



Dear Step study participant,

This letter is to inform you that further vaccinations in the Step study have been stopped.

Like many clinical trials, our study is monitored by a Data & Safety Monitoring Board (DSMB). This board is a committee of clinical trial experts, statisticians and ethicists. Review by the DSMB is a regular part of clinical trial monitoring and its members see data that shows who is receiving study vaccine and who is receiving placebo.

At a planned meeting on 18 September 2007, the DSMB for the Step study reviewed data from the study and concluded that the study would not be able to show efficacy of the vaccine. The DSMB therefore recommended that further vaccinations be stopped in the study, because it would not meet its efficacy endpoints, and the study sponsors and Protocol Team leaders agreed with this recommendation.

The vaccinations are being stopped because the vaccine did not show efficacy. The Step study was designed to look at 2 questions related to efficacy:

1. Does the vaccine prevent HIV infection? and
2. Does the vaccine reduce the amount of virus in people who were vaccinated and then later develop HIV infection?

A planned "interim" analysis of data that answer these questions showed disappointing results. The analysis compared results in people who got the vaccine to results in people who did not get the vaccine. The vaccine did not reduce the incidence of HIV infection and did not reduce the amount of virus in people who became infected with HIV.


We would like you to remain in the study so that we can continue to monitor aspects of your health and your immune response to the study vaccine. You will not receive any more injections. Your study visits will continue with the same procedures that we told you about in the study informed consent form.


Knowing this new information may change how you feel about staying in the study. If you decide to leave the trial, your decision will not affect the care you receive at this institution. However, your participation continues to be important. The information we learn will provide key insights that can guide future HIV vaccine development.

If you have any questions about the Step study or this information from the DSMB meeting, please call your Research Associate/Counselor. We would be happy to arrange for you to talk with one of the clinicians or other study personnel here at SFPDH HIV Research Section.

Thank you for being part of the Step study. Finding an HIV vaccine can only move forward with the commitment of volunteers like you.

Sincerely,


Susan Buchbinder, MD
Principal Investigator


Jonathan Fuchs, MD
Co-Principal Investigator