Drug/Device Trials

Introduction

All clinical trials that use an approved drug or investigational product supplied to the institution from a sponsor must have the protocol reviewed by the Medical Staff Pharmacy and Therapeutics Committee (P&T Committee).

P&T Committee Forms must be attached to the IRB Application prior to submission. Download the forms from the IRB Web site. Complete and save the form, then upload it directly to your electronic IRB application

Drugs

What is an Investigational New Drug (IND)?

A drug permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing. There are three IND types; all require an IND application:

- An Investigator IND is submitted by the physician who both initiates and conducts an investigation and who immediately directs how the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows the FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.232 or Sec. 312.34.3 It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.

There are two IND categories: Commercial and Research (non-commercial). Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this

time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Research Pharmacy for INDs

All studies using pharmaceutical agents for human administration must use the Nebraska Medicine Investigational Drug Service (Research Pharmacy). Phone: 402-559-5255

Storing Investigational Drugs

All investigational drugs for human consumption must be stored and ordered through the Investigational Drug Service.

> **Investigational drugs cannot be stored in individual clinics.**

Devices

What is a medical device?

Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with microchip technology and laser surgical devices. Medical devices also include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. If a product is labeled, promoted, or used in a manner that meets the definition outlined in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act, it will be regulated by the FDA.

What is a 510(k)?

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to a Premarket Approval (PMA).

What is a post marketing trial?

A post marketing trial is one wherein the device is approved but the sponsor is required to continue to collect data to satisfy the FDA that the device is safe and effective.

If my study uses a device Nebraska Medicine already stocks, can I use existing inventory to keep my costs down?

No. Study devices are strictly regulated and must be labeled and secured; substitutions of non-study devices, even when identical to hospital stocks, are prohibited. The PI is ultimately responsible for ensuring appropriate storage, security, dispensing, and record-keeping for investigational devices.

Investigational Device Exemption (IDE)

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

Information on IDE and exempt devices can be found on the FDA Web site.

Contact SPAdmin for UNMC regulations for IDE, or visit their frequently asked questions page for more information.

Who is responsible for filing the IND/IDE seeking an exemption?

The IND is generally obtained by the PI, their research coordinator, or the Industry Sponsor.

Investigational Device Exemption (IDE). A sponsor must submit a separate IDE for any clinical investigation involving an exception from informed consent under the provisions of 21 CFR 50.24.

For Investigator initiated research, the PI or coordinator generally obtains the IND.

For Industry initiated research, the Industry Sponsor generally obtains the IND.

What is a sponsor-investigator and how do their responsibilities differ from a typical investigator?

A sponsor-investigator both initiates and conducts, alone or with others, a clinical investigation. The role does not include a corporation or agency as the study lead, although a corporation or agency may provide funding to conduct the trial. A sponsor-investigator has the obligations of both an investigator and a sponsor. An investigator who is also a sponsor must comply with all FDA requirements applicable to investigators and sponsors.

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