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Dynamic Reactivation of HSV-2 and the Genital Immune Response

-  Men and Women
-  Biopsy study
-  Blood draws

Purpose: The purpose of the study is to study the immune response to genital HSV-2 asymptomatic shedding and how that compares to the immune response to when a person experiences a clinical outbreak.

Study Visits and Procedures: The study will enroll men and women who are 18 years or older, test positive to HSV-2 (by blood test) and have had at least one genital herpes outbreak in the past year. Participants must be HIV negative.

This study is very time intensive. Involvement in the study will last for one year, some participants involvement will only last one month. The study is divided into 2 phases, the Swabbing Phase and the Outbreak Phase.

During the Swabbing Phase, participants will come to clinic 5 days a week (Monday through Friday) for 30 days. At each visit multiple, site specific genital swabs (up to 22 swabs per subject) will be collected from the genital area. The swabs will be sent to the lab for testing for HSV DNA. If one of the swabs is positive for HSV DNA, the participant will be asked to return to the clinic for a biopsy of the positive site. Participants will then be asked to return to the clinic 6 weeks, 12 weeks and 24 weeks after the biopsy for a repeat biopsy of the same site.

During the Outbreak Phase, subjects will be followed for up to one year for a genital herpes outbreak. When a participant experiences an outbreak, they will be asked to come in to clinic as soon as the outbreak is noticed. A biopsy will be obtained that same day and again at 6 weeks, 12 weeks, and 24 weeks after the initial biopsy.

<i>We Need:</i>	<i>We Provide:</i>
<ul style="list-style-type: none"> • Men and women age 18 to 65 • History of symptomatic genital herpes outbreaks, with at least one outbreak in the past year • HIV-negative • Women cannot be pregnant or planning to become pregnant, and must use birth control throughout duration of study 	<ul style="list-style-type: none"> • HSV and HIV testing • \$50 per biopsy and \$50 at the end of the “swabbing” phase



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