

Frequently Asked Questions

What is the STD YMSM study?

The STD Young Men who have Sex with Men (YMSM) study looks to understand how asymptomatic, rectal bacterial STD's may alter the mucosal environment of sexually active YMSM and influence HIV transmission.

Who is eligible for the study?

The population being studied for this protocol will be HIV negative or HIV positive YMSM (aged 18-24 years) in the following groups:

- Group 1: YMSM diagnosed with asymptomatic rectal gonorrhea (GC) that has not yet been treated.
- Group 2: YMSM diagnosed with asymptomatic rectal Chlamydia (CT) that has not yet been treated.
- Group 3: YMSM with secondary or early/latent syphilis that has not yet been treated
- Group 4: YMSM with no history of bacterial STD in the preceding 6 months

What are the inclusion criteria for this study?

Group 1

- Man who has sex with men aged 18-24 years
- Able to provide informed consent in English
- Diagnosis of asymptomatic rectal GC, untreated
- Willing to undergo peripheral blood and rectal biopsy sampling
- Willing to have STD treated at Hope Clinic as part of research study
- Willing to abstain from anal sex for 1 week after rectal biopsy procedure
- Willing to answer sexual behavior questions

Group 2

- Man who has sex with men aged 18-24 years
- Able to provide informed consent in English
- Diagnosis of asymptomatic rectal CT, untreated
- Willing to undergo peripheral blood and rectal biopsy sampling
- Willing to have STD treated at Hope Clinic as part of research study
- Willing to abstain from anal sex for 1 week after rectal biopsy procedure
- Willing to answer sexual behavior questions

Group 3

- Man who has sex with men aged 18-24 years
- Able to provide informed consent in English
- Diagnosis of secondary or early latent syphilis, untreated
- Willing to undergo peripheral blood and rectal biopsy sampling
- Willing to have STD treated at Hope Clinic as part of research study
- Willing to abstain from anal sex for 1 week after rectal biopsy procedure

- Willing to answer sexual behavior questions

Group 4

- Man who has sex with men aged 18-24 years
- Able to provide informed consent in English
- No history of STD per self-report x 6 months
- Willing to undergo peripheral blood and rectal biopsy sampling
- Willing to abstain from anal sex for 1 week after rectal biopsy procedure
- Willing to answer sexual behavior questions

What is a rectal biopsy and what are the risks?

Dr. Kelley or a nurse practitioner trained by Dr. Kelley will be performing all rectal biopsies with the assistance of the study coordinator. Prior to biopsy sampling, 1-2 swabs will be used to collect rectal secretions for GC and/or CT. Biopsy specimens about the size of a sunflower seed will be collected. As there are no pain nerves in the rectum (only stretch), most participants describe this process as uncomfortable, but not painful.

Common side effects of the rectal biopsy procedure are discomfort/irritation and the sensation of needing to pass stool, as well as limited bleeding for 1 to 3 days after the procedure. Infection and profuse bleeding are extremely rare complications of this procedure and could require further intervention, such as urgent endoscopy or hospitalization for antibiotic therapy. The risk of such difficulties is less than 1 in 5,000 each time the procedure is done. Having anal sex during the week following the biopsies can increase the risk of sexually transmitted diseases including HIV, and participants are asked to abstain from receptive anal intercourse for 1 week after the procedure. Of note, Dr. Kelley's team has performed >250 such procedures at the Hope Clinic with zero complications.

What will happen during study visit?

Visit 1: Eligibility will be determined, screening blood work and HIV test.

Visit 2: Bloodwork, Rectal Swab, rectal biopsy, and STD treatment. Visit 2 will be scheduled within 3-10 days from visit 1.

Is there compensation for participating?

Visit 1: participants will receive \$25 for completion of study visit

Visit 2: participants will receive \$125 for completion of study visit