**The University of Texas Southwestern Medical Center at Dallas**

**Institutional Review Board**

**Protocol Template (for Investigator Initiated Studies)**

**Title:**

**1. Introduction and Purpose:**

**2. Background:**

**3. Concise Summary of Project:**

**4. Study Procedures:**

**5. Sub-Study Procedures:**

**6. Criteria for Inclusion of Subjects:**

**7. Criteria for Exclusion of Subjects:**

**8. Sources of Research Material:**

**9. Recruitment Methods and Consenting Process:**

**10. Potential Risks:**

**11. Subject Safety and Data Monitoring:**

**12. Procedures to Maintain Confidentiality:**

**13. Potential Benefits:**

**14. Biostatistics:** (omit this section for peer-reviewed research such as cooperative group, or NIH- sponsored studies, and for industry-sponsored research which has been submitted to FDA)