DEFINITIONS:

I. CLINICAL INVESTIGATION: Any experiment in which a drug (or biologic or device) is administered or dispensed to, or used involving, one or more human subjects. In this context, experiment refers to any use of a drug except for the use of a marketed drug in the course of medical practice. (21 CFR 312.3(b))

II. DRUG: A product that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body and achieves its intended effect through chemical action or metabolism within or on the body.

III. FOOD AND DIETARY SUPPLEMENTS generally are not regulated as drugs. However, those that are intended or promoted to be used in the diagnosis, cure, mitigation, treatment or prevention of disease are considered drugs.

IV. BIOLOGIC: A biological or related product derived from living sources (e.g., humans, animals, microorganisms) and regulated by the FDA, including blood, vaccines, allergens, tissues and cellular and gene therapies. Studies of unlicensed biologics are generally regulated according to the IND regulations. FDA regulations related to the general use and licensing of biologics are found in 21 CFR 600 and 601.

V. INVESTIGATIONAL NEW DRUG APPLICATION (IND): An IND exempts an investigational new drug from pre-marketing approval requirements that would otherwise be applicable and allows the drug to be lawfully shipped for the purpose of conducting clinical investigations of that drug (21 CFR 312.1(a)).

VI. INVESTIGATIONAL NEW DRUG refers to an unapproved drug or biologic (or approved drug or biologic for an unapproved indication) used in an FDA-regulated clinical investigation. The term also includes biological products used in vitro for diagnostic purposes. Clinical investigations that involve FDA regulated drugs are subject to the requirements of 21 CFR 312.

VII. DEVICE is an instrument, apparatus, machine or similar article that is used for the diagnosis, mitigation, cure, prevention or treatment of disease and does not work through chemical action or metabolism within the body.
VIII. INVESTIGATIONAL DEVICE EXEMPTION APPLICATION (IDE): An IDE exempts an unapproved or uncleared device (or an approved or cleared device for an unapproved or uncleared indication) in a research study involving humans (i.e., an IDE is an investigational exemption) from certain statutes and regulations. With this exemption, the unapproved or uncleared device can be shipped and used in human research.

IX. INVESTIGATIONAL DEVICE: Medical device that is the subject of a clinical study designed to evaluate the effectiveness or safety of the device, or a clinical evaluation of certain modifications or new intended uses of a legally marketed device. Clinical investigations that involve FDA regulated devices are subject to the requirements of 21 CFR 812.

X. PREMARKET APPROVAL (PMA) APPLICATION: A PMA is the most stringent type of marketing application for medical devices, FDA approves a PMA based on presence of sufficient valid scientific evidence and reasonable assurance that the device is safe and effective for its intended use. Once approved, it can be marketed and sold within its approved labeling.

XI. PREMARKET NOTIFICATION (510(K)): A 510(k) application is submitted to FDA before a manufacturer plan to market a device. If the FDA agrees that the new device is substantially equivalent to a legally marketed device for which a PMA is not required, the manufacturer may market it immediately. FDA does not require clinical data for most 510(k)s. However, if clinical data are necessary to demonstrate equivalence, the clinical study must comply with IDE, IRB and human subject protection regulations.

XII. SIGNIFICANT RISK DEVICE: Significant risk device (SR) is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject. The SR determination encompasses the proposed use and not the device alone (e.g., need for additional procedures, such as surgical implantation, as part of the study should be included in risk assessment.

XIII. NONSIGNIFICANT RISK DEVICE: A device not meeting the definition of SR device. Examples of significant and nonsignificant risk devices are available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm126622.htm

POLICY:
I. The UIC HSPP follows federal, state and institutional regulations in reviewing research involving the use of drugs, biologics or devices.

II. When reviewing research involving the use of a drug or biologic, the UIC IRBs determines whether the drug requires an IND or the investigation meets one of the FDA exemptions from the requirement to have an IND. If an IND is required, the IRB verifies the IND number prior to approving the research.

III. When reviewing research evaluating the safety or effectiveness of a device, the UIC IRB determines whether the device requires an IDE, fulfills the requirements for an abbreviated IDE, or the protocol meets one of the FDA exemptions from the requirement to have an IDE. If an IDE is required, the IRB verifies the IDE number prior to approving the research.

IV. The UIC IRBs coordinate their oversight of research involving investigational or unlicensed test articles with the Investigational Drug Services at UIC and JBVAMC to ensure the process for the handling of test articles restricts their use to approved protocols and under the direction of approved investigators.

V. The UIC IRBs does not have oversight responsibility for use of a marketed drug, biologic or device in the course of medical practice for a non-approved (“off label”) indication.

VI. UIC policy currently does not allow planned emergency research.

PROCEDURES:

I. Research Involving Drugs and Biologic Products.
   A. Investigators must submit to OPRS for IRB review the documents described in the Initial Review Application: Health and Biological Sciences, including Appendices A-1 and E.
   B. Initial review for IRB approval of a study involving the research-related administration of a drug or biologic occurs at a convened IRB meeting, unless the research activities present no more than minimal risk and an IND is not required in accordance with expedited review categories.
   C. An IND is commonly required for any clinical study that proposes the use (e.g., as a research tool to explore a biological phenomena or disease process) or evaluation (i.e., pharmacokinetics, safety and/or effectiveness) of an unapproved drug or biological product or unapproved indication or use for a marketed drug or biologic.
   D. If the investigator is requesting the drug or biologic (unapproved or marketed) be exempt from IND requirements, the investigator must justify this request on Appendix A-1. Alternatively, the investigator may provide the IRB with communications from the FDA indicating that an exemption from the IND regulations has been granted.
   E. The FDA has issued a specific guidance for the use of lawfully marketed drugs and biologicals in oncology protocols. This guidance provides details
and examples of those regimens that do and do not require an IND. (Refer to FDA Guidance for Industry: IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer).

F. If the investigator has not provided an IND or letter from the FDA granting an exemption from IND requirements, the IRB reviews and determines whether the research meets one of the FDA exemption requirements below. The IRB documents their determination in the meeting minutes or, when the review occurs by expedited procedures, the expedited reviewer’s Review Guide.

1. Exemption 1:
   a. The drug product is lawfully marketed in the United States.
   b. The investigation is not intended to be reported to 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.
   c. If the drug that is undergoing investigation was lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product.
   d. 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. The investigation is conducted in compliance with 21 CFR 50 and 56.
   f. The investigation is conducted in compliance with the requirements of 21 CFR 312.7 (Promotion and charging for investigational drugs).

2. A clinical investigation involving use of a placebo does not require an IND if the investigation does not otherwise require submission of an IND.

3. Exemption 2:
   a. A clinical investigation involving an in vitro diagnostic biological product that meets the following:
      (1) Product is blood grouping serum, reagent red blood cells, or anti-human globulin;
      (2) The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and
      (3) The diagnostic test was shipped in compliance with 21 CFR 312.160.

4. Exemption 3: A drug intended solely for tests in vitro or in laboratory research animals if shipped in accordance with 21 CFR 312.160.

5. Exemption 4: Clinical bioavailability or bioequivalence study are exempt from the requirement for an IND except when one or more of the criteria described below are met:
a. The drug product contains a new chemical entity (21 CFR 320.31(a)(1)), radioactively labeled drug product (21 CFR 320.31(a)(2)) or cytoxic product (21 CFR 320.31(a)(3)).

b. The study involves a drug product containing an already approved, non-new chemical entity and is:
   (1) A single-dose study in normal subjects or patients where either the maximum single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application,
   (2) A multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application, or
   (3) A multiple-dose study on an extended release product on which no single-dose study has been completed.

6. Exemption 5: A clinical bioavailability or bioequivalence study being conducted for approval of an abbreviated new drug application or supplemental new drug application other than studies described in 5.a. and 5.b. above as long as samples of the reference standard and test article are retained as described in 21 CFR 320.38 and 320.63.

G. Clinical investigations that are exempt from IND requirements still require IRB review and approval.

H. If the IRB determines that there may potentially be significant risk or decreased acceptability involved with the use of a drug utilizing a different route of administration, dose, or in a non-FDA approved population and/or disease, the IRB can request that the investigator contact the FDA for review of the proposed clinical investigation to determine whether the use qualifies for an exemption from the IND requirements.

I. The research application involving the use of a drug or biological product, unless the research is exempt from the IND regulations, must be include evidence that the FDA has issued an Investigational New Drug (IND) number. The IRB Assistant Directors or IRB Coordinators will confirm that the IND number provided in the IRB submission matches that recorded on the sponsor protocol, communication from the sponsor, or communication from the FDA. The Investigator's Brochure is not an acceptable mechanism for verification. Validation of the IND number is required before IRB approval.

J. Handling of Investigational Drugs or Biologics.
   1. University of Illinois Medical Center at Chicago.
      a. Clinical investigations of drugs or biologics at the University of Illinois Medical Center at Chicago must follow the policy and procedures established by the Department of Hospital Pharmacy Services.
      b. The UIC OPRS Drug Study Registration Form (Appendix E) must be reviewed and approved by the Investigational Drug Service (IDS) prior to submission for IRB review and approval of
any research involving the use of approved or investigational drugs.

c. UIC Medical Center policy require that all inpatient studies use the services of the Investigational Drug Service (IDS) for the storage, control and dispensing of the study drug.

d. Outpatient studies may use the services of IDS, however the option not to use the IDS for storage, control and dispensing of the drug or biologic exists. If the investigator opts to handle the investigational agent themselves, a process for handling the investigational drug must be provided to the IRB on Appendix A-1 for review and approval. The IRB obtains the input of IDS or other qualified pharmacist in confirming the adequacy of the drug control plans. Drug accountability records along with storage and dispensing of investigational drug are subject to audit by IDS and the OVCR Research Compliance Office.

2. Jesse Brown VAMC. The Department of Pharmacy handles the storage, control and dispensing of investigational drugs and biologics for all inpatient and outpatient studies as described in the document, *Investigational Drugs Policy & Procedures at the Jesse Brown VA Medical Center.*

3. Other sites. When the UIC IRB serves as the IRB record for clinical investigations of drugs and biologics at other institutions, the investigator must describe the process for handling the investigational drug. The IRB will seek input from a qualified individual from that institution to confirm their concurrence with the plan before approving the research.

II. Research Involving Medical Devices.

A. Investigators must submit to OPRS for IRB review the documents described in the Initial Review Application: Health and Biological Sciences, including Appendix A-2.

B. Initial review for IRB approval of a study involving the research-related use of a medical device may be reviewed by expedited procedures when research activities are no greater than minimal risk and (i) an IDE is not required; or (ii) the device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. Clinical investigations for which an IDE is required are reviewed at a convened meeting.

C. Research with devices falls into three categories:
   1. Investigations exempted from the IDE regulations;
   2. Investigations of significant risk devices to determine safety and effectiveness of the device;
   3. Investigations of nonsignificant risk devices to determine safety and effectiveness of the device.

D. When the investigator indicates on Appendix A-2 that the research is exempt from the requirement for an IDE and has not provided a letter from the FDA granting an exemption, the IRB reviews and determines whether the research meets one of the FDA exemption requirements. The IRB documents their
determination in the meeting minutes, or, when the review occurs by expedited procedures, the expedited reviewer’s Review Guide.

1. A device legally marketed in the US that is used or investigated in accordance with the indications in the FDA-approved labeling.
2. A diagnostic device (that is, an in vitro diagnostic device) if the testing:
   a. Is noninvasive,
   b. Does not require an invasive sampling procedure that presents significant risk,
   c. Does not by design or intention introduce energy into a subject, and
   d. Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
3. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
4. A custom device as defined in 21 CFR 812.3(b), unless the device is being used to determine safety or effectiveness for commercial distribution.
5. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.
6. A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

E. Clinical investigations that are exempt from IDE regulations still require IRB review and approval

F. Significant Risk (SR) versus Non-Significant (NSR) Risk Devices.
   1. Unless exempt from the requirements for an IDE, an investigational device must be categorized as either a SR device or a NSR device.
   2. The initial risk assessment is made by the sponsor.
   3. Next, the IRB must review the sponsor’s SR or NSR assessment and modify the determination if the IRB disagrees with the sponsor. If the FDA has already made the SR or NSR determination, their determination is final and the IRB does not need to duplicate effort.
   4. The IRB’s determination regarding the appropriate SR/NSR category must occur at a convened meeting. The determination and reason for the determination are documented in the meeting minutes. The documentation should include the SR/NSR determination letter from the FDA, if the FDA has already made a determination.
   5. The sponsor through the investigator provides the IRB with the following information: explanation of their risk determination, description of device, reports of prior investigations, proposed
investigational plan, subject selection criteria and other information pertinent to the IRB deliberation.

6. The IRB’s risk determination should consider the device, the proposed use of the device and any protocol-related procedures (e.g., surgery). The following criteria for a SR device guide the IRB in making their determination:
   a. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
   b. Is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject;
   c. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
   d. Otherwise presents a potential for serious risk to a subject.

7. If the IRB determines that a study, submitted by the sponsor for approval as a NSR device represents a SR device, the IRB Assistant Director or coordinator notifies the investigator and sponsor of this decision. The investigator will be instructed to re-submit the protocol as a SR device study and to provide documentation from the sponsor of an approved IDE (i.e., copy of the letter from the FDA providing approval or conditional approval of the IDE).

8. If the IRB concurs with the sponsor’s assessment of a NSR device, the IRB proceeds with its review and approval of the device study following the criteria at 21 CFR 56.111. The study may begin without submission of an IDE application to the FDA. Conduct of the NSR device study must follow the "abbreviated" requirements described at 21 CFR Sec. 812.2(b).

G. SR Device Research.
   1. When research is submitted for IRB review and approval as a SR device, the investigator is responsible for providing the IRB with the IDE number and a copy of the letter from the FDA providing approval or conditional approval of the IDE to confirm the validity of the IDE. The IRB Assistant Directors or coordinators will confirm submission of this documentation prior to IRB approval.
   2. Initial IRB review occurs at a convened meeting.
   3. For SR devices that are implanted, the IRB must assess the exit strategy for the device to ensure that human subjects are adequately protected once the study ends, if applicable.

H. Handling of Investigational Devices.
   1. University of Illinois Medical Center at Chicago. The process for handling the investigational device must be provided to the IRB on Appendix A-2 for review and approval. The IRB review of the proposal includes assessing the adequacy of the device control plans. Device accountability records along with storage, dispensing and disposition of
the investigational device are subject to audit by the OVCR Research Compliance Office.

2. Jesse Brown VAMC. The process for handling the investigational device must be provided to the IRB on Appendix A-2 for review and approval. The IRB review of the proposal includes assessing the adequacy of the device control plans. Device accountability records along with storage, dispensing and disposition of the investigational device are subject to audit by the JBVAMC Research Compliance Officer.

3. Other sites. When the UIC IRB serves as the IRB record for clinical investigations of devices at other institutions, the investigator must describe the process for handling the investigational device. The IRB will seek input from a qualified individual from that institution to confirm their concurrence with the plan before approving the research.

III. 510(k) Premarket Notification (PMN).
   A. Any investigator considering the submission of a 510(k)/PMN may contact the UIC OPRS for guidance.
   B. The FDA must be notified 90 days in advance of intent to market a medical device.
   C. Submission of a PMN to the FDA is required if there is the intention to introduce a device into commercial distribution for the first time or to reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected.
   D. The change or amendment could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use.

IV. Radioactive Materials. Oversight of radioactive materials used in research at UIC is handled by the Radioactive Drug Research Committee, a subcommittee of the UIC Human Radiation Safety Committee in the UIC Environmental Health and Safety Office, which is chartered as a Radioactive Drug Research Committee (RDRC) by the FDA under 21 CFR 361.1. Most research involving human subjects and radiation is covered by an IND or an IDE, and must be reviewed and approved by the IRB. IRB review occurs after review and approval is obtained from the RDRC. The radiation safety section of the Environmental Health and Safety Office provides assistance to investigators in planning human research studies and obtaining the necessary approvals for human research studies involving radioactive materials (http://www.uic.edu/depts/envh/).

V. Expanded Access to Investigational Drugs and Devices
   A. Investigational Drugs.
      1. Treatment IND.
         a. Treatment IND [21 CFR 312.34 and 312.35] provides a mechanism for providing eligible subjects with investigational drugs for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments. A treatment IND may be granted after sufficient data have been
collected to show that the drug "may be effective" and does not have unreasonable risks.

b. Four requirements must be met before a treatment IND can be issued: 1) the drug is intended to treat a serious or immediately life-threatening disease; 2) there is no satisfactory alternative treatment available; 3) the drug is already under investigation, or trials have been completed; and 4) the trial sponsor is actively pursuing marketing approval. A treatment use under a treatment IND may begin 30 days after FDA receives the protocol or on earlier notification by FDA that the treatment use described in the protocol may begin.

c. UIC policy is that treatment IND studies require prospective IRB review and informed consent.

2. Group C Treatment IND. The "Group C" treatment IND was established by agreement between FDA and the National Cancer Institute (NCI). The Group C program is a means for the distribution of investigational agents to oncologists for the treatment of cancer under protocols outside the controlled clinical trial. Group C drugs are generally Phase 3 study drugs that have shown evidence of relative and reproducible efficacy in a specific tumor type. They can generally be administered by properly trained physicians without the need for specialized supportive care facilities. Group C drugs are distributed only by the National Institutes of Health under NCI protocols. Although treatment is the primary objective and patients treated under Group C guidelines are not part of a clinical trial, safety and effectiveness data are collected. The usage of a Group C drug is described in its accompanying "Guideline Protocol" document. The Guideline Protocol contains an FDA-approved informed consent document which must be used if there has been no local IRB review. UIC policy is that Group C treatment IND studies require prospective IRB review and informed consent.

3. Parallel Track. The FDA's Parallel Track policy [57 FR 13250] permits wider access to promising new drugs for AIDS/HIV related diseases under a separate "expanded access" protocol that "parallels" the controlled clinical trials that are essential to establish the safety and effectiveness of new drugs. It provides an administrative system that expands the availability of drugs for treating AIDS/HIV. These studies require prospective IRB review and informed consent.

4. Emergency Use. Refer to the UIC HSPP policy Emergency Use of Test Article.

B. Investigational Devices.

1. Compassionate Use. The FDA allows the use of an unapproved device in circumstances where the device is the only option available for a patient faced with a serious or life-threatening condition that does not meet the criteria of an emergency. Prior FDA approval is required before compassionate use occurs. As a first step, the clinician should seek the approval of the IDE holder and provide them with the following
information: 1). description of the patient’s condition and circumstances necessitating, 2). discussion of why alternative therapies are unsatisfactory, 3). an identification of any deviations from the approved labeling required to treat the patient and 4). patient protection measures that will be followed (refer to “Emergency Use of Test Article” policy). The IDE holder must then submit an IDE supplement to the FDA for approval. Once FDA approval is obtained, the investigator should submit the protocol including appropriate schedule for monitoring the patient, UIC Emergency Use application form, information provided to the FDA concerning the 4 points above, informed consent document and copy of the letter from the FDA approving the IDE supplement to the IRB for review and approval. Subject should not be treated with the device until FDA and IRB approval are obtained. Following compassionate use of the device, a follow-up report should be submitted to FDA in which summary information regarding patient outcome is presented. If problems occurred as a result of device use, they should be discussed in the follow-up report. A copy of the follow-up report should be submitted to the UIC IRB.

2. Treatment Use.
   a. Approved IDEs specify the maximum number of clinical sites and the maximum number of human subjects that may be enrolled in a study. During the course of a clinical trial, if the data suggest that the device is effective, then the trial may be expanded to include additional patients with life-threatening or serious diseases. To qualify for a treatment use IDE, the disease or condition must be life threatening or serious, and patients must have no comparable or satisfactory alternatives to the investigational device. FDA will consider the use of an investigational device under a treatment IDE if all of the following criteria are met:
      (1) The device is intended to treat or diagnose a serious or immediately life threatening disease or condition;
      (2) There is no comparable or satisfactory alternative device or other therapy to treat or diagnose that stage of the disease or condition in the intended patient population;
      (3) The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or the clinical trials have been completed; and
      (4) The sponsor of the investigation is actively pursuing marketing approval/clearance of the investigational device with due diligence.
c. Treatment use may begin 30 days after FDA receives the treatment IDE submission, unless FDA notifies the sponsor otherwise.

d. A licensed practitioner who receives an investigational device for treatment use under a treatment IDE is considered an “investigator” under FDA regulations and is responsible for meeting all applicable investigator responsibilities, including responsibilities to obtain prospective IRB approval and informed consent.

   a. The sponsor of a clinical investigation is permitted to continue to enroll subjects while a marketing application is being prepared by the sponsor and/or reviewed by the Agency if there is: 1) a public health need for the device and 2) preliminary evidence that the device is likely to be effective and no significant safety concerns have been identified for the proposed indication.
   b. The continued enrollment of subjects in an investigation while a marketing application is being prepared by the sponsor and/or reviewed by ODE is known as an “extended investigation.” A sponsor’s request for an extended investigation is as an IDE supplement. There is significant overlap between the treatment IDE regulation and the Continued Access Policy. The continued access policy and the treatment IDE regulation are intended to provide additional access to an unapproved device, once preliminary evidence regarding safety and effectiveness is available to FDA. However, because a treatment IDE can be submitted earlier in the IDE process, i.e., once promising evidence of safety and effectiveness has been collected under the IDE but while the clinical study is ongoing, it provides access to a wider group of patients at an earlier stage in the IDE process. The treatment IDE regulation also has a more narrow application than the Continued Access Policy in that treatment use is intended to address only those patients who have an immediately life-threatening or serious disease or condition whereas the Continued Access Policy, which is applied after completion of the clinical trial, may be considered for any clinical investigation.

4. Emergency Use. Refer to the UIC HSPP policy Emergency Use of Test Article.

5. Humanitarian Use Device. Refer to the UIC HSPP policy Humanitarian Use Device (HUD).

VI. Sponsor-investigators (Local Principal Investigator is the IND or IDE holder). Refer to the UIC HSPP policies and procedures related to sponsor-investigators for detailed information:
   A. Sponsor-Investigator Holding an IND
   B. Sponsor-Investigator Holding an IDE
REFERENCES:

FDA Guidance for Industry: IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer
FDA Guidance: Significant Risk and Nonsignificant Risk Medical Device Studies
Draft Guidance for Industry and FDA Staff - In Vitro Diagnostic (IVD) Device Studies - Frequently Asked Questions -

REVISION LOG:

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