

## **Risk List for Informed Consent**

### **General Disclaimer**

The drugs used in this study may have side effects, some of which are listed below. Please note that these lists do not include all the side effects seen with these drugs. These lists include the more serious or common side effects with a known, or possible relationship. If you have questions concerning the additional study drug side effects, please ask the medical staff at your site.

### **Use of Combination Antiretroviral Drugs**

**Immune Reconstitution Syndrome:** In some people with advanced HIV infection, signs and symptoms of inflammation from other infections may occur soon after anti-HIV treatment is started.

The use of potent antiretroviral drug combinations may be associated with an abnormal placement of body fat and wasting. Some of the body changes include:

- Increase in fat around the waist and stomach area
- Increase in fat on the back of the neck
- Thinning of the face, legs and arms
- Breast enlargement

### **Non-Nucleoside Reverse Transcriptase Inhibitor**

#### **Etravirine (ETR, Intelence™)**

*Tibotec, Inc.*

The following serious side effects have been associated with the use of etravirine:

- Serious and life-threatening rash and allergic reactions. If you get a rash with any of the following symptoms contact your Health Care Provider right away:
  - Fever
  - Hives or sores in your mouth, or your skin blisters and peels
  - Trouble swallowing or breathing
  - Swelling of your face, eyes, lips, tongue, or throat
  - Yellowing of the skin or whites of the eyes, dark urine, or pain on the right side of the stomach

Other serious side effects:

- Muscle break down causing muscle aches, pain or weakness which can be serious

Additional side effects include:

- Numbness, pain, or tingling in the hands or feet