**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**