Protocol for the
RESPECT Study ("Rewarding STI Prevention and Control in Tanzania")
October 2010

SECTION 1: PURPOSE AND BACKGROUND OF STUDY

At its core, the global AIDS epidemic is fueled by risky sexual behavior. Over 80% of HIV infections occur through sexual contact with an infected partner, and could have been avoided through the adoption of safer sexual behaviors. Despite isolated – and, often temporary – successes, behavior change interventions promoting safer sexual behavior have proven remarkably ineffective at stemming the tide of the epidemic. New, innovative approaches to behavior change are desperately needed, particularly for young people in their child-bearing years who are becoming sexually active. Of the 4.3 million *new* HIV infections that occur each year globally, 80 percent occur among this age group.

The primary aim of this study is to evaluate the impact of a novel behavioral intervention for preventing HIV and other sexually transmitted infections (STIs) among youth and young people in the Kilombero/Ulanga districts in southern Tanzania. This intervention uses a type of economic incentive called "conditional-cash transfers" (CCTs) to motivate safe sexual behavior among youth by linking cash rewards to negative laboratory test results from periodic STI screenings. The basic premise is that safer sexual practices can be encouraged by using CCTs to make risky decisions more costly.

The decision to have sex involves a trade-off between the short-term benefit of sexual pleasure and intimacy and the long-term (probabilistic) cost of getting pregnant or acquiring an STI (O'Donoghue and Rabin, 2000). Thus, risky decisions may be the result of realistic assessment of trade-offs and probabilities, or may result from problems associated with undervaluing the future (e.g. excessive "discounting"). Of course, this is a stylized view of the decision making process that may be conditioned and constrained by the cultural, social, and economic context. A large body of research has focused on how poverty, lack of economic opportunity, and powerlessness closes off options to the point that the individual does not experience his or her engagement in risky sexual behavior as the outcome of a deliberate "decision."

Nevertheless, evidence from the fields of economics, behavioral economics, and clinical psychology has shown that decision-making under conditions of uncertainty is highly responsive to incentives. Applied to the area of sexual health, the evidence is suggestive of a decision-making process that is at least partially informed by an explicit assessment of costs and benefits, even among the socially and economically disadvantaged. Gertler et al. (2005) found in a study of Mexican sex workers that "risky sex" carries a 23% higher price tag than sex with condoms. In a study of informal sex workers in Western Kenya, Robinson and Yeh (2009) found that sex workers charge more for anal sex and that risky sexual activity fluctuates in response to consumption expenditures and income shocks experienced within the household. Such findings suggest that an appropriately-designed and well-targeted intervention would be able to alter the cost-benefit parameters of the decision to engage in risky sexual behavior.

We plan to conduct a two-arm randomized control trial to test the hypothesis that a system of rapid feedback and positive reinforcement – using cash as the primary incentive – can be used to promote safer sexual activity among youth and young people who are at high risk of HIV infection. CCTs have proven remarkably effective at inducing and reinforcing positive behavior change in many areas of social and health policy, but they have not yet been evaluated for their effectiveness as an AIDS prevention intervention.

In the CCT intervention to be tested in this trial, cash payments will be conditional on the avoidance of risky sexual behaviors (or, alternately, on the adoption of safe sexual behaviors). Since self-reported sexual behavior data is notoriously unreliable and subject to strong reporting biases, we will instead link cash payments to objective measures – like STI test results – that serve as proxies for risky sexual behavior. Only STIs which have been incontrovertibly linked to risky sexual activity will be linked with cash payments. Youth will be

monitored on a regular basis for STIs and will be rewarded with cash each time their STI test results are all negative.

For our study population in Tanzania, cash payments will be linked to several STI test results: Chlamydia, gonorrhea, syphilis, HSV-2, and trichomonas. With the exception of HSV-2, which can be treated but not cured, each of these STIs is curable. This is a critical point, since youth who test positive for an STI can continue to participate in the intervention after they have been treated and cured of the infection. Thus, learning is encouraged through positive reinforcement, and mistakes can be corrected and overcome. For both ethical and practical reasons, the cash transfers will not be tied to HIV status, and HIV acquisition will not result in being dropped from any arm of the study.

The proposed intervention is also likely applicable to a variety of social and cultural settings due to the nature of the intervention, which is neutral about the specific behaviors required to remain free of infection. For example, individuals may choose to abstain, use condoms, or reduce the number and concurrency of sexual partners. While information about how to prevent infection will be provided to all participants, the specific decision will rest in the hands of the individuals themselves.

Recognizing that girls and young women may lack the power to actively participate in decisions affecting their sexual/reproductive health, we have added a psychosocial intervention (gender-based counseling and life-skills training) to strengthen and reinforce the effects of the CCT intervention on behavior change. The psycho-social component of the intervention will thus serve to improve the decision-making capacity of participants by focusing on STI education, gender-power imbalances, and making deliberate choices in the domain of sexual/reproductive health. Limited empirical evidence suggests that economic interventions in combination with psycho-social support have greater impact than either type of intervention taken singly.[i] [ii] [iii]

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Because this is such a novel approach, there are many unanswered questions on how an intervention using such an approach could be – or should be – designed. What is the appropriate target population? Adolescents? Geographical hot spot areas? Set within residential communities or within social networks? What is the appropriate amount of cash to dispense? What interval of testing/payment is needed? For how long should the intervention run? What happens when the money runs out? What are the risks? How do the risks differ in different potential target population groups? What epidemiologic setting is most appropriate?

These are absolutely critical questions that have never been examined in terms of CCTs & STIs/HIV prevention, which is why we are casting a 'wide net' in this first study and are focusing on an epidemiological context that is 'typical' of the East African areas where youth are at higher-risk of HIV.

We have been careful in the design of this study to ensure that we explicitly consider each of these fundamental questions and ensure that we are using the best empirical evidence available. In some cases, that means we have been able to draw on empirical work in other areas; in other cases it means that we have built the question into the study ourselves because there is little evidence to guide intervention design decisions.

In this study, we will implement the intervention for one year in two districts in southern Tanzania and evaluate its impact by randomly assigning 18-30 year old participants and their spouses to receive either the CCT intervention or STI testing/treatment alone. A follow-up assessment will be conducted 12-months after the intervention ends. This two-year randomized trial thus has two main arms: a treatment arm which receives the CCT intervention for 1 year starting after baseline, and a control arm which does not. Both study arms will receive STI testing, basic STI/HIV counseling, and treatment five times over the 2-year period, as well as the psychosocial /group-counseling intervention for the first year. Individuals in the treatment arm will then be randomly assigned to receive either a Tsh 10,000 or Tsh 20,000 (roughly $10 or $20, as referred to in this protocol) cash reward group. This will further allow sub-study of the effect of varying sizes of cash transfers.

We have 3 primary research objectives:

1. Evaluate the impact of the combined CCT/counseling intervention on STI incidence overall – and by specific subgroups – during the intervention period. This will enable a characterization of the immediate and short-term effects of the intervention and to identify responsiveness in different potential target groups. Economic outcomes will be evaluated as well.

2. Examine the long-term effects of the intervention – and its withdrawal – on STI incidence and economic outcomes by conducting a final round of STI testing and surveying in the same population 12-months after the intervention has ended.

3. Compare the impact of the CCT intervention in the high-value cash transfer arm to that in the low-value cash transfer arm. This will permit us to better understand thresholds and non-linearities in the price effects, and the findings will have important implications for how the intervention could be brought to scale, if found to be effective.

In addition, the Control-R4 sample to be newly recruited at round 4 (not initially envisioned as part of the study) will be used to test the impact of enrollment in the original Control group. Specifically, the Control-R4 sample will allow testing of the effects of the extensive access to counseling, testing and treatment provided to original Control subjects in the main study. The main study was designed to test the effects of cash rewards, over and above the effects of such counseling/testing/treatment, thus the original Control group itself received extensive intervention. This original Control group intervention has so far included baseline, 4-month, and 8-month counseling/testing/treatment, as well as a year of monthly group counseling. This package of services to baseline participants is expected to result in decreased STI incidence based on prior research, but the extent of that prior research is limited, thus there is considerable scientific value in quantifying the STI benefits of this precise package of preventive efforts. The Control-R4 will serve as a comparison group to this original Control group, allowing estimation of the STI improvement due to original Control enrollment.

Study area

This study will take place in two rural districts in southern Tanzania, Kilombero and Ulanga, located in the region of Morogoro. The Ifakara Health Research and Development Center (IHRDC) manages the Ifakara Demographic Surveillance System (DSS) in this region. The Ifakara DSS site was incepted in September 1996 and is among the largest demographic surveillance system in all of Africa, collecting basic sociodemographic household-level information on births, pregnancies, deaths, and migration on a quarterly basis. Basic data on asset ownership, ethnicity, education levels, and economic activity is also collected, although at less frequent intervals. A baseline census was conducted between September and December 1996, and each household has been visited once every four months ever since. A total of 56 villages are covered with a population of about 95,000 people in 20,000 households.

In Tanzania and other East African countries, the majority of new HIV infections occur among young people, aged 15-30,[iv] and the Kilombero/Ulanga district appears to be strongly affected. The infection rates in the Morogoro region as a whole are higher than many other parts of the country. At the district level, accurate data are often lacking, but the data that are available suggest a consistent pattern. Results of an antenatal survey of young mothers conducted in 2003 revealed an overall HIV prevalence of 13.0% for the Kilombero/Ulanga district as a whole. In Kilombero, overall HIV prevalence was 19.2%, compared to 9.8% in Ulanga (with apparent "hot spots" in a few areas – e.g. Lupiro).[v] In addition, a 2006 study conducted by our research team found an aggregate STI prevalence rate of 19% amongst 500 youth randomly selected from five villages in the Kilombero/Ulanga DSS region.

In the last quarter of 2005, IHRDC added a youth sexual and reproductive health module to a socio-demographic survey administered within the DSS area. For this module, approximately 4000 youth between the ages of 12-24 were randomly selected from the DSS database to participate in the study. Preliminary analyses indicate that age at sexual debut is low, frequency and concurrency of partners is high, and condom use is low, all indicating the urgent need for new youth-focused prevention approaches. Among respondents who had ever had sex, 78% had their first sexual contact between the ages of 14 and 18. Among female respondents, 62% did not use a condom in their last sexual encounter, while 38% of males did not use condoms. Among out-of-school youth, 86% did not use condoms in their last sexual encounter.

Qualitative assessment of behavioral impacts of intervention

In an effort to supplement the quantitative data being collected through survey at baseline and follow up at 12 and 24 months, we will also collect qualitative data at each time point. In-depth interviews will be performed with a small sub-set (about 90-100) of the enrolled study participants just after enrollment and again after the 4-month results have been received. The qualitative data collected will help us to gain a more complete understanding of how the conditional cash transfers provided for those who remain uninfected impact the decision-making processes of participants, especially regarding sexual and reproductive health. In-depth interview transcripts will provide a more nuanced explanation as to why the cash transfers did or did not facilitate behavior change relating to risky sex and will enable us to understand why an increase in income may or may not influence perceptions of risk, gender inequities and self-efficacy in sexual reproductive health decision-making, ties with dependents, and the decision to engage in transactional sex. These qualitative data will be further supplemented by Conversational Journal data collected by local community diarists, following a methodology successfully developed by Swidler and colleagues for use studying sexual behaviors in neighboring Malawi.

Study background

Mass information, education, and communication (IEC) campaigns, typically the centerpiece of countries' AIDS prevention strategies, have been shown to have had relatively little impact on patterns of HIV transmission and the trajectory of the epidemic (Bertrand et al., 2006). Numerous studies have shown that information alone is typically insufficient to change risk behavior. However, accurate information is indisputably a basic ingredient in informed policy discourse, and IEC in conjunction with condom promotion and distribution likely results in higher condom use and significantly lower STI incidence (Bertozzi et. al., 2006). Nonetheless, in many African countries, infection rates continue to rise even as awareness about risks and consequences of HIV infection has increased within the general population (World Bank, 2006). In Tanzania, the awareness of HIV prevention methods in the youth population is high but has not fully translated into safer sexual behaviors. Almost 80% of young people know that using condoms reduces the risk of contracting HIV, but fewer than half reported using a condom the last time they had sex (MEASURE DHS, 2007).

Psycho-social interventions, such as peer-to-peer counseling, have had a significant and measurable impact on unsafe behaviors, but have not been shown to be cost-effective as a strategy for reaching young people (Hutton et al., 2003). These types of interventions may be costly when brought to scale due to the emphasis on an individualized or small group therapy approach, although there has been some experimentation with more easily scalable, community-based approaches. A multi-country trial of a community-based VCT approach is currently underway (Coates and Szekeres, 2006).

One plausible explanation for the lack of progress with behavior change interventions is that most interventions have focused exclusively on AIDS prevention messages, rather than sexual and reproductive health more broadly. These single-intervention approaches to behavior change have presumed a degree of individual control over decision making that does not speak to the reality of women's and girl's circumstances in sub-Saharan Africa, nor to the dilemma that many face in balancing economic needs, the desire to bear children, and the need to protect themselves from HIV and other STIs. Furthermore, few interventions have been developed to explicitly address critical characteristics of the risk environment, most notably poverty and gender inequalities that give rise to risky behaviors.

Many public health experts have argued that a more aggressive approach to behavior change in Africa is needed, pointing out that "instances where HIV infections appears to be falling … [were] linked to successful programs aimed at changing behavior, notably in Kenya, Uganda, and Zimbabwe" (Jack, 2007). New, innovative prevention programs are particularly needed to reduce transmission among young people in their child-bearing years who are becoming or who have recently become sexually active. Of the 2.5 million *new* HIV infections that occur each year globally, 80 percent occur among this age group.

Adolescence and young adulthood often represents a period of risk-taking and experimentation, but it also means that young people are at their most receptive and open to change, before social and sexual norms have been firmly established. It is possible that an intervention strategy which seeks to mitigate the effects of the broader risk environment facing young people and emphasizes increased control and deliberation in decision-making will have a greater impact.

This research proposal aims to test a radically different approach to prevention, and to target the age demographic group that can derive the most benefit from it.

The proposed study is a randomized control trial to evaluate a new intervention that uses "conditional cash transfers" (CCTs) in conjunction with counseling and training to encourage safe sexual behavior among young people in East Africa. The basic premise is that safer sexual practices can be encouraged by using CCTs to make risky decisions more costly.

Conditional cash transfer (CCT) programs provide cash to poor households in exchange for their active participation in educational and health care services. CCT programs have proven remarkably popular among developing country governments, sweeping the globe from Mexico to several other Latin American countries, including Columbia, Honduras, Jamaica, and Nicaragua, and much more recently, to Africa. The principle of conditionality – which may be applied differently in practice, but generally requires families to send their children to school or to receive a range of health care services, such as nutritional counseling, childhood vaccination programs, etc. – distinguishes CCT programs from the more traditional social assistance programs which provide cash or vouchers directly to poor or otherwise distressed families with no strings attached. The CCT programs emphasize the use of market-oriented "demand-side" interventions as an instrument for longer-term human capital investments. Ideally, they are designed to complement, rather than replace, the more familiar "supply-side" investments which channel resources directly towards schools, clinics, and service providers.

International collaborative team

This research collaboration brings together investigators from the Ifakara Health and Research Development Centre (IHRDC) in Tanzania, the University of California, Berkeley, and the World Bank. This study is being reviewed by the IRBs at both the local (IHRDC) and national (National Institute for Medical Research) levels in Tanzania.

This research will be conducted in villages in the Kilombero/Ulanga districts in southern Tanzania, in close collaboration with researchers at the Ifakara Health and Research Development Centre (IHRDC). Since 1996, IHRDC has managed a Demographic Surveillance System (DSS) in these two districts covering over 95,000 people in 25 villages, one of the largest DSS in all of Africa. As part of the DSS core activities, basic socio-demographic household-level information on births, pregnancies, deaths, and migration is collected from all households in the DSS area on a quarterly basis. The Ifakara DSS has served as a platform for dozens of health studies – mostly related to malaria – since its inception. IHRDC has stringent standards for protecting confidentiality of research data and study participants which are in line with CPHS standards for U.S.-based research. All research conducted through IHRDC must be approved by a formal Institutional Review Board (IRB) at both IHRDC and the Tanzanian National Institute for Medical Research (NIMR).

Our local Tanzanian collaborators at IHRDC have extensive experience conducting research in the DSS area and are highly qualified to conduct research. They are highly knowledgeable of local community attitudes and cultural norms as well as cultural sensitivities in the DSS area. All IHRDC-based team members are native Tanzanians who speak fluent Kiswahili (the local language) and English. The local PI on our study, Dr. Rose Nathan, is a senior demographer at IHRDC and served as the director of the Ifakara DSS site for four years where she oversaw all DSS activities and associated research. The project coordinator on our study, Ms. Sally Mtenga, has worked on numerous studies in the area and currently serves as the secretary for the IHRDC Institutional Review Board. She has written and reviewed over a dozen informed consent forms for studies in the DSS area and has also led community sensitization efforts for HIV VCT programs in the area. This IHRDC research team, together with our collaborators from the World Bank and UCSF, conducted an STI prevalence

study in 2006 to assess the feasibility of this larger trial in this area. The Tanzanian collaborators at IHRDC will work closely with the US-based team throughout the design and implementation of the study to ensure that we remain respectful of cultural norms, attitudes, and sensitivities as well as of local laws.

SECTION 2: SUBJECTS

Main study

We will randomly select from the DSS database men and women aged 18-30 who live in the study villages in the Kilombero/Ulanga districts in southern Tanzania, as well as their spouses ages 16 and over.

We will select 10 villages located in or near to the Kilombero/Ulanga DSS research area where STI/HIV transmission is relatively high in the youth population (the 'hot spots' in the DSS). Potential sites have been identified through consideration of our own 2006 STI prevalence study that focused on 5 villages, a 2003 antenatal clinic HIV survey, as well as the location of villages in terms of their accessibility to roads, train stops, commercial centers, bars/pubs, etc. (whereby higher accessibility to each of these typically translates into higher HIV/STI transmission rates in the area).

Inclusion criteria consist of males and females, aged 18-30 (and spouses ages 16 and over) who reside in selected villages in the Kilombero/Ulanga districts in southern Tanzania and who consent/assent to participate in the study. Exclusion criteria will include: currently pregnant, intention to permanently migrate out of the DSS area within the next year, and unwillingness to participate if assigned to the control arm. These criteria will not be formally incorporated into a screening questionnaire or interview. Rather, they will simply be reiterated in all of the recruitment materials and informed consent form(s), as well as reviewed by study staff at the time of enrollment.

Prospective participants will be identified through the DSS database, oversampling lower socioeconomic status households. The local P.I. and DSS staff will randomly select potential participants from the DSS database after restricting the sampling frame to the target age group (18 to 30) and target villages of residence. Following a phase of community sensitization, fieldworkers will visit the households of the randomly-selected young men & women to invite them to participate in the study. If the individual is eligible and interested in participating in the study, that individual will be invited to the study station the following week, and may be enrolled in the study once the informed consent form is complete.

Individuals will be randomized to study arms at the individual-level, although spouses will always be placed in the same arm as each other. First sub-villages will be randomized to either "high spillover" (75% of enrollees are in treatment arm) or "low spillover" (25% of enrollees are in treatment arm) villages. Participants will then be randomly assigned to the treatment group (n=1500) or control group (n=1500), with on average a 50/50 chance of being assigned to either group. Participants assigned to the treatment group will be further randomized to either the "high-value" cash transfer group (n=750) or the "low-value" cash transfer group (n=750). .

Qualitative sub-study

For the qualitative sub-study, participants will be recruited from the main study sample during the second study station visit at either baseline or month-4. A random selection of approximately 90-100 participants drawn from both the treatment and control arms will be recruited at baseline and asked if they would be willing to participate in the qualitative sub-study. At month 4, five participants from the treatment arm who tested positive for one or more STI (and therefore did not receive the cash reward) will be invited to participate. The only inclusion criteria are attendance at the study station during the time of sub-study recruitment and consenting to participate in both interviews, but we will impose quotas by gender, marital status and study arm.

Round 4 Control Group ("Control-R4")

At the 12-month (round 4) follow-up study point we will recruit a small additional control group (to be termed "Control-R4") to compare against our original control group enrolled at the round 1 baseline (we now term this

original control group recruited at round 1 "Control-R1"). This will allow us to test whether the intensive counseling and treatment activities given to Control-R1 over the first year of the study resulted in changed sexual behavior and decreased STI incidence, as compared to the new Control-R4 group that was not enrolled during the first year of the study. Although not originally envisioned in the study design, the decrease in STI incidence that we have observed among the Control-R1 group during the first eight months of the study suggests that there may be important scientific gains to studying the Control-R1 group as an intervention group in and of itself. In order to do so, we will draw a new random sample of community members who were eligible for the original study recruitment but who were not enrolled. To minimize the potential for contamination due to sexual mixing across control groups, we will only draw this new Control-R4 sample and make comparisons among married individuals. To enhance power, we will only enroll one person per marital couple into this new sample. Other eligibility criteria will be identical to the original baseline enrollment criteria: The individuals must have been aged 18-30 and married at the time of the initial recruitment one year ago; they must also be currently living in one of the 10 study villages, not be pregnant, and not be planning on permanently migrating out of the study area during the next year. As at baseline, potentially eligible individuals will be identified in the existing Demographic Surveillance Survey computerized database of village residents; study personnel will visit their household to explain the study and verify eligibility; and eligibles will be invited to come to the study station the following week to complete informed consent and enroll if they so choose. All Control-R4 participants will be placed in the same study group, so no randomization will occur. The Control-R4 group will receive free voluntary counseling and testing for HIV and the same set of STIs as original study participants (plus free treatment and referral as is done for original study enrollees).

Number of subjects

Main study

We plan to enroll a total of 3000 individuals in the study. Assuming a refusal/ineligibility rate of 20%, we will recruit 3600 individuals.

By convention, STI prevention trials are often powered to detect a magnitude of 30% difference in STI incidence across study arms. Thus, the proposed study has been powered to detect differences of a magnitude of 30% between aggregate STI incidence rates in the treatment versus control arm.

Power calculations are based on a comparison of aggregate STI incidence rates between two, equal-sized study arms using a log rank test and assuming a two-sided alternative hypothesis. By basing the calculations on a two-arm comparison, we ensure sufficient power to detect differences of a 30% magnitude or greater in the treatment arm compared to the control arm. Other assumptions include:

1. Annual (aggregate) incidence rates in research sites will be constant;
2. (Aggregate) incidence rates may vary between 15%-20% across research sites;
3. Total trial will be 12 months;
4. Overall annual censoring (i.e., drop-out) rates will be as high as 20% per year

Based on these assumptions, a total sample size of 3000 individuals (e.g., 1500 per main study arm) will be sufficient to provide at least 90% power to detect an intervention-related reduction in STI incidence as small as 24%, significant at the 5% level. We will retain at least 80% power to detect a reduction as small as 20% with this sample size. Collectively, these results indicate that the proposed sample size is large enough to provide ample power to detect meaningful effects for the overall effect of the intervention under a range of possible incidence rates, and making very conservative assumptions about loss to follow-up. Further, we should retain adequate power to investigate intervention effects in subgroups of participants defined by factors such as age and gender.

Qualitative sub-study

We are planning to interview 90-100 participants at each time point. We will likely need to recruit approximately 120 participants to yield 90 completed interviews. In round 2 we will include five additional interviews: three men and two women who have tested positive after 4 months will be asked to participate in an in-depth interview the week after receiving test results.

Round 4 Control Group ("Control-R4")
In Round 4 we plan to enroll approximately 400 new individuals into the "Control-R4" study group. Based on original recruitment success, we anticipate inviting approximately 600 people in order to achieve the target enrollment. The target enrolment number of 400 was chosen based on power calculations of sample size needed to test the hypothesis that the Control-R4 STI rates at round 4 are significantly higher than the round 4 STI rates of the original control (Control-R1) group that has received counseling, testing, and free treatment over the first 12 months of the study.

SECTION 3: RECRUITMENT

Main study
We will randomly select approximately 3600 individuals, aged 18-30, from households in the study villages (3000 plus 20% extra to allow for expected refusal/ineligibility). Prospective participants will be identified through the DSS database. The DSS collects basic socio-demographic household-level information on births, pregnancies, deaths, and migration from all households in the DSS area on a quarterly basis, making it an excellent platform for drawing random samples. To minimize 'spillover effects' across the intervention and control groups (where 1 non-marital sexual partner is in one arm & the other partner is in the other arm), we will enroll not more than 30% of age-eligible youth from any one village, and we will designate some villages as "high treatment penetration" villages and others as "low treatment penetration" villages, by varying the percent of the eligible population who is enrolled in the treatment arm.

Following a phase of community sensitization, fieldworkers will visit the households of the randomly-selected young men & women to invite them to participate in the study. Potential participants will be given an invitation that contains information about the study, plus the informed consent form to read, and instructions to come to a nearby 'study station' the following week for screening & potential enrollment if they are interested in participating (see below for details on the study stations).

Qualitative sub-study
We will recruit participants for the qualitative study at two points in time using the same recruitment methods. The first recruitment will take place during the baseline visit to the study station. At the end of this visit, an interviewer for the qualitative study will verbally recruit a stratified random selection of 90-100 participants. The sample of participants selected for the qualitative sub-study will be stratified by treatment arm, gender and marital status. In addition we plan to interview approximately 10 HIV-positive participants, all in the treatment arm, and 8 participants who have spouses also enrolled in the study. We will use purposive sampling to meet these recruitment criteria if they are not met by the initial random selection of participants. All participants will be asked if they would be willing to participate in the qualitative sub-study.

The second recruitment will take place at month-4, during the second visit to the study station. All participants interviewed in at the baseline visit will be interviewed again at the 4-month visit. In addition to these interviews, immediately following their post-test counseling session, an interviewer for the qualitative study will verbally recruit a random selection of 5 participants from the treatment arm who tested positive for one or more STI (and therefore did not receive the cash reward). These participants will be asked if they would be willing to participate in the qualitative sub-study.

Round 4 Control Group ("Control-R4")
The Control-R4 group will be selected and recruited using the same procedures described above as were used for the original baseline sample. Potentially eligible individuals will be identified in the existing Demographic Surveillance Survey computerized database of village residents; study personnel will visit their household to explain the study and verify eligibility; and eligibles will be invited to come to the study station the following week to complete informed consent and enroll if they so choose.

Recruitment Materials

Main study and Control-R4 sample
Recruitment invitations will be delivered to the households of selected individuals a few days before the study team arrives for enrollment and baseline study activities. These invitations will inform recipients that they have been randomly selected to participate in a new study. The invitations will also specify where and when the recruit should go to meet with the study team for possible enrollment and baseline data collection.

The purpose of the study will be described briefly, eligibility criteria will be detailed, and the names and institutional affiliations of the researchers will be given. The name and contact information for the in-village study representative – as well as the IHRDC study contact person – will be provided. The invitation will list the same key points about study participation that are listed in the informed consent form (and comprehension assessment). The same language will be used to ensure consistency across all communication materials.

Qualitative sub-study
Potential participants will be verbally recruited using the attached recruitment script.

SECTION 4: INFORMED CONSENT

Main study and Control-R4 sample
The main study will involve informed consent for study enrollment. The consent will also ask for agreement for long-term specimen storage and possible future research testing, as well as for linking to DSS data for future research.

All potential study participants must provide written informed consent to enroll in the main study. Participants are not required to consent to long-term specimen storage and DSS data access; participants may choose not to consent to these future research activities and still be enrolled in the study. Informed consent forms will be written and reviewed with participants in Kiswahili, the local language. Forms will be translated into Kiswahili and back-translated into English before study implementation.

Please note that we have adopted many "best practices" for obtaining informed consent and view informed consent as a process: involving the communities at outset, building participants' understanding of the study over time before obtaining written informed consent, assessing participants' understanding within the informed consent forms, using visual aids to enhance participants' understanding, and monitoring participants' understanding and perceived risks throughout the study. Specific activities relating to the informed consent process are detailed below.

Community sensitization phase
The process of obtaining informed consent will begin with a period of community sensitization several weeks before recruitment begins. In each study village, study staff will work with village leaders to build understanding of and support for the study within the villages. Study staff will give presentations at community meetings to explain the study and will encourage questions from all interested/concerned community members. A drama group will be hired to perform in each village, focusing the performance on the key points of the study

Recruitment phase
During the recruitment phase, we will continue to build and reinforce participants' understanding of the study. Fieldworkers will visit the households of the randomly-selected young men & women to invite them to participate in the study. Potential participants will be given an invitation that contains key information about the study and instructions to come to a nearby 'study station' the following week for potential enrollment. The fieldworker will read the invitation aloud to potential participants as needed, depending on literacy level of the recruit, and answer any questions. Recruits will be encouraged to contact the village study representative – or any other available study staff member – with any questions that they may have about their potential involvement in the study.

Enrollment – signing of the informed consent
Potential participants are asked to visit their local 'study station' during the 1-week enrollment period (a few days after recruitment) to review the informed consent materials with a study interviewer and possibly enroll in the study.

When a potential participant visits the study station, he/she will meet with a study interviewer in a quiet, private area of the study station to review the informed consent materials. Before reviewing the form, the interviewer will first review the eligibility criteria for the study with the potential participant. If the individual reports that he/she is eligible and interested in participating in the study, that individual may be enrolled in the study once the informed consent form is complete.

The interviewer will then review the material in the informed consent form with the potential participant. Visual aids like calendars and samples of specimen collection materials will be available for each interviewer to use during the review to enhance participants' understanding. The review will involve either reading the informed consent aloud to the participant or having the participant read the form (depending on the literacy level and preferences of the participant) and answering any questions the participant may have. When consent forms need to be read to non-literate potential participants by the interviewer, a witness will be present to verify that the contents of the form have been read and to sign the form.

Once the informed consent has been reviewed with the participant, the interviewer will conduct a "comprehension assessment" to ensure that the participant understands all information required to make an informed decision about whether to enroll in the study. An Informed Consent Comprehension Checklist (see attached) will assist interviewers in assessing participant comprehension and targeting follow-up educational efforts.

The checklist will not be presented to participants as a "test," but rather as a way of double-checking that the interviewer has fulfilled their responsibility to provide all information needed for the participant to make an informed decision about enrolling in the study. The checklist is structured around eight open-ended questions that correspond with the elements of informed consent required for research in the U.S. Each question will be read to the participant, giving him or her time to respond to each one.

For each question, the checklist specifies particular points that must eventually be included in the participant's response. If the participant does not mention one or more of the required points, the study interviewer will follow-up with another open-ended question to elicit a response about that point. All required points must be satisfactorily addressed by the participant, and checked off, before proceeding to the final informed consent decision and signing or marking of the enrollment informed consent form. Note that we have explicitly included these required points in the recruitment invitation and in the final 'review' section of the informed consent form to reinforce these key points.

The informed consent forms for the main study will contain a 'review' section where the participant and/or parents will be asked to acknowledge that they understand specified key points of the study before consenting to enroll in the main study (signing). Participants will also be asked to indicate whether they consent to the optional long-term specimen storage and/or DSS data access by initialing designated spaces. For all participants that cannot sign their name, spaces will be provided where participants may place a thumbprint.

Ongoing assessments
Study participants will be asked to resign the informed consent at each visit to the study station at which interviews are conducted and samples collected.

<u>Qualitative sub-study</u>
For the qualitative sub-study, participants will be recruited during their baseline visit to the study station. A random selection of 90-100 participants will be asked if they would be willing to participate in the qualitative sub-study.

Informed written consent from all persons agreeing to be part of the qualitative sub-study is required for participation. The consent form will clearly indicate that the interviews will be audio tape-recorded and that these recordings will be transcribed and translated into English by a member of the study staff. The consent form will also indicate that no other identifying information will be collected as part of study participation. The participant's name will not be associated with the recorded interview, only the study identification number will be linked to the recording. The participant will also be notified clearly that the information collected through this sub-study will be linked to other information collected from them as part of the larger cash reward study, but the linking will occur only by the use of the study identification number, not by the name or other identifying information of the participant. Finally, the consent form will include a brief description of the study and will indicate clearly what agreeing to participate means for them, address any confidentiality and potential harm concerns, explain that even after agreeing to be part of the study, the participant may chose to stop the interview at any time, and briefly explain how the data will be used.

Consent forms will be available to potential participants in Kiswahili. Forms will be translated into Kiswahili and back-translated into English before study implementation. Consent forms will be read to non-literate potential participants by the interviewer.

The consent process will take place in a private area of the study station, with only the research staff, participant, and witness (if applicable) present. All participants will be informed both verbally, and in the printed consent form that their decision to leave this study will not affect access to the usual medical care they get now or in the future, and that their decision will not affect their ability to take part in the larger cash reward study or in any other research studies.

Qualitative monitoring with Conversational Journals

We are requesting a waiver of informed consent for community members whose conversations are captured in the conversational journals. Community diarists will be anonymously reporting in nightly journals the conversations pertaining to the study that they have heard around them during their daily activities. In many cases these will be conversations in public places, thus the diarists will be observing public behavior, and no consent would ordinarily be required. However, an important subset of the conversations related to the study may be carried out in private places. For these latter conversations it would not be feasible to obtain informed consent from the conversants, thus that component of the research could not be practicably carried out without a waiver of informed consent.

To help ensure that the conversational journals will present no risk of harm any greater than that encountered from everyday life, the journalists will be instructed to record all conversations anonymously. Only those subsets of conversations directly relevant to the study will be recorded in the diary, so that a third party reading the diary should not be able to infer the identity of the conversants.

SECTION 5: STUDY PROCEDURES

Main study

OVERVIEW

The study will last about two years, beginning in late-2008 and ending in late-2010. Most of the study activities will happen in the first year. There will be four rounds of study activities in the first year (about every four months) and one round at the end of the second year.

Round 1 (early 2009)	-	Baseline
Round 2 (mid 2009)	-	4-months after baseline (Treatment group eligible for CCT)
Round 3 (late 2009)	-	8-months after baseline (Treatment group eligible for CCT)
Round 4 (early 2010)	-	12-months after baseline (Treatment group eligible for CCT)
Round 5 (early 2011)	-	24-months after baseline (post-intervention follow-up)

Each study round, all participants will be asked to come to the study station twice: once to provide a biological specimen for STI testing, and a second time (about three weeks later) to pick up test results and (if eligible) cash payments. During each study round, study counselors will provide pre- and post-counseling to all participants to ensure that the participants understand the meaning of their test results, etc. Participants will be interviewed once per study round as well. Short (10- to 15-minute) surveys will be administered during the first visit of each intervention round (Rounds 2 and 3). Longer surveys will be administered at baseline and at follow-up.

Participants will also be invited to attend the counseling "group discussions" which will be held every month in the first year.

Study activities will take place on a rolling basis over each study round. The study teams will move from village-to-village each week, visiting all 10 villages twice per round. Because of the rolling nature of study activities, we must describe the chronology in terms of calendar quarters, rounds, and study months rather than exact calendar dates.

For clarity, the intervention and study procedures are presented in detail first and then listed in chronological order.

RANDOMIZATION

This study proposes to randomize at the individual-level. Participants will first be randomly assigned to the treatment group (n=1500) or control group (n=1500), with on average a 50/50 chance of being assigned to either group. Participants assigned to the treatment group will be further randomized to either the "high-value" cash transfer group (n=750) or the "low-value" cash transfer group (n=750). Participants in all three study groups will then be randomly assigned to either receive additional counseling (n=1500) or receive no additional counseling (n=1500).

INTERVENTION PROCEDURES

All study participants will be monitored on a regular basis for several STIs that serve as proxies for risky sexual contact, will receive standard pre- and post-test counseling, and will receive free STI treatment through the local public health facilities as needed. Participants in the treatment arm will receive conditional cash transfers (CCTs) of Tsh10,000 or Tsh20,000 (approximately $10 and $20) each reward round that they avoid becoming infected by any of the conditioned STIs. Participants in the control arm will not be eligible to receive cash rewards for negative STI test results at any point during the study.

<u>STI testing, STI treatment, and conditional-cash transfers</u>

Biological markers of risky sexual behavior

The biological markers selected for the intervention have been selected from a list of STIs that are commonly used within the epidemiological literature as proxies for risky sexual behavior, and that are known to be prevalent in the Kilombero/Ulanga districts. Participants will be tested for each of the following six STIs during the five rounds of STI testing: *Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium* [Round 1 testing was not possible]*, Treponema pallidum* (syphilis), and HSV-2 (herpes simplex II). Participants will not be tested for syphilis and HSV-2 in rounds 2 and 3. During the three cash payment rounds, participants in the treatment group will receive a cash payment of Tsh10,000 to Tsh20,000 each round when curable STI test results are negative (excluding Mycoplasma genitalium). Once participants test positive for HSV-2, they will not be tested for it again since it is a lifelong infection. Cash payments will only be conditional on HSV-2 status the first time they test positive.

We plan to test participants for HIV three times over the study period (baseline, month 12, and month 24) to measure the impact of the intervention on HIV incidence. These HIV tests are not part of the intervention *per se* because cash payments are **never** conditional on HIV status (meaning a participant may test positive for HIV and still be eligible to receive cash if all other STI test results are negative). Rather, the HIV tests are a biological measure for the overall RCT evaluation.

The battery of HIV/STI tests that we intend to use in the study have been selected to ensure that only minimally invasive procedures are needed for specimen collection, and that collection procedures can be easily performed by field staff.

HIV/STI pre-counseling

All study participants will be offered HIV/STI testing, based on the "three C's" (informed consent, counseling and confidentiality). This expanded HIV/STI pre-test counseling builds on the recommendations of the Tanzanian Ministry of Health and Social Welfare's National AIDS Control Programme and the World Health Organization. During pre-test counseling, the study counselor will describe the testing and post-test counseling process, discuss the confidentiality of testing and results, and individuals' right to decline testing. The counselor will provide information on HIV/AIDS and STIs in order to clarify misinformation and/or misconceptions, ensure that any decision to take the HIV/STI tests is informed and voluntary, and prepare the participant for a positive result. The counselor will also carry out a risk assessment, help the participant develop a risk prevention/reduction plan, and explore potential obstacles and problems that participants may encounter when implementing this plan. This will include the provision of male condoms, directions for use, and information on contraceptive and disease prevention efficacy. Thus, the pre-test counseling will address the following issues at a minimum:

- Knowledge of STIs, HIV/AIDS, and difference between HIV and AIDS
- Modes of transmission
- Advantages/disadvantages of knowing one's HIV status
- How the tests work, and what the possible results are
- Risk prevention/reduction assessment and plan, including condom demonstration

Participants will be asked to return to the study station during a specified period of time to receive their test results and post-test counseling (described in the "STI/HIV post-counseling" section below).

Specimen collection procedures

Each round of testing, participants will be asked to provide biological specimens that will be sent to the IHRDC laboratory for STI testing. All specimen collection will take place at the study station during the first visit of each study round. Specimens will be handled discreetly by study staff and will be labeled with a unique barcode to protect the confidentiality of study participants. Specimens will not be labeled with any information that directly identifies an individual participant.

Blood draw: A single venous blood sample of approximately 5-10 mL will be collected from each participant to test for syphilis, HSV-2, and HIV. We will have three certified phlebotomists as part of the field team to collect these samples. Blood-based tests will be conducted only at baseline, 12-month, and 24-month rounds. Again, the cash payments for the treatment group will **never** be conditional on the results of the HIV test(s). Once a participant tests positive for HSV-2, he/she will not be tested for HSV-2 again.

Vaginal swab sample (females only): Female participants will be asked to provide a self-administered vaginal swab sample for laboratory tests at each round. Participants will be asked to collect this sample in a private area of the study station, using a long "Q-tip" that easily inserts into the vagina. This type of specimen collection has been used successfully in numerous studies in Tanzania (ref) and in our own team's 2006 STI prevalence study in the Kilombero/Ulanga districts. Female research study staff will explain specimen collection procedures to participants, will provide participants a diagram showing how to collect the specimen, and will be available if the participant wishes to have assistance. This sample will be used to test for four STIs: Chlamydia, gonorrhea, *M. genitalium*, and trichomonas. Vaginal swab sampling is the preferred method of sample collection for women (vs. urine or cervical samples) because it has the highest diagnostic accuracy in women and it is the easiest to collect in the field.

Urine sample (males only): Male participants will be asked to give a small sample of "first-catch urine" (about 20-30 mL) for laboratory tests each round. Male participants will be asked to not urinate for at least one hour before giving the sample. This sample will be used to test for four STIs: Chlamydia, gonorrhea, *M. genitalium*, and trichomonas.

Laboratory testing methods
All samples will be sent to the microbiology laboratory at IHRDC in Ifakara for testing. For efficiency/cost savings, we will first use pooled testing of samples, then retesting individuals' samples in those pools that indicate positive results. All test results will be available within 7-10 days and will be returned to participants the following week. Ten percent of all samples, and a subset of positives, will be sent to the University of California Chlamydia Laboratory for confirmation analysis.

Urine samples and self-collected vaginal swabs will be tested for Chlamydia, gonorrhea, *M. genitalium*, and trichomonas. Detection of these organisms will be done with the GenProbe Aptima (GenProbe Inc, San Diego, CA) assays. These nucleic acid amplified tests (NAATs) have been extensively evaluated, and are considered the most sensitive and specific NAATs available. The methodology involves target capture of specific rRNA, transcription mediated amplification, and end detection of amplicons with hybridized probes using chemiluminescence. The AC2 assay simultaneously detects CT and NG, whereas the MG and TV assays are individual analyte specific reagents (ASR). These assays have a turnaround time of 4 hrs. NAAT specimens can be pooled for testing in low-prevalence settings. We anticipate the use of a pooling protocol for some of the NAATs.

Blood specimens will be tested for herpes simplex II virus (HSV-2), *T. pallidum* (syphilis), and HIV. For HSV-2, we will use the Focus HerpeSelect HSV-2 ELISA IgG assay (Focus Technologies, Cypress, CA) to detect serum antibodies. This is a FDA approved ELISA that utilizes purified HSV recombinant glycoprotein G2 antigens immobilized on polystyrene microwells. Higher cut points needed for sera from Africa will be used. Positive results do not distinguish between active or past infection. *T. pallidum* will be identified using RPR with reactive tests confirmed by TPPA . Active syphilis is defined as RPR+/TPPA+. For HIV, we will use rapid test for initial results, confirmation of positives, and tie-breaking.

For each participant, specimens will be labeled with a dated barcode that will link their samples (and test results) to their study identification code in the laboratory computer database. All laboratory test results will be stored in a password-protected database on a computer in the laboratory, separate from all other study data. The laboratory test result reports will be automatically generated (using standard laboratory management software) for each study participant once all tests have been completed for their village in a given round. These reports will then be double-checked by laboratory staff for accuracy and then returned to study participants in a standardized format.

As part of the accuracy checking of STI result reports generated for study participants, several procedures have been implemented:

- The computer programs that translate results into reports have been extensively bug-checked.
- The data entry interface has been modified so as to reduce the possibility of results being entered into incorrect fields, and also to prevent invalid responses (such as blank spaces) from being entered.
- In addition to lab staff double-checking any data entry for accuracy, the lab director must hand-check every positive report against a raw printout of lab results, and sign a flow sheet each time he does so.
- The local Ifakara director of the Ifakara Health Institute will spot-check the result printouts for study participants against raw result printouts. This will be done prior to results being delivered to subjects each week.

HIV/STI post-counseling
Participants will be asked to return to the study station at a specified time to receive their test results and HIV/STI post-test counseling. A trained study counselor will return the results to the participant in a private, soundproof area of the study station. Post-test counseling will differ depending on whether the result is negative or positive. However, all post-test counseling will contain the following core elements:

- Confirmation of participant's readiness to receive the HIV/STI test result

- Provision of HIV/STI test results and time for reflection.
- Assessment of individual's comprehension of results and additional explanation if necessary.
- Discussion of support system.
- Discussion of partner testing and notification.
- Explanation of active measures for staying healthy (remaining negative/avoiding re-infection and transmission of STI/HIV to others)
- Referrals for additional counseling and support

Counselors will describe the window period and the importance of repeated testing as well as following the risk reduction plan for individuals who test negative for HIV/STIs. With participants who test positive, emphasis will be placed on helping the individual cope with the test result, determining sources of social support and arranging for appropriate referrals. The importance of seeking treatment – and completing treatment – will also be emphasized to ensure that those who test positive have the opportunity to test negative in the next round.

Distribution of cash payment

Following post-counseling, those participants in the treatment group who tested negative for all conditional STIs will receive their conditional-cash payment in envelope from a study staff person (who is not their counselor). The Tsh 2,500 (about $2) inconvenience fee will be given to the participant in the same envelope. Participants who test positive for one or more STIs will not receive a conditional cash payment for that round. The participant will still receive the Tsh 2,500 inconvenience fee in an envelope from a study staff person.

CCT cash payments will only be distributed during Rounds 2, 3, and 4 (or study month 4, 8, and 12). These cash payments will serve to reward safe sexual behavior that occurred in the interval since the last test.

Lottery prizes

Control group participants who report to the study station and complete their interview at rounds 2, 3, and 4 will be eligible for a prize drawing, determined by lottery. Treatment group participants will also be eligible as long as they have tested negative for all rewarded STIs that round. All participants reporting for the interview at round 5 will be eligible for a lottery as well, regardless of their STI status. The prizes will be Tsh100,000, given to one man and one woman in each village in each round (about 1 in 150 chance of winning during each round).

Treatment of STIs

All study participants testing positive for any STI will be offered free treatment and counseling for the condition. The treatment will be administered by the health staff at the nearest health facility, and will be equivalent to the national standard of care – syndromic management of STIs. Treatment kits are provided free of charge to health facilities, but the study team will provide extras to ensure that there are sufficient kits in-stock to treat the study population.

Participants who test positive for an STI during the study will be provided with 2 vouchers (one for participant and one for them to give to a sexual partner) for free treatment at the local health clinic, to be used within one month. For confidentiality purposes, the vouchers will not include their name or name of the STI; it will contain a coded indicator of STI for use by clinic personnel. In order for treatment group participants to be eligible for rewards in the next round, they must have reported to the clinic for treatment of their STIs.

We will work with the local health centers to ensure that 1) adequate supplies of the first -line drugs are available onsite to treat the STIs included in this study; 2) the drugs will be provided free of charge to study participants; and 3) their staff members are prepared to provide STI counseling services to any study participant that requests it. The research team will prepare and provide a short refresher course on STI counseling and treatment to the local health staff.

Participants testing positive for HIV will be referred to the Chronic Disease Clinic based at St. Francis Hospital for further evaluation. This clinic provides free testing and treatment to HIV positives. Participants who are HIV positive will be permitted to remain enrolled in our study should they so choose.

Group-based counseling program

The psycho-social counseling involves a group-based program that uses participatory learning approaches such as critical reflection, role plays and drama to promote gender-equitable relationships and encourage deliberate decision-making in sexual and reproductive health (specifically, the prevention of HIV, other STIs, and unintended pregnancy). The intervention is based on Stepping Stones, a curriculum focused on gender, HIV, communication and relationship skills that addresses why people behave in the ways they do, and how to change behavior. This curriculum has been used in over 40 countries (including Tanzania) and translated into at least 13 languages.

The intervention consists of 12 monthly group sessions, each lasting approximately two hours that bring together 20-30 participants of the same sex and similar age for structured group discussions facilitated by trained study staff. It will begin with a set of activities designed to foster comfort and trust within the group and establish ground rules for the remaining sessions. Subsequent sessions will address sexual health, HIV, and STIs, gender norms and expectations; explore why people behave the way they do; and facilitate and support behavior change. Principles of confidentiality will be explained at the launch of the intervention and reinforced throughout. We will emphasize that the study will not reveal personally identifying/identified information and request participants to also maintain confidentiality. The intervention sessions will be conducted in each community in a private, confidential space. We will provide reminders about these sessions to a randomly chosen half of study participants.

DATA COLLECTION PROCEDURES

Data collection for the primary research questions will occur in conjunction with implementation of the intervention, with a few separate data collection activities involving subgroups of participants. Although we will use STI biological markers as our primary impact measure for the study, we will also gather additional information on participants, such as survey responses about sexual behavior using indicators and scales that have been validated in the epidemiologic and behavioral social science literatures. Because we will be working in partnership with our Tanzanian colleagues at IHRDC, we will have access to further socio-demographic data collected on individuals and households in the DSS research area.

Biological markers of risky sexual behavior

The same biological markers/STIs monitored as part of the intervention will be used in the study evaluation as well (described below). In addition, we will test for HIV at baseline, month 12, and month 24 so that we have a measure of the study's impact on HIV, as well as additional outcome measures. The conditional-cash payments in the intervention will never be conditional on HIV test results.

Surveys and interviews

All study participants will be interviewed five times as part of the main study. Study counselors will conduct one-on-one interviews with study participants during each study round using structured questionnaires. All questionnaires will be written and read aloud in the local language (Kiswahili) and will be administered in a private, soundproof area of the study station. Since some participants may feel uncomfortable responding to sensitive survey questions aloud, participants may respond to sensitive questions using non-verbal cues (pointing, nodding, etc.).

Baseline survey**:** During the first visit to the study station at baseline, study counselors will interview all participants using a structured baseline questionnaire. Participants will be asked a series of questions regarding demographics, sexual behavior, economic activity, knowledge and beliefs about HIV & STIs, etc. during a face-to-face interview with a study counselor. This baseline survey will take about one hour to complete.

Short surveys**:** During the 4-month and 8-month intervention rounds (Rounds 2-3), study counselors will interview all participants using a structured short questionnaire. This short survey will take 10-15 minutes to complete and will contain questions that enable us to monitor for adverse events (e.g., reported physical abuse) or study implementation problems (e.g., STI treatment availability) as well as changes in sexual behavior and economic activity.

Follow-up survey**:** During the 12-month and 24-month follow-up rounds, study counselors will interview all participants using a structured follow-up questionnaire. Participants will be asked a series of questions similar to those asked at baseline regarding sexual behavior, economic activity, knowledge and beliefs about HIV & STIs, etc. This follow-up survey will take about one hour to complete.

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Some study participants may be asked to participate in additional surveys or interviews that are being conducted to provide additional insights into this study. The possible activities include the following:

Linking to existing DSS: Because we will be working in partnership with our Tanzanian colleagues at IHRDC, we will have access to socio-demographic data collected on individuals and households in the DSS research area. We will link existing DSS data with the data collected for this study in order to add information about the socio-demographic background and history. The main study informed consent form contains a place where participants can agree to allow us to access and utilize their DSS data. Data from the DSS will not be linked for those participants not providing consent.

Supplemental study of economic attitudes: A subset of participants may be invited to participate in a sub-study to learn more about participants' attitudes towards risk, the future and trust. At the round 3 visits participants would be invited to respond to a supplemental questionnaire, and then participate in games in which they would be eligible for small payments. If this activity is undertaken then an IRB amendment will be submitted to approve exact study details.

CHRONOLOGY OF INTERVENTION & STUDY PROCEDURES

Round 1 – Baseline

Study station visit #1 (week 1) Total participant time: ~2.5 hours

- Informed consent for main study
- Enrollment for main study
- Baseline questionnaire
- HIV/STI pre-test counseling
- Specimen collection for STI/HIV testing (blood and urine/vaginal swab)
- Randomization
- Inconvenience fee payment

Laboratory testing (weeks 1-3) Total participant time: 0

- Blood samples (HIV, syphilis, and HSV-2)
- Urine/vaginal swab samples (Chlamydia, gonorrhea, *M. gen*, and trichomonas)

Group counseling sessions (once per month) Total participant time: 8 hours

Study station visit #2 (week 4) Total participant time: ~1 hours

- Laboratory test result distribution
- HIV/STI post-test counseling
- Inconvenience fee payment

Round 2 – Month 4

Group counseling sessions (once per month) Total participant time: 8 hours

Study station visit #1 (week 1) Total participant time: ~1 hour

- Short questionnaire

- STI pre-test counseling
- Specimen collection for STI testing (urine/vaginal swab)
- Inconvenience fee payment

Laboratory testing (weeks 1-2)
- Urine/vaginal swab samples (Chlamydia, gonorrhea, *M. gen*, and trichomonas)

Study station visit #2 (week 3) Total participant time: ~1 hour
- Laboratory test result distribution
- STI post-test counseling
- Cash reward payment
- Inconvenience fee payment

Round 3 – Month 8

Group counseling sessions (once per month) Total participant time: 8 hours

Study station visit #1 (week 1) Total participant time: ~1 hour
- Short questionnaire
- STI pre-test counseling
- Specimen collection for STI testing (urine/vaginal swab)
- Inconvenience fee payment

Laboratory testing (weeks 1-2)
- Urine/vaginal swab samples (Chlamydia, gonorrhea, *M. gen*, and trichomonas)

Study station visit #2 (week 3) Total participant time: ~1 hour
- Laboratory test result distribution
- STI post-test counseling
- Cash reward payment
- Inconvenience fee payment

Round 4 – Month 12

Group counseling sessions (once per month) Total participant time: 8 hours

Study station visit #1 (week 1) Total participant time: ~1.5 hours
- Follow-up questionnaire
- HIV/STI pre-test counseling
- Specimen collection for STI/HIV testing (blood and urine/vaginal swab)
- Inconvenience fee payment

Laboratory testing (weeks 1-3)
- Urine/vaginal swab samples (Chlamydia, gonorrhea, *M. gen*, and trichomonas)
- Blood samples (HIV, syphilis, and HSV-2)

Study station visit #2 (week 3 or 4) Total participant time: ~1 hour
- Laboratory test result distribution
- HIV/STI post-test counseling
- Cash reward payment
- Inconvenience fee payment

Round 5 – Month 24

Study station visit #1 (week 1) Total participant time: ~1.5 hours

- Follow-up questionnaire
- HIV/STI pre-test counseling
- Specimen collection for STI/HIV testing (blood and urine/vaginal swab)
- Inconvenience fee payment

Laboratory testing (weeks 1-3)

- Urine/vaginal swab samples (Chlamydia, gonorrhea, *M. gen*, and trichomonas)
- Blood samples (HIV, syphilis, and HSV-2)

Study station visit #2 (week 3 or 4) Total participant time: ~1 hour

- Laboratory test result distribution
- HIV/STI post-test counseling
- Inconvenience fee payment

Qualitative sub-study

We will conduct one-on-one in-depth interviews during which we will ask open-ended questions using an interview guide. Interviews will be conducted in Swahili by a Tanzanian trained in qualitative interviewing techniques.

After participants are enrolled at baseline, provide their initial lab tests, and complete the quantitative survey, a small sub-set of participants will be asked if they would be willing to participate in an in-depth interview, to take place twice during the duration of the study. The first interview will be scheduled 1-3 weeks after enrollment.

Interviews in later rounds will take place just after the STI results have been given to participants. In addition to the original participants, five interviews will be recruited at round 2 who tested positive and therefore will not receive their conditional cash transfer. These five additional people will be asked to participate in the in-depth interviews at the time they receive their test results, and will be consented at the time of the in-depth interview.

Structure and Content of Interviews
All interviews will be conducted in Swahili by trained Tanzanian interviewers hired for the purposes of this study. Interviews will be recorded with an audio tape recorder, transcribed in Swahili, and then translated into English. Participants consenting to the in-depth interviews will set up an appointment with the study interviewer. The interviews will take approximately 45 to 60 minutes. Participants will be compensated approximately $3 (Tsh 3,000) for their time at each interview.

While the questions asked during the in-depth interview will be open-ended, an interview guide will be followed to ensure that all the relevant topic areas are covered in each interview. The qualitative data collection will focus mainly on how the cash incentive fits in with life decisions and life plans of men and women in rural Tanzania and what strategies men and women in rural Tanzania believe will be effective and plan to use in an effort to avoid infection with STIs or HIV.

Qualitative monitoring with Conversational Journals

Using a methodology developed by Watkins and Swidler termed conversational journals, we will hire ten diarists (one in each study community) who are “cultural insiders” the communities in which the CCT trial is taking place. Swidler and Watkins have very successfully used this method as part of their HIV research in Malawi (Swidler and Watkins; Tavory and Swidler). Conversational journals provide a method to get at interpretation and meaning not just at the individual level, but at more collective level, and to capture the dynamic nature of meaning and interpretation on a daily basis. Text from journals kept by the hired “cultural insiders” journaling the details of conversations that they overhear or participate in will be analyzed to try to get at interpretation and meaning.

In the context of the RCT, journalists will be instructed to capture all conversations and events that relate to the study, the researchers, the incentive, and sexual behavior and partnerships generally. Data collected from the conversational journals will not include names or identifying information of anyone that the diarists are writing about. If the diarists mistakenly include names in their notebooks, names will be redacted upon review of the journals.

Round 4 Control Group ("Control-R4")

The Control-R4 sample group will be enrolled for only one round of the study (round 4), thus for only 3 weeks. During that round, study procedures for recruitment, enrollment, and informed consent will be identical to those at round 1 for the main sample described elsewhere (note that since all are enrolled in the same group, there will be no randomization step). After informed consent, the round 4 procedures for the Control-R4 group will be identical to those described above for the main control group (Control-R1):

- As described in the Section 7 Overview above, the Control-R4 participants will have two visits to the study station. At the initial enrolment visit they will complete a 30-minute interview, have individual pre-test counseling, and provide a blood and urine sample. At the second visit 2-3 weeks later they will receive their test results, post-test counseling, and free treatment vouchers.
- The pre and post-test counseling will be identical to that described above (the group counseling sessions in the village will have finished by round 4, so Control-R4 participants will not be involved in any group counseling).
- The blood and urine specimen collection procedures will be identical to those described above.
- The STIs tested for will be identical to those listed above at round 4 (including HIV).
- The laboratory testing procedures will be identical to those described above.
- The inconvenience fees and inclusion in the lottery will be identical to those described above for control group enrollees.
- Free STI treatment vouchers will be identical to that described above.
- The round 4 survey questionnaire for the Control-R4 enrollees will be identical to that used for the main study enrollees at round 4 (except that sections U and W will be omitted for the Control-R4 enrollees, as indicated by the questionnaire skip patterns).
- Control-R4 enrollees will not be invited to participate in any supplemental studies (such as qualitative sub-study).

Description of locations for intervention/study activities

Enrollment, STI testing, basic counseling, and surveys

'Study stations' will be temporary structures set up in each village that will serve as the location where intervention/study activities take place, including enrollment, specimen collection, test result and cash payment distribution, survey administration, etc. Dedicated areas will be set up within the stations that allow for privacy during specimen collection, results distribution and counseling, and survey administration. These stations will be conveniently located within each village and will be open hours that are respectful of school, employment, and other commitments. Home visits will only occur when participants fail to appear at the study station during their designated week (permission to follow-up in the home will be obtained from participants at the outset of the study). All of these strategies are in place to minimize pulling participants away from productive pursuits as well as maintain their privacy. Note the study stations will move with the field teams from village-to-village and will only be set up in each site for 2 weeks per round (one week for specimen collection and one week for results distribution).

Group counseling sessions

The intervention sessions will be conducted in each community in a private, confidential space (either a community facility or a private house, depending on what is available in a given community).

Study personnel and time

Time

Please see the time estimates for each of the study procedures listed in the chronology above. Twenty-four of these hours are spent in the group counseling sessions. Still, no more than 3.5 hours of study activities per month will ever be required.

Personnel
Please see the study procedure details above for specific listings of personnel to be involved. Here, we provide more detail about the personnel that is interacting with participants.

Phlebotomists: We will hire phlebotomists who have been certified by national authorities in Tanzania to conduct the blood draws.

Study counselors: We will hire individuals who are certified VCT counselors through Tanzania's National HIV/AIDS Programme to serve as study counselors in this study. This certification ensures that study counselors are knowledgeable about HIV/AIDS counseling and testing procedures in the Tanzanian context. Study counselors will receive additional training through this study to enable them to effectively counsel participants through the specific study-related issues. Study counselors will also facilitate group counseling sessions.

Fieldworkers / Interviewers: We will hire experienced fieldworkers/interviewers to assist with questionnaire administration and specimen processing in the field.

Laboratory staff: The microbiology laboratory staff at IHRDC, managed by Boniphace Jullu, has extensive experience in processing biological samples for large randomized trials. The lab has effective procedures in place to for maintaining participant confidentiality for all specimens.

Qualitative sub-study
Interviews will be conducted in Swahili by a Tanzanian trained in qualitative interviewing techniques.

Conversational diarists
Ten local community residents (each in a separate study village) will be hired to anonymously record conversations overheard in the village regarding the study. The interviewers will undergo training in appropriate techniques for recording data and ensuring confidentiality of the anonymous conversations recorded.

Round 4 Control Group ("Control-R4")
The Control-R4 study activities will take place at the same study station as for the main enrollees, during the same weeks, with the same study personnel. We anticipate that the initial visit will take approximately 2 hours, and the second visit to pick up results will take less than one hour.

Data Collection Instruments:

Main study

Baseline survey: During the first visit to the study station at baseline, study counselors will interview all participants using a structured baseline questionnaire. Participants will be asked a series of questions regarding demographics, sexual behavior, economic activity, knowledge and beliefs about HIV & STIs, etc. during a face-to-face interview with a study counselor.

Short surveys: During the 4-month and 8-month intervention rounds (Rounds 2-3), study counselors will interview all participants using a structured short questionnaire. This short survey will take 10-15 minutes to complete and will contain questions that enable us to monitor for adverse events (e.g., reported physical abuse) or study implementation problems (e.g., STI treatment availability) as well as changes in sexual behavior and economic activity.

Follow-up surveys: During the 12-month and 24-month follow-up rounds, study counselors will interview all participants using a structured follow-up questionnaire. Participants will be asked a series of questions similar to

those asked at baseline regarding sexual behavior, economic activity, knowledge and beliefs about HIV and STIs, etc.

Qualitative sub-study
While the questions asked during the in-depth interview will be open-ended, an interview guide will be followed to ensure that all the relevant topic areas are covered in each interview. The qualitative data collection will focus mainly on sexual reproductive health decision-making and the influence that additional income might have on the decision-making process.

Round 4 Control Group ("Control-R4")
The round 4 survey questionnaire for the Control-R4 enrollees will be identical to that used for the main study enrollees at round 4 (except that sections U and W will be omitted for the Control-R4 enrollees, as indicated by the questionnaire skip patterns).

Identifiable Personal Information

Main study and Control-R4 sample
Identifiable personal information will be collected in this study in the form of photos and names of study participants. These photos and names will only be used to verify the identity of study participants when they come to the study station to provide a specimen, pick up results, and/or pick up cash payments. The photos and names will be stored in a password-protected computer database that will not be directly connected to any other databases containing study-related data.

Qualitative sub-study
Identifiable personal information will be collected in this study in the form of audio tape-recorded interviews. The audio tapes will not include the names of the participant; the interview will be identified on the tape recording by the participant's study identification number.

SECTION 6: RISKS/DISCOMFORTS

Main study and Control-R4 sample

STI testing and treatment

Specimen collection
The specimen collection methods for HIV and STI testing used in this study are well-established and are in routine use across the world. Nonetheless, there are some physical, psychological, and social risks associated with these testing procedures that we must prepare for.

Physical risks
i) There is a chance that a participant may experience mild amount of pain during the blood draw or may feel dizzy following the blood draw. Light bruising at the site of the blood draw is also possible.

Trained phlebotomists will conduct the blood draws, using standard techniques to minimize pain and bruising as well as dizziness and other common responses. Since the volume of blood being collected is relatively small (only 5-10 mL), few participants are expected to experience dizziness. Juice will be available at the study station during blood draws to help any participant feeling dizzy recover. Any participant feeling dizzy will be encouraged to remain seated until they are feeling better.

ii) There is a very slight chance that needles or other specimen collection materials could be improperly handled and put participants and study staff at risk of a variety of infections.

All specimens will be collected with unused, sterile supplies. Needles will be disposed of in an appropriate 'sharps' container and swabs and urine cups will be properly disposed of immediately after processing. All study staff involved in specimen collection will be trained on the proper handling of collection materials.

iii) There are no known physical risks associated with the collection of samples from self-administered vaginal swabs or from urine. Hand sanitizer will be available for participants to wash up after collecting their own specimens.

Psychological and social risks

i) There is a chance that a participant will feel anxious about being tested for HIV and STIs.

It is common for people to feel anxious because of fear of the potential illness itself (HIV, in particular), fear of abandonment or divorce if found to be positive, fear of abuse within a relationship if found to be positive, or fear of being stigmatized in one's community.

During pre- and post-counseling, counselors will help participants think through responses to such possibilities to reduce anxiety (e.g., identify the support systems that exist in a participant's life that can help them respond to such possibilities, etc.). Counselors will review the meaning of each test and the range of possible test results. In the rare case that a participant is concerned about her own safety following HIV/STI testing, counselors will connect the participant with the local services for dealing with such domestic violence matters.

ii) Some participants may experience discomfort or anxiety during the specimen collection procedures

Female participants may be uncomfortable with collecting a vaginal swab specimen. Female study staff members will review collection instructions with participants, and will have actual sampling supplies as well as instruction sheets with simple diagrams available for facilitating communication. A private area will be set aside in the study station for female participants to collect these samples. To ensure complete privacy, only one participant will be allowed in at a time.

Some participants may be uncomfortable with needles and blood draws. The phlebotomists have also been trained on appropriate ways to work with clients who have such concerns.

Physical risks

i) There is a very small chance that a participant who is truly positive for HIV or another STI receives a test result indicating they are negative. Such a false negative result could delay treatment for the infected participant, prolonging the infection and any associated discomfort. A false negative result could also put future sexual partners of the participant at risk of acquiring the infection.

For each of the diagnostic methods we will be using, false negatives are unlikely.

ii) There is also a very small chance that a participant who is truly negative for HIV or another STI receives a test result indicating they are positive. Such a false positive result could lead to a participant unnecessarily receiving treatment for an STI they do not have.

For each of the diagnostic methods we will be using, false positives are unlikely. The testing protocols that we are using for HIV and syphilis already require that all positives undergo a confirmation test before results can be returned to study participants. Such confirmation testing significantly decreases the possibility of false positive results.

If a false positive result is not detected and a participant is treated unnecessarily, it is unlikely that the treatment itself will cause anything more than mild discomfort to the participant.

iii) Participants who receive false positive results face the same risks as participants who receive truly positive results.

Psychological and social risks
i) Psychological/social risks of false negatives.

ii) Participants who receive false positive results face the same risks as participants who receive truly positive results. Participants who receive false positive results, however, face additional psychological and social risks.

HIV/STI testing – results reporting
Despite the benefits to participants' learning their HIV/STI status, participants will face certain risks once their HIV/STI status is known.

Physical risks
i) There is a small chance that participants could experience physical abuse in their home – by a partner, a parent, or another household member – when their HIV/STI status becomes known.

Physical abuse of individuals within households following HIV/STI testing does occur, particularly against women, when their HIV/STI becomes known. This has been shown to occur when HIV/STI results are either positive or negative. Physical abuse occurs most often when the results indicate a couple is discordant or when the status of one partner is unknown but the other is positive (typically the women is known and the man is unknown)

We will respond to the risk of such abuse in a number of ways. First, counselors will monitor for physical abuse of participants by 'formally' asking participants about such events in the short survey during each round of testing. In these sessions, counselors will also informally discuss how safe the participant feels at home. If there is any indication that study activities are resulting in physical abuse of a participant, the counselor will contact the study coordinator for consultation. Counselors will also help participants think through strategies for preventing or diffusing test-result-associated abuse during pre- and post-counseling.

Psychological/social risks
i) There is a small chance that participants could be abandoned – by a partner (divorce) or a parent – when their HIV/STI status becomes known.

ii) It is very likely that participants who test positive for HIV or an STI could feel anxious about notifying their partner(s) of their HIV/STI status.

iii) There is a chance that participants who test positive for HIV or an STI could feel guilty about having HIV or an STI.

HIV/STI testing – STI test results as an indicator of risky sexual behavior
i) There is a risk of treatment failure in participants who sought out treatment for any one of the treatable STIs. Treatment failure could occur because of poor patient compliance with the treatment regimen, pathogen resistance to the available treatment, unanticipated interaction with other medications, or other causes.

If a participant experiences treatment failure, he/she may test positive in a second round of testing even if he/she has not engaged in risky sex during that period. If a participant tests positive again after having already sought treatment for a given STI (and possibly not engaging in risky sex), a repeat positive test result may warp their association between STI acquisition and risky sexual practices.

ii) There is a risk that some participants may engage in risky sexual behavior but not get 'caught' because they do not 'catch' an STI during their risky encounters, and then become overconfident of their ability to avoid STIs.

iii) There is a small risk that participants may try to self-treat for STIs prior to STI testing if they have had risky sexual contact and wish to "cover it up". This could lead to unnecessary treatment.

HIV/STI testing - diagnostics

We will use among the most accurate diagnostic methods to test for HIV and STIs that are available for routine use. These laboratory-based techniques are well-established and are the standard diagnostic techniques used in the U.S., Europe, and across the world. Nonetheless, there are some physical, psychological, and social risks associated with such testing that we must prepare for.

The primary risks associated with diagnosing HIV and STIs are related to the possibility of false positive and/or false negative test results. A false positive test result means that a specimen is truly negative, but identified as positive by the diagnostic test. A false negative test result means that a specimen is truly positive, but identified as negative by the diagnostic test.

Risks unique to the treatment group

Physical risks

i*) It is possible that the intervention could exacerbate existing power imbalances in couples, leading to domestic violence*, as pressure on the couple increases to change their patterns of sexual activity. If the cash reward was expected by the parent or partner but was not received due to a positive test result, the study participant could be vulnerable to violence. Violence could also erupt if a disagreement arises over who controls the study-related money (i.e., who gets to decide how the money is spent).

We will respond to the risk of such abuse in the same ways as listed above for the abuse stemming from HIV/STI test result reporting.

ii) It is possible that participants who receive cash payments may use the money from one round of testing (assuming they are not "caught" and test negative on the battery of tests conducted) to engage in more activities which involve physical risks (purchasing sex, alcohol or drugs, etc.).

If such behavior does result, we believe the likelihood of recurrence is low. Frequent STI testing can help 'catch' any participant that has become infected during such activities and can discourage such activities in the future by withholding cash payments. Throughout the study, participants will be reminded that the intention of the cash is to reward safe sexual behaviors, and that negative test results are no guarantee that they will not become infected if they continue to engage in risky behaviors.

iii) A few participants who do not receive a cash payment because of positive results may seek out alternate ways of obtaining/earning cash in order to deliver the cash expected by household members. Such alternate ways may involve commercial sex work, stealing, or other risky enterprises.

We will respond to the risk of such abuse in the same ways as listed above for the abuse stemming from HIV/STI test result reporting.

iv) Small risk that participants could be targeted (e.g., robbery, theft) because of the cash.

Psychological/social risks

i) Feel a loss of privacy.
ii) Create conflict and tension in the household that does not lead to physical abuse.
iii) Feel that the cash creates a sense of coercion to engage in certain behaviors.

Qualitative sub-study

The primary potential risk to subjects is a loss of confidentiality with regard to interview responses, HIV status, or identity and the impact of discussing sensitive subject matter about HIV status, partner's HIV status, the decision to have or not to have children, and power dynamics in sexual relationships. We will minimize this risk

by performing initial and follow-up training of staff to ensure understanding of ethical issues in this type of research and the procedures to minimize risk. Additionally, in an effort to prevent negative impacts of discussing these sensitive issues, the interviewer will preface this set of questions as potentially sensitive and remind participants that they are under no obligation to answer and can feel free to stop the interview at any time. The participant may feel threatened by the interviewer. Every effort will be made to ensure that the participant is comfortable in the interview situation, and if the participant is uncomfortable at any point, the interview will be stopped. The interviews will be audio tape-recorded. As this is considered identifiable information, there is an associated confidentiality risk to the participant. Every effort will be made to protect the confidentiality of the participant. No names or other identifiable information will be included in the audio recording—only the study identification number will be used.

SECTION 7: BENEFITS

Main study

Individuals who choose to participate in the study will benefit in a variety of ways, independent of their group assignment.

- Participants will have five opportunities to learn whether or not they are infected with HIV or STIs. They will be tested using the best, most accurate tests that are available.
- Participants who are found to be infected with one or more of the treatable STIs (CT, GC, syphilis, M.Gen, and trich) will receive free treatment that will cure them of the infection. Participants whose test results indicate that they are infected with HIV will be referred to the VCT clinic for further evaluation. The VCT clinic only provides testing, and then refers the positives to the Chronic Care Clinic run out of the district hospital. All HIV positives are regularly monitored for CD4 count and viral load. Note that the VCT clinic provides free treatment to all HIV-positive individuals, but may not begin treatment until a patient has passed a specific clinic stage of disease.
- Free condoms will be available to all participants each time they visit the study station
- Participants will have access to trained counselors who will assist with any questions or concerns participants may have about this testing, their sexual health, etc.

Participants in the cash groups will have the opportunity to benefit from this study in other ways.

- Increase household income by up to $60 over the one-year study (note that this is included here because the cash incentives at the heart of the CCT intervention are not compensating participants for their time in the study; rather they are incentives for rewarding positive behavior change)
- Gain more control over household spending decisions
- If this intervention is effective, some participants in the treatment group will gain skills and capacity to exert control over the conditions under which sexual activity occurs.

Participants receiving the group-counseling portion of the intervention

- Will learn more about sexual health and will gain communication and relationship skills through participating in the group discussions.

Qualitative sub-study

The individual participants will not directly benefit from enrolling in the qualitative sub-study. The potential group-level and societal-level benefits of the qualitative research will be the design and implementation of a novel HIV prevention program in Tanzania guided and informed by the discussions and responses gathered during the in-depth interview process. Such an HIV prevention program may lead to better overall health in the community and greater access to economic resources for members of the community.

The risks posed to the subjects as part of the proposed qualitative sub-study are minimal and every precaution will be taken so that these risks are avoided as much as possible. The anticipated benefits that the members of community and Tanzanian society generally will receive over the long-term include improvement of overall quality of life as regards heath and economic outcomes for young women and men both regionally in the Kilombero/Ulanga Districts, and potentially nationally as well.

Importance of knowledge to be gained (main study and qualitative sub-study)

The knowledge that will be gained as a result of the proposed research includes a more complete understanding of how the conditional cash transfers provided for those who remain uninfected impact the behaviors and outcomes of participants, especially as regards sexual and reproductive health. In-depth interview transcripts will provide a more nuanced explanation as to why the cash transfers did or did not facilitate behavior change relating to risky sex as compared to those in the control group and will enable us to understand why an increase in income may or may not influence perceptions of risk, gender inequities and self-efficacy in sexual reproductive health decision-making, and the decision to engage in risky sex. This enhanced understanding will allow the eventual design of an improved HIV prevention program based on the results of both the qualitative sub-study and the larger cash reward study. Because the risks incurred by all study subjects are minimal, and the knowledge that will be gained by the responses provided in the in-depth interviews has the potential to greatly enhance the results of the quantitative data collection in the cash reward study and eventually guide and inform an HIV prevention program, the risks that the study subjects may be exposed to can be construed as reasonable. In addition, adequate warnings of the potential risks to study subjects and options for discontinuation of the interview and for skipping sensitive questions are available to all participants.

Round 4 Control Group ("Control-R4")

The Control-R4 sample is unique in that individuals are being recruited without any chance of being randomized to the original cash incentive treatment group. Despite this, these subjects are being offered significant benefits, with very low risk:

- They will have the opportunity to learn whether or not they are infected with HIV or STIs. They will be tested using the best, most accurate tests that are available. This is a significant benefit, because STI testing is not routinely available in the study villages; STIs are generally only treated syndromically. Furthermore, existing study participants have repeatedly expressed their appreciation for the opportunity to be tested for HIV through our study. Although HIV testing is sporadically available in these communities, it is typically conducted by a local health worker who lives in the study area, and participants have expressed concern about lack of confidentiality, thus often have been unwilling to be tested in the community. By contrast, since our study employs personnel from outside the area, subjects have expressed a high degree of interest in testing through our study.
- Participants who are found to be infected with one or more of the treatable STIs (CT, GC, syphilis, M.Gen, and trich) will receive free treatment that will cure them of the infection. Participants whose test results indicate that they are infected with HIV will be referred to the VCT clinic for further evaluation. The VCT clinic only provides testing, and then refers the positives to the Chronic Care Clinic run out of the district hospital. All HIV positives are regularly monitored for CD4 count and viral load. Note that the VCT clinic provides free treatment to all HIV-positive individuals, but may not begin treatment until a patient has passed a specific clinic stage of disease.
- Free condoms will be available to all participants each time they visit the study station
- Participants will have access to trained counselors who will assist with any questions or concerns participants may have about this testing, their sexual health, etc.

Importance of knowledge to be gained (Control-R4 sample)

The Control-R4 sample will allow testing of the effects of the extensive access to counseling, testing and treatment provided to Control-R1 subjects in the main study. The main study was designed to test the effects of cash rewards, over and above the effects of such counseling/testing/treatment, thus the Control-R1 group itself received extensive intervention. This Control-R1 intervention has so far included baseline, 4-month, and 8-month counseling/testing/treatment, as well as a year of monthly group counseling. This package of services to baseline participants is expected to result in decreased STI incidence based on prior research, but the extent of that prior research is limited, thus there is considerable scientific value in quantifying the STI benefits of this precise package of preventive efforts. The Control-R4 will serve as a comparison group to this Control-R1 group, allowing estimation of the STI improvement in Control-R1.

SECTION 8: ALTERNATIVES TO PARTICIPATION

Main study and Control-R4 sample
Prospective subjects may be diagnosed and treated for STIs through local public health facilities under the national policy of syndromic treatment. Since this approach involves STI treatment based on collections of symptoms rather than laboratory diagnoses, this means that only symptomatic STIs could be identified and treated under routine care. Laboratory diagnoses of STIs are not currently available in southern Tanzania.

Voluntary counseling and treatment (VCT) services for HIV/AIDS are available to all individuals living in the Kilombero/Ulanga district. The diagnostic and counseling approach adopted by our study corresponds to that provided by VCTs in the area.

There are no alternatives to the group counseling or the cash reward that are offered by our study for STI/HIV prevention activities. Since this study is fundamentally a prevention study, an appropriate alternative for prospective subjects is to simply do nothing.

SECTION 9: CONFIDENTIALITY

Main study and Control-R4 sample
Study participants will be identified by a unique and confidential study ID. Participant names will not be used on any study-related data or specimens, and the study team will follow all confidentiality procedures that are followed by the Ifakara investigators and field team involved in DSS research. Blood samples, vaginal swabs, and urine samples will be sent to the laboratory coded only with study numbers (via barcode) and date.

Information about participation in this study will remain confidential.

- All information collected in this study will be labeled with a unique 10-digit code. Names – or any other identifying information – will never be used on surveys, biological specimens, test results, or study reports. Only anonymized study-related information will be shared with researchers who are collaborating on the conduct of this study.

- The results of STI and HIV tests will be disclosed only to the participant and their counselor. Other study staff will have access to only anonymized results. The study team will not share laboratory test results with anyone, including partner(s) or parents or friends. In line with the National VCT Guidelines, participants who test positive for HIV or any STI will be urged to notify their partner(s) so they can also seek testing and treatment.

- The study team will also not share information regarding study group assignment (e.g., control group, high-value cash group, etc.) with anyone outside of the study team.

Qualitative sub-study
In order to protect against risks to privacy of individuals or confidentiality of data, no personal identifying information will be included in the audio recording of the interview. However, the audio recording in and of itself is considered identifiable information, and therefore every effort will be made to protect the confidentiality of the recordings and of the participant. The privacy and confidentiality of the patient will be protected in the following ways:

- The interviews will take place in a private area with only the research staff interviewer and the participant present to ensure confidentiality.
- In order to protect against risks of participants feeling uncomfortable being asked questions that are sensitive in nature, participants will be assured, both verbally during the interview and on the written consent form, that they are free to skip any question that they prefer not to answer, and that they are free to discontinue the interview at any time.

- All participants will be informed both verbally during the interview and in the printed consent form that their decision to leave this study will not affect the medical care they get now or in the future, and that their decision will not affect their ability to take part in other research studies.
- The name or other identifiable information of the participant will not be audio recorded or collected in any other way. Only the study identification number will be associated with the interview.
- If the participant, in the course of the interview, states any information that would allow their identification, this information will be removed during transcription of the interview.

Dworkin and Anke Ehrhardt, "Going Beyond "ABC" to Include "GEM": Critical Reflections on Progress in the HIV/AIDS Epidemic," American Journal of Public Health, January 2007, Vol. 97, No.1.

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[iii] Pronyk et al "Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomization trial."

[iv] (Tanzania Ministry of Health/NACP, 2005),

[v] (Source: technical presentation given by R. Urassa,