

## **DAIDS Core Risk List (side effects/risks of study drug) Template for DAIDS Informed Consent Form**

**GENERAL INSTRUCTIONS for DAIDS Medical Officers (MOs): Address the Virologic Failure and Development of Resistance in the risk section of the DAIDS Sample Informed Consent Form, if appropriate. This topic is not addressed in this core DAIDS Risk List (side effects/risks of drugs used in the study).**

**The risks of side effects from the study drug listed below apply to the risk section of the DAIDS Sample Informed Consent Form. These side effects/risks should be addressed in the risk section of the DAIDS Sample Informed Consent Form.**

### **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 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, symptoms from other infections or certain diseases may occur soon after starting combination anti-HIV treatment but can also occur later. Some of these symptoms may be life threatening. If you start having new symptoms, or notice that existing symptoms are getting worse after starting your antiretroviral therapy, tell your healthcare provider right away.

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

### **Integrase Inhibitor**

#### **Raltegravir, (RAL, Isentress™)**

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

- Serious skin and allergic reactions including a rash which can become severe or life-threatening and can be fatal. If you develop a rash with any of the following symptoms stop using raltegravir and contact your Health Care Provider right away:

- Fever
- Generally ill feeling
- Extreme tiredness
- Muscle or joint aches
- Blisters or sores in mouth
- Blisters or peeling of the skin
- Redness or swelling of the eyes
- Swelling of the mouth or face
- Problems breathing

Sometimes allergic reactions can affect body organs, like the liver and cause liver problems which can lead to liver failure. Contact your Health Care Provider right away if you have any of the following signs or symptoms of liver problem:

- Yellowing of the skin or whites of the eyes
- Dark or tea colored urine
- Pale colored stools/bowel movements
- Nausea/vomiting
- Loss of appetite
- Pain, aching or tenderness on the right side below the ribs

In some patients receiving raltegravir blood tests showed abnormally elevated levels of a muscle enzyme—creatin kinase which may cause muscle pain, tenderness or weakness this type of muscle break down can be serious and lead to kidney damage including kidney failure. Contact your HCP right away if you have any unexplained muscle pain, tenderness, or weakness.

Additional side effects include:

- Nausea
- Headache
- Tiredness
- Trouble sleeping
- Weakness
- Stomach pain and diarrhea
- Dizziness
- Depression, including suicidal thoughts and actions
- Feeling anxious, paranoia
- Clumsiness and lack of coordination
- Changes in behavior, like low or high activity in children
- Easy bleeding (decreased blood clotting, low platelet count)

**Note:** Raltegravir chewable tablets contain phenylalanine, a component of the sugar substitute aspartame. Phenylalanine can be harmful to children and adults with phenylketonuria, a birth defect that can lead to a variety of health problems.