

## **Guidelines for Protection of Human Subjects Plan**

### **HUMAN SUBJECTS**

#### **Risks to Human Subjects**

*Human Subjects Involvement, Characteristics and Design*

*Sources of Materials*

*Potential Risks*

#### **Adequacy of Protection Against Risks**

*Recruitment and Informed Consent*

*Protections Against Risk*

#### **Potential Benefits**

#### **Importance of Knowledge to be Gained**

**Data Safety and Monitoring Plan.** For clinical trial designs.

#### **Inclusion of Women and Minorities**