Investigational Drug, Biologic and Device Policy

I. Investigational Drug or Biologic

A. Investigational New Drug Application (IND)
   1. Research use of an unapproved investigational drug or biologic must be done under an IND (Investigational New Drug) application process through the FDA.
   2. Current Federal law requires that a drug or biologic be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA.

B. Sponsor Responsibilities
   1. Sponsor-initiated protocols require the sponsor to file the IND Application with the FDA.
   2. All FDA/sponsor IND correspondence must be submitted to the CCI/IRB with the Research Application.

C. Investigator Responsibilities
   1. Investigator-initiated protocols require the PI to file an IND Application with the FDA. The IND Application and instructions are found at http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm
   2. The FDA IND application and all subsequent correspondence between the FDA and the investigator must be submitted to the CCI/IRB.
   3. Although FDA regulations permit research to begin 30 calendar days after the IND Application has been filed, the CCI/IRB will make the final determination on a case-by-case basis to assure that research subjects will not be subjected to unreasonable risk.

D. IND Exemption
   An IND exemption applies to the clinical investigation of a drug product that is lawfully marketed in the United States. In order to be exempt from the requirement for an IND, the investigator must apply for an exemption to the CCI/IRB advising that all of the following conditions have been met. As part of the protocol review, the CCI/IRB will determine the appropriateness of the exemption.
   1. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
2. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
3. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.

E. **Treatment Use of An Investigational Drug**
   The FDA permits an investigational drug to be used for treatment use under a treatment protocol or Treatment IND when:
   1. The drug is intended to treat a serious or life-threatening disease. (See also the [Emergency Use Drug or Biologic Policy](#))
   2. There is no comparable or satisfactory alternative drug or other therapy available to treat that stage of the disease in the intended patient population.
   3. The drug is under investigation in a controlled clinical trial under an IND in effect for the trial, or all clinical trials have been completed, and
   4. The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational drug with due diligence.
   5. Treatment protocols require review and approval by the CCI/IRB.

II. **Medical Device**

B. **Definition**
   A medical device is defined, in part, as any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized. Medical devices also include diagnostic aids, such as reagents and test kits for *in vitro* diagnosis.

C. **Investigational Device Exemption (IDE)**

   1. An investigational device is a medical device that is the subject of a clinical study designed to evaluate the effectiveness and/or safety of the device. Clinical investigations undertaken to develop safety and effectiveness data for medical devices must be conducted according to the requirements of the IDE regulations [21CFR part 812].
   2. Unless exempt from the IDE regulations, an investigational device must be categorized as either "significant risk" (SR) or "non-significant risk" (NSR).
   3. Significant Risk studies require submission to the FDA for an IDE. The FDA IDE application and all subsequent correspondence between the FDA and the sponsor/investigator must be submitted to the CCI/IRB.
   4. NSR studies require the usual CCI/IRB review and approval with regard to informed consent, record keeping, and study monitoring.
5. Device studies require review and approval by the CCI/IRB.
6. If an investigator proposes the initiation of a claimed NSR investigation to the CCI/IRB, and if the CCI/IRB agrees that the device study is NSR and approves the study, the investigation may begin immediately, without submission of an IDE application to FDA.
7. Any safety and efficacy data collection on a significant risk device for other than approved indication requires an IDE in advance of IRB approval.

D. Significant Risk (SR) and Non-Significant Risk (NSR) Definitions

1. An SR device study is defined as a study of a device that –
   1. presents a potential for serious risk to the health, safety, or welfare of a subject and
      1. is intended as an implant; or
      2. is used in supporting or sustaining human life; or
      3. is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or
      4. otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2. An NSR device investigation is one that –
   1. does not meet the definition for a significant risk study.


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