Study Protocol and Related Documentation

All study protocols **are required** to contain:

1) A statement of the study's objectives and purpose.

2) **Bio-Medical Only**: For studies of drugs (including biologics, medical foods and food additives), each investigator's name, address, and statement of their qualifications, as well as each subinvestigator's name; the research facility's name and address' and each reviewing IRB's name and address. For device studies, this information is contained in the Investigational Device Exemption (IDE) investigational plan, rather than in the protocol.

3) Subject selection and exclusion criteria and the estimated number of subjects to be studied. For device studies, the actual number or subjects must be given.

4) A description of the study design, including any controls to be used, and a description of methods to minimize bias on the part of the subjects, investigators and analysts.

5) **Bio-Medical Only**: For drug and biologic studies, the method of determining the dose to be administered, the planned maximum dosage, and the duration of subject exposure to the drug. For device studies, the method for determining the treatment parameters, including administration and duration of subject exposure to the medical device.

6) A description of the observations and measurements to be made to fulfill the study's objectives.

7) A description of clinical procedures, laboratory tests, and other measures to be taken to minimize risk and to monitor the effects of the test and control articles.