***Guidelines for Applications Involving Animal Testing of New Chemical Entities (NCEs)***

***Question #1: What class of compound is your experimental agent?***

***(Include this information in Section2.D. and/or 2.J)***

Anti-viral:\_\_\_\_ Cardiovascular:\_\_\_\_\_\_ Topical:\_\_\_\_\_

Anti-microbial:\_\_\_\_ Neurological:\_\_\_\_\_ Immunosuppressive:\_\_\_\_\_

Anti-neoplastic:\_\_\_\_ Pulmonary:\_\_\_\_\_ Immunostimulant:\_\_\_\_\_

Anti-fungal:\_\_\_\_\_ Renal:\_\_\_\_\_\_ Hormonal:\_\_\_\_\_

Anti-coagulant:\_\_\_\_\_ Gastrointestinal:\_\_\_\_\_ Other:\_\_\_\_\_\_\_

Describe the mechanism of action (MOA) for your experimental agent.

***Question #2: Is your experimental compound structurally and/or pharmacologically similar to any existing chemical agent(s)? (Include this information in Section 2.D, 2.J., and/or 3.G.)***

If YES, provide Safety Data Sheet (SDS) and/or details regarding published efficacy and/or toxicology studies. This may include a summary of effects observed in animals and/or humans for a specific class of chemical entity.

If NO, provide relevant information regarding *in vitro* and/or cell based efficacy studies performed in your laboratory. This information includes, but is not limited to, effective doses (ED50 values), inhibitory doses (IC50 values), and/or lethal doses (LD50 values). Provide information describing molecular/cellular target (name of enzyme, receptor, nucleic acid, etc.) and/or cell line being used for determination of efficacy.

***Question #3: Have you performed cell based toxicology studies on your NCE? (Include this information in Section 2.J and 3.G.)***

If YES, provide IC50 or LD50 values for your chemical agents against normal cells?Provide information describing the cell line(s) being used for determine the efficacy of your NCE.

If NO, provide a rationale for why these studies have not been performed.

***Question #4:*** ***Are there special protocols and/or equipment needed to minimize risk of exposure to your NCE? (Include this information in Section 2.J and 3.G.)***

If YES, describe the protocols and/or equipment that will be used to minimize risk of exposure.

If NO, explain why special protocols and/or equipment are not needed to minimize risk of exposure to your chemical entity. This may include results of *in silico* and/or computational studies.

***Question #5:*** ***Have you assessed if your compound a mutagen or teratogen? (Include this information in Section 2.J and 3.G.)***

If YES, provide results of Ames test and/or other genotoxic data for your NCE. Include dates of testing. Indicate if commercial sources were used for testing. Describe the protocols and/or equipment that will be used to minimize risk of exposure.

If NO, provide a rationale for why these studies do not need to be performed or discuss why they have not been performed. Discuss plans to assess if your compound is a mutagen or teratogen.