

Frequently Asked Questions

What is the RAMS study?

Episodic receptive anal intercourse and mucosal susceptibility to HIV among MSM (RAMS) study looks to understand the immune effects on the rectum of abstinence, frequent receptive anal intercourse (RAI) with a condom, and frequent RAI without a condom in adult men who have sex with men (MSM).

Who is eligible for the study?

The population being studied for this protocol will be HIV negative aged 18-49 years who have sex with an HIV negative man in a monogamous relationship.

What are the inclusion criteria for this study?

- HIV Negative men 18-49
- Monogamous relationship with another HIV negative man for at least 45 days with no plans to terminate the relationship during the study
- Engaging in unprotected intercourse with ≥ 2 episodes in the previous month
- 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, and rectal biopsy. All men will be asked not to bottom or put anything in their rectum for 7 days after the biopsy procedure to allow time to heal. All men will also be instructed to have sex with a condom for 3 consecutive days before study visit 3 and to begin recording

when they bottomed at least 4 weeks prior to study visit 3. Visit 2 will be scheduled within 10 days to 8 weeks from visit 1.

Visit 3: Bloodwork, Rectal Swab, and rectal biopsy. All men will be asked not to bottom or put anything in their rectum for 7 days after the biopsy procedure to allow time to heal. All men will also be instructed to have sex without a condom for 3 consecutive days before study visit 4 and to begin recording when they bottomed at least 4 weeks prior to study visit 4. Visit 3 will be scheduled within 6-22 weeks from visit 2.

Visit 4: Bloodwork, Rectal Swab, and rectal biopsy. All men will be asked not to bottom or put anything in their rectum for 7 days after the biopsy procedure to allow time to heal. Visit 4 will be scheduled within 6-22 weeks 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

Visit 3: participants will receive \$125 for completion of study visit

Visit 4: participants will receive \$125 for completion of study visit