

## **This letter gives information about HIV resistance.**

### **What Is Resistance?**

To understand resistance to medicines used to treat HIV, we need to understand some things about the virus itself.

When a person becomes infected with HIV, the virus enters the person's body and begins to multiply or make copies of itself. The more copies the virus makes, the more damage it does to the body's immune system. If the HIV infection is not treated, over time it will do so much damage that the person will become sick and eventually die of AIDS.

The medicines used to treat HIV infection are called antiretrovirals (ARVs). When taken properly, ARVs stop the virus from making copies of itself and help people with HIV to feel better and live longer. Taking ARVs properly usually means taking 3 different ARV medicines, because it takes more than one ARV medicine to stop HIV from making copies of itself. However, ARVs are not perfect, and sometimes they are not able to stop all of the HIV in a person's body from making copies. When this happens, the virus that is able to continue making copies of itself is called "resistant" to the ARV medicine that is being taken. This does not mean the virus is resistant to all types of ARV medicines.

### **Why Is Resistance to ARV Medicines a Problem?**

When resistance happens, an ARV medicine is no longer able to stop HIV from making copies of itself. In this case, the person needs to stop taking the ARV medicine that is no longer working and start taking a different ARV medicine. Because of this, a person who has resistant HIV has fewer choices of the ARV medicines that they can take to help them stay well.

### **Why Is Resistance to ARV Medicines a Concern in the VOICE Study?**

The VOICE Study is testing 2 ARV medicines: Tenofovir and Truvada. Truvada contains Tenofovir and another ARV medicine, Emtricitabine.

We know that Tenofovir and Truvada work very well with other ARV medicines to treat HIV infection. The VOICE Study is testing whether these ARV medicines, in the form of a gel or tablet, can prevent women from getting HIV. We do not know if these ARV medicines work to prevent women from getting HIV. This research study is being done to find that out.

The possibility of developing resistance to ARV medicines is a concern in this research study. Some participants in the study may get HIV infection through unprotected sex while using the study ARV medicines (Tenofovir or Truvada). People who have HIV typically need to take 3 ARV medicines to stop the virus from making copies of itself. If participants become infected with HIV while in the study and keep using Tenofovir or Truvada, which have 1 or 2 ARV medicines, the virus in their body could become resistant to these ARV medicines.

### **How Can Resistance to ARV Medicines be Avoided in this Research Study?**

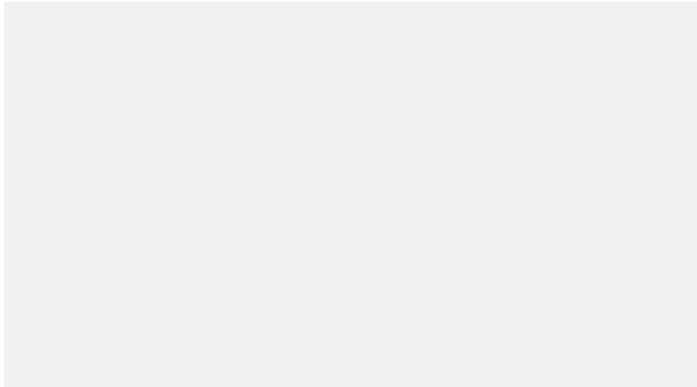
There are three ways to avoid resistance in this research study:

- **Avoid Getting HIV:** Use a condom correctly with every partner, every time you have sex. Free condoms will be given to all study participants. Resistance to ARV medicines cannot occur in a person who does not have HIV.
- **Attend Study Visits Every Month:** HIV testing will be done monthly. If testing shows that a participant has become infected with HIV, she will immediately stop using gel or tablets to avoid developing resistance to Tenofovir and Truvada. If study visits are missed, a participant might get HIV, not know it, and keep using gel or tablets. This could cause resistance to ARV medicines.
- **Do Not Share Gel or Tablets:** Sharing gel or tablets with other people, even with your partner, could be harmful. Participants in the research study get health checks and HIV tests every month. People who are not in the study do not get these checks. If people who are not in the study use the gel or tablets, it could cause health problems that are not being checked by a study nurse or doctor. Also, these people could have HIV and not know it. If these people use study gel or tablets, this could cause resistance to ARV medicines.

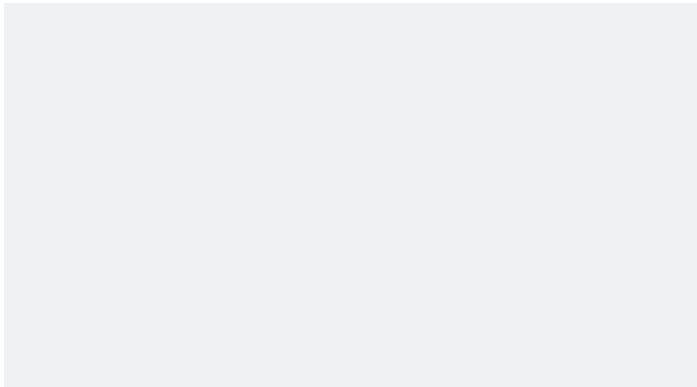
### **The Study Staff Are Here to Help.**

Study staff are available to inform and counsel study participants, their partners, and other community members about resistance and any questions or concerns they may have. Study staff will also discuss the importance of attending monthly study visits and not sharing gel or tablets. Participants are asked to tell the study staff if they are having problems attending monthly study visits or are not able to stop others using their study gel or tablets. Study staff will work with participants to develop strategies to address any problems they may have.

*To learn more about the research study,  
you may visit the study clinic at:*



*You may also contact:*



# The **VOICE** Study

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Information about HIV Resistance

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