Criteria for Clinical Trials Registration Worksheet

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PI:		Study #:	
Study Title:			

Section I:

1	Is this a small feasability study? *(only applies to Device Studies)*	
2	Is this a Phase I study? *(only applies to Drug studies)*	
3	Is this an observational study?	
4	Is the study drug over the counter (OTC), and used per an existing OTC monograph (i.e. labeling)?	

If you answered YES is in any box (1 thru 4), registration at clinicaltrials.gov is **NOT** required. Proceed to Section IV.

Section II:

5	Does the study involve an FDA regulated "Drug" or "Device" (i.e. under an IND, NDA, IDE, 510K), or available only by prescription?	
6	Is this a pediatric post market surveillance study of a device?	

If you answered YES in either box 5 OR box 6, registration at clinicaltrials.gov **IS** required. Proceed to Section V.

Section III:

7	Is this study an adequately controlled clinical investigation characterized by each of the elements below?	
	a. Study objectives are well defined and stated clearly. b. The scientifically valid design of the study allowing quantitative comparison with a control is precisely specified in the protocol. (Typical methods would include - parallel, sequential or crossover designs. Controls can be Dose Comparison Concurrent Control; No Treatment Concurrent Control; Active Treatment Control and Historical Control). c. Subject selection should assure some have the disease or condition for which the trial is intending to measure the efficacy/safety of the investigational product(s) under study. d. The method of assigning patients to treatment and control groups (such as randomization) minimizes bias. e. Adequate measures (such as blinding) are taken to minimize bias on the part of researchers/analysts/subjects. f. The methods of assessment of subjects' response are objective, well-defined and reliable. g. Study design and analysis should yield statistically valid results.	

If you answered YES in box #7, registration at clinicaltrials.gov **IS** required. Proceed to Section V.
If you answered NO, proceed to section IV.

Section IV: Does your clinical trial meet the definition below?

Clinical Trial: Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behaviorial treatments, diatery interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. The ICMJE member journals will start to implement the expanded definition of clinically directive trials for all trials that begin enrollment on or after 1 July 2008. Those who are uncertain whether their trial meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal. The ICMJE secretariat office is unable to review specific studies to determine whether registration is necessary. If researchers or others have questions about the need to register a specific study, they should err on the side of registration or consult the editorial office of the journal they wish to publish the study in. (ICMJE)

If YES, you must register your trial at an ICMJE approved site. A list of those sites can be found at http://www.icmje.org/faq_clinical.html.

Section V: If the clinical trial requires registration, you must provide proof of registration to the IRB. If you are not sure whether or not your trial must be registered, please contact Research Integrity at ext. 49408 or 88166 for assistance.