to the police** **3. Multispectral interventions- Intervention by Gender departments,, CBOs, Paralegal, Ministry of Education, Children department**

Participants#2: Women for qualitative focus group

Women participating in the qualitative focus groups will be provided with appropriate counseling and referral services for any problems that become apparent during the focus group discussion, including GBV support or referral for HIV services.

Participants#3: Men's survey

Men participating in the survey will be referred as needed for appropriate counseling, testing, and HIV treatment services.

D. Describe the **research burden** for participants, including time, inconvenience, out-of pocket costs, etc.

Participants#1: ANC Client

Women enrolled in the group 3 may experience some burden to explain the purpose of the test kit to the partner, explain about the importance of HIV testing especially among couples when the woman is pregnant. The woman will take the burden of taking the important message to the partner which may sometimes be viewed as lack of trust in the partner.

Participants#2: Women for qualitative

The women enrolled for the focus group discussions will have little inconvenience on time. The focus group discussions will take about one to two hours. However, travelling to the place where FGD will take place and

back home might take considerable amount of time. No out of pocket cost will be incurred by the woman as lunch and transport will be provided.

Participants#3: Men survey

Men who will participate in the survey will have inconvenience of time when they are doing the survey. The survey will take about 40 minutes.

E. Describe how **participant privacy** will be protected during data collection if **sensitive questions** are included in interviews.

Data security will be carefully maintained at all times, with limited secure access to data. In general, during data collection, risks to confidentiality will be minimized to the extent possible through direct entry into the secure database, without the use of paper forms.

Participants#1: ANC Clients

- At enrollment in ANC clinic, women will be administered the screening and baseline questionnaire and counseling in a private area. During follow-up, data collection will be conducted by SMS, telephone interviews, and in-person interviews at the clinic. All data collection techniques will provide a secure and private environment for data collection.

Participants#2: Women for qualitative at end

Qualitative interviews and focus groups will be conducted in a private area where the women cannot be seen or heard by anyone not participating. Data will be carefully kept confidential and we will emphasize the importance of maintaining confidentiality around the focus group discussions.

Participants#3: Men survey

The survey for men will be conducted in a private location to ensure confidentiality of responses. Data will be carefully maintained for confidentiality.

VIII. Direct Personal and Social Benefits

A. Describe any **potential direct benefits** the study offers to participants ("payment" for participation is not a direct personal benefit).

All ANC clients enrolled will receive at least the standard information on HIV prevention and testing, and encourage their male partners to be tested. Study group 1 will receive the standard MOH letter to bring home.
ANC clients in study group 2 will receive an improved letter which specifies that the male partner should be tested. The third study group will receive counseling on how to encourage male partner self-testing, as part of couple testing at home, and will receive 2 HIV self-test kits to take home. Should a male test for HIV and seek further clinical testing and care if HIV positive, this may be a direct benefit to the woman and family.

All women will receive SMS messages at intervals following enrollment encouraging them to report male partner self-testing to the study. All women will be given a resource sheet on where to go for clinical services or services for victims of violence. All women will go through an initial baseline questionnaire and will be followed up for endline questionnaire, which should raise some awareness of HIV testing and prevention/care.

B. Describe **potential societal benefits** likely to derive from the research, including value of knowledge learned.

Given the high rate of HIV sero-discordance among married couples in Kenya, the low rates of acceptance of male partner testing at ANC clinics, and the high health facility contact with many pregnant women during their pregnancies and delivery (approximately 50% of women in the project areas deliver in a health facility), the ANC platform provides an

opportunity to offer the HIV oral self-test kit as a way to increase the rate of HIV testing for male partners of pregnant women without requiring men to come to the health facility for an initial HIV test. Increasing male partner testing in the antenatal period has the potential to reduce MTCT and resulting pediatric infections, and new infections among adults, which could have resulted from not knowing one's HIV status.

IX. Payment:

A. Describe the form, amount, and schedule of payment to participants. Reimbursement for travel or other expenses is not "payment," and if the study will reimburse, explain.

ANC clients enrolled as study subjects at the health facility will not be paid any compensation or reimbursement. Male partners who do the self-test for HIV will also not be paid any compensation or reimbursement. Participants who will agree to participate in the focus group discussions will be provided with lunch and refunded transport .

B. Include the possible total **remuneration** and any consequences for not completing all phases of the research.

There is no remuneration for any participant. There is no consequence of not self-testing for HIV or seeking HIV testing in a clinic (primary outcome of the study). There is no consequence for not participating in the baseline or endline structured interview with study staff, or not participating in a focus group.

X. Study Management

A. Oversight Plan

1. Describe how the **study will be managed**.

The PI for the project, Anthony Gichangi, will be responsible for overseeing the activities of research staff and ensuring compliance with approved study protocols and practices. The PI will work closely with Co-Investigators to facilitate the training of staff and data collectors on the study's goals and objectives, research ethics, consent processes and tablet data collection methods. PIs will be responsible for ensuring quality control and conducting data quality spot checks in collaboration with A+K staff and MOH staff who are already conducting site visits related to PMTCT activities.

To ensure integrity of the data and adequate time to carry out study activities without overburdening MOH staff, study research assistants (RAs) with a nursing/clinical background will be hired at each facility to oversee the recruitment and follow-up process with study participants on a day-to-day basis.

The existing Aphia plus Kamili (A+K) clinical team, which routinely interacts with health workers, facility and district administrators, and county-level supervisors through A+K activities, will be leveraged during supervision visits at start-up to facilitate introduction of the study at county and facility levels and on a monthly basis if appropriate. A+K will also support psychosocial support groups in study sites for easier linkage to care and follow-up and form part of the Data Safety Monitoring Board.

2. What are the **qualifications of study personnel** managing the project?

Name	Role	Institution	Background	Study Responsibilities

Name	Role	Institution	Background	Study Responsibilities
Dr. Anthony Gichangi, Ph.D.	Principal Investigator	Jhpiego, Kenya	Dr. Gichangi is the acting Monitoring, Evaluation and Research (MER) Director for Jhpiego in Kenya. Dr. Gichangi, a Kenyan, has a Ph.D. in biostatistics and over 10 years of experience in applied statistics, statistical consulting, leading research, surveillance and programmatic activities in public health.	Responsible for achieving project objectives in Kenya including: providing overall direction, coordination and oversight for data analyses and conceptualization of publications, and providing leadership for writing of articles, presentations and other publications.
Dr. Mildred Mudany, Ph.D.	Co-Investigator	Jhpiego, Kenya	Dr. Mudany is the Chief of Party (Program Director) of A+K, a $100 million, five-year project funded by USAID to provide an integrated service delivery package to more than 1,000 health facilities, 400 school programs and 200 community units in 11 counties in Kenya's Central and Eastern regions. Dr. Mudany, a Kenyan physician, has many years of experience in PMTCT and national HIV policies and guidelines. She works closely with the MOH and NASCOP in development of policy guidelines, national curricula, job aids and national algorithms.	Dr. Mudany will provide overall technical guidance and overall field supervision in the implementation of the study. She will lead the study research assistants to ensure that the research follows the protocol and national guidelines. Dr. Mudany will also be a serve in the DSMB to ensure that any unanticipated events are properly handled and appropriate measures are taken to ensure the safety of subjects. She will also serve as the key interface between the project and county health officials where the study will be implemented.
Dr. Stephen Mutwiwa, MD, MPH, PhD	Co-Investigator	Jhpiego, Kenya	Dr. Mutwiwa is Deputy Chief of Party and National Technical Advisor of the A+K program. A Kenyan physician specializing in Public Health and Health Systems Research, Dr. Mutwiwa has 15 years of experience managing public health programs both in the government and nongovernmental sectors. For six years, he has been leading large USG-funded HIV and RH/FP/maternal, newborn and child health programs.	Dr. Mutwiwa will provide technical guidance and overall field supervision in the implementation of the study. Additionally, he will lead the study research assistants to ensure that the research follows the protocol and national guidelines. Dr. Mutwiwa will also serve in the DSMB to ensure that any unanticipated events are properly handled and appropriate measures are taken to ensure the safety of subjects.

Name	Role	Institution	Background	Study Responsibilities
Tom Marwa, MPH	Co-Investigator	Jhpiego, Kenya	Mr. Marwa is a public health practitioner and researcher with eight years' experience in implementing quality public health and operational health research programs in HIV/AIDS and RH. As Senior Technical Advisor, he currently serves as an MER advisor with experience in HIV programs in Kenya. Mr. Marwa has worked extensively with NASCOP Division of RH and other implementing partners on designing training approaches and assessment, performance quality improvement, baseline tools, supportive supervision visits and data audits.	He will oversee recruitment of the study staff, study participants, training of research staff, procurement of the project supplies and equipment, and the day-to-day management. He will report to the PI and other Co-Investigators on the study's progress, any protocol violations and incidents. Mr. Marwa will ensure that all the key staff are informed about the study progress, communicate decisions made by the study team or DSMB to the field staff and ensure that study protocol is followed.
Dr. Jeff Korte, Ph.D.	Co-Investigator	Medical University of South Carolina (MUSC), USA	Dr. Korte is a tenure-track Assistant Professor of Epidemiology in the Department of Public Health Sciences at MUSC in Charleston, South Carolina, with a PhD in Epidemiology. He studies sexually transmitted infections and high-risk behavior in the US and internationally. Dr. Korte has had two NIH-funded grants related to the human papillomavirus and a 3ie-sponsored replication study to evaluate male circumcision for HIV prevention	Dr. Korte will be responsible for ensuring that the evaluation is implemented with independence. He will provide overall direction and leadership on the process of the impact evaluation, oversight of the data analysis along with PI and Jhpiego staff, co-write reports, articles and presentations of the project.
Eva Bazant, Dr.P.H, MPH	Co-Investigator	Jhpiego, Baltimore, MD	Dr. Bazant, with a doctorate from Johns Hopkins Bloomberg School of Public Health, Population, Family and Reproductive Health division, is a program evaluator and health services researcher with 15+ years of experience in international maternal and reproductive health and HIV prevention, and has a focus on evaluation of quality improvement and health provider performance in Sub-Saharan Africa.	Dr. Bazant will primarily contribute to study design, setting up the study, quantitative and qualitative data analysis, and writing and dissemination. Dr. Bazant works closely with local staff and travels to field studies. Dr. Bazant, along with PI and Jhpiego and MUSC staff, will co-write reports, articles and presentations of the project.

3. How will personnel involved with the data collection and analysis be **trained in human subjects research** protections? (Use the JHSPH Ethics Field Training Guide on our website.)

Data collectors will be trained on the study in a multi-day training workshop, covering the important points of the approved study protocol, including privacy and confidentiality. We have a session to review and discuss

important points in the *JHSPH Ethics Field Training Guide*, available in English and Kiswahili. We will review data collection procedures, which will ensure ethical conduct of research and data integrity.

4. If the PI will not personally be on-site throughout the data collection process, provide details about **PI site visits**, the supervision over consent and data collection, and the communication plan between the PI and study team.

The PI, Dr. Gichangi is based in Nairobi. He will oversee the hiring of study staff (hired study nurses), design and conduct of the training of study nurses and be present for the training. During implementation, the PI will visit the sites at least once or twice. Several times each week, especially during enrollment of participants, the PI will be in phone contact with the Implementation Lead, Dr. Stephen Mutwiwa, based in Embu, and the implementation team. The PI will oversee the data collection process, data management, and analysis and reporting to the donor and the 2 IRBs, and dissemination of findings to local and international stakeholders.

B. **Recordkeeping**

Describe how you plan to ensure that the study team follows the protocol and properly records and stores study data collection forms, IRB regulatory correspondence, and other study documentation. For assistance, contact housecall@jhsph.edu.

We will ensure local Jhpiego staff have copies of the approved protocol, tools and stamped consent forms for enrollment. We will review important points in person with each study staff to ensure understanding.

We will have a schedule for data collection and monitor data collection daily.

C. **Safety Monitoring**

1. Describe how **participant safety will be monitored** as the study progresses, by whom, and how often. Will there be a medical monitor on site? If yes, who will serve in that role?

2. If a **Data Safety Monitoring Board (DSMB),** or equivalent will be established, describe the following:
   a. The DSMB membership, affiliation and expertise.

   For the overall project, a DSMB will be formed. It will include Jhpiego investigators, Aphia Plus Kamili leaders, County officials, and representatives of the Kenya National AIDS & STI Control Programme-NASCOP.

   b. The **charge or charter to the DSMB.**

   The DSMB will monitor the outcomes, women's reports of male partner testing, on a monthly basis, as the data are coming in from the follow up. The DSMB will especially monitor social harms. All potential and actual social harms will be reported to the PI and other investigators as soon as possible and the PI will determine how to investigate and report any incidents, depending on the nature of the potential and actual harms. Each month the DSMB will be contacted for feedback. There will be 2 or more meetings once enrollment starts. In any given study site, where approx. 100 ANC clients will be enrolled, if there are 5 or more GBV cases reported at that site that are somehow related to or perceived to be related to the study, then the PI will confer with the DSMB by telephone or email to strengthen GBV prevention and services.

   c. Plans for providing **DSMB reports to the IRB.**

DSMB meeting minutes or decisions will be shared with the IRB within 30 days.

3. Describe plans for **interim analysis and stopping rules**, if any.

   If in a site, there are 15 severe cases of social harm (confirmed) out of 100 enrolled participants, the study will be stopped at that site.

D. **Reporting unanticipated problems/adverse events (AE's) to the IRB (*all studies must complete this section*):**
Describe your plan for reporting to the IRB and (if applicable) to the sponsor. Include your plan for government-mandated reporting of abuse or illegal activity.
NOTE: The IRB does not require submission for all AEs, only those that are **unanticipated, pose risk of harm to participants or others, and are related to the study**.

Adverse events will be reported to the IRB within 10 days of the PI learning of them and determining that the event qualifies as an adverse event.

E. **Other IRBs/Ethics Review Boards:**
If other IRBs will review the research, provide the name and contact information for each IRB/ethics review board and its Federal Wide Assurance, if it has one (available on OHRP's website at http://www.hhs.gov/ohrp/assurances).

Kenya Medical Research Institute (KEMRI),
P.O. Box 54840-0020, Nairobi, Kenya
Tel: (254)(020)2722541,
http://www.kemri.org

For reporting of adverse events: The Secretary, KEMRI Ethics Review Committee, P. 0. Box 54840-00200, Nairobi; Telephone numbers: 020-2722541, 0722205901, 0733400003; Email address: ERCadmin@kemri.org

F. **Collaborations with non-JHSPH Institutions:**
For studies that involve collaboration with non-JHSPH institutions, complete the chart below by describing the collaboration and the roles and responsibilities of each partner, including the JHSPH investigator. This information helps us determine what IRB oversight is required for each party. Complete the chart for all multi-collaborator studies.
Insert Name of Institutions in Partner column(s); add additional columns if necessary.

	JHSPH **Jhpiego**	Partner 1 **MUSC**	Partner 2
Primary Grant Recipient	X		
Collaborator	X	X	

For the following, indicate "P" for "Primary", "S" for "Secondary" as appropriate to role and level of responsibility.) Add additional items if useful.

1	Human subjects research ethics training for data collectors	P		
2	Day to day management and supervision of data collection	P		
3	Reporting unanticipated problems to the JHSPH IRB/Sponsor	P		
4	Hiring/supervising people obtaining informed consent and/or	P		

	collecting data			
5	Execution of plan for data security/protection of participant data confidentiality, as described in Sect. 5.	P	S	
6	Biospecimen processing, storage, management, access, and/or making decisions about future use	n/a		

XVI. Investigational Medical Devices N/A

Complete this section if your study will involve an investigational medical device (diagnostic, non-significant risk, significant risk).

A. List the name(s) of the study product(s), the manufacturer/source of each product, and whether or not it is powered (electric, battery). Provide product information. If it is electric, upload documentation of clinical engineering approval.

Name of study product	Manufacturer/Source	Powered?

B. List each study product by name and indicate it's approved/not approved status.

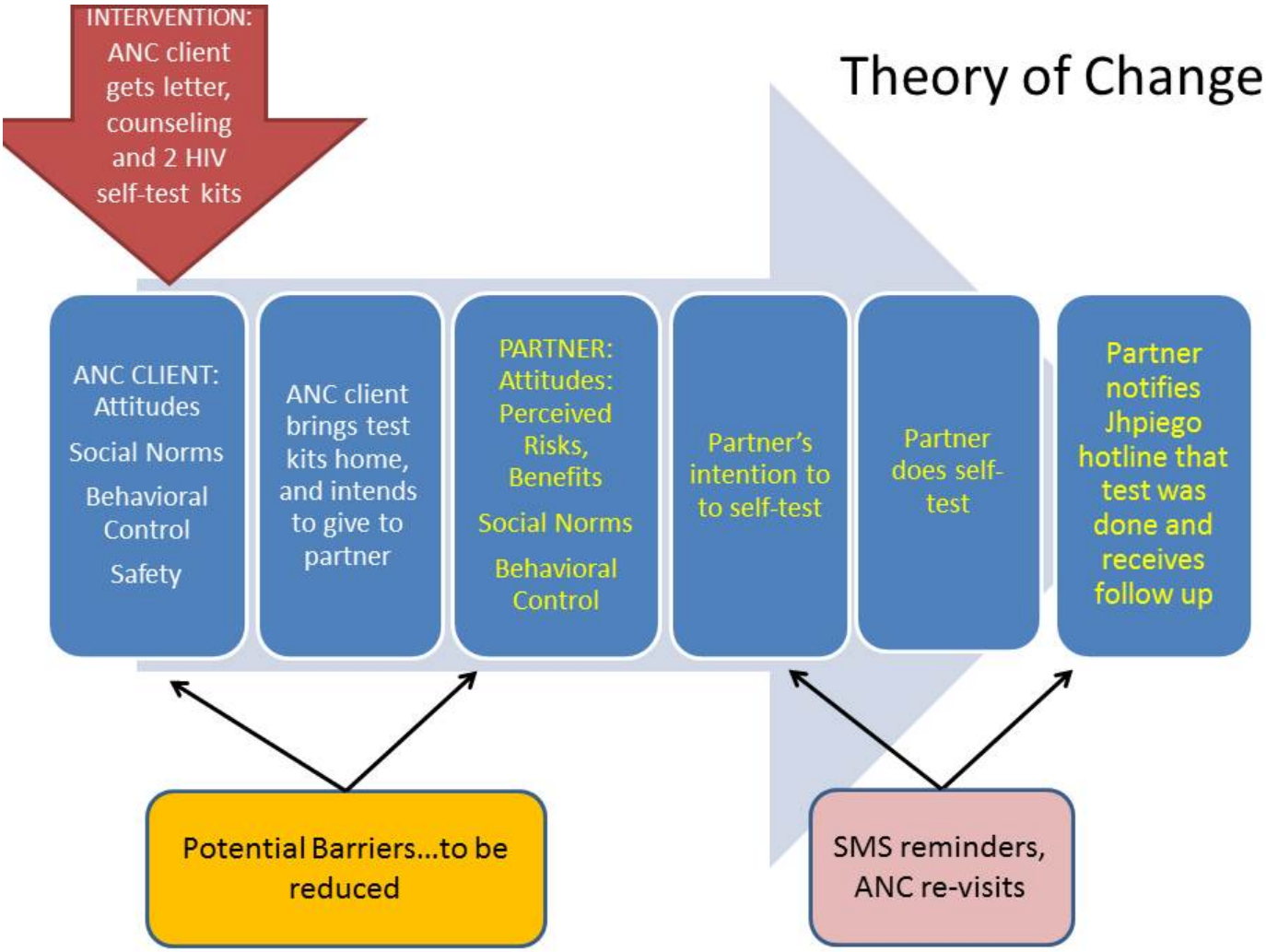
Approved by the FDA and Commercially Available	Approved by Another Gov't Entity (provide name and approval information)	Not Approved

C. If the investigational device is a Significant Risk Device, provide the IDE number given by the FDA, or if not under FDA jurisdiction, explain why it is appropriate to use this device in this study.

D. If you believe the investigational device is not IDE exempt under 21CFR 812.2(c), but is a "Non-Significant Risk" device considered to have an approved IDE application, provide information from the manufacturer supporting that position.

E. If your investigational device is Exempt from the FDA IDE regulations, explain which section of the code applies to your device and why it meets the criteria provided. If it is a diagnostic device, provide pre-clinical information about the sensitivity and specificity of the test and the anticipated failure rate. If you plan to provide the results to participants or their physicians, justify doing so.

Appendix 1: Theory of Change


Theory of Change
INTERVENTION: ANC client gets letter, counseling and 2 HIV self-test kits
ANC CLIENT: Attitudes
Social Norms
Behavioral Control
Safety
ANC client brings test kits home, and intends to give to partner
PARTNER: Attitudes: Perceived Risks, Benefits
Social Norms
Behavioral Control
Partner's intention to to self-test
Partner does self-test
Partner notifies Jhpiego hotline that test was done and receives follow up
Potential Barriers...to be reduced
SMS reminders, ANC re-visits

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[xv] Formula: $n = 2 \times [z_\alpha + z_\beta]^2 \times p \times (100 - p) / d^2$ where p is the true success percent (6%) and d is chosen equivalence limit.
[xvi] Formula: $n = [z_\alpha + z_\beta]^2 \times [p_1 \times (100 - p_1) + p_2 \times (100 - p_2)] / (p_2 - p_1)^2$ where p_2 is success in Group 1 and p_2 is success in Group 2.