As a part of the drug development process, US pharmaceutical companies and other funding agencies such as the National Institutes of Health (NIH) sponsor thousands of clinical drug trials each year. Only after a careful review of the data obtained during these research trials by the FDA along with a determination by the FDA that a reasonable assurance of safety had been made during this process, is a new drug released to market. Similarly, the process occurs when a previously approved drug is released for a new indication.

The FDA is responsible for approving all prescription drug products prior to market availability in the United States. Once a drug product is approved by the FDA, it is considered to be “labeled “ or “approved” for the indication identified during the research process, and is available by prescription or over the counter to the general public.

The goal of a clinical drug trial is to identify how effective a drug product may be in treating or managing a disease process (efficacy) while not putting the patient at risk for adverse complications (safety). The drug trial undergoes rigorous and well-controlled testing in the laboratory (if appropriate), advancing to research with animals as subjects before continuing on for investigation with human subjects. Only after the investigational drug has shown a positive result in one or both areas, does the process proceed to the type of clinical trial that nurses would most likely encounter.

This article reviews the FDA-regulated clinical trials process and the responsibilities of the sponsor, the investigator, and the members of the research team, particularly the nurses. Many drug studies occur in hospitals and outpatient physician offices and may also be concurrently conducted at multiple sites across the United States. Nurses may be involved in such a drug study by collecting data, answering questions from patients who are participating in the study, or assessing patients for potential side effects to the investigational drug, especially as adverse event information is received from distant sites. It is important that nurses understand the FDA regulatory requirements as well as the guidelines for conducting human research involving investigational new drugs.

FDA-REGULATED RESEARCH

To ensure that drugs introduced to the market are acceptably safe and effective for their claimed indications, studies evaluating new drugs must be carried out...
according to strict guidelines from the FDA. As an investigational drug enters into the clinical trial process, it progresses through three phases prior to becoming eligible for submission for FDA approval. All phases of the clinical trial have carefully developed inclusion and exclusion criteria, making the sample very medically homogeneous for data analysis.

Phase I clinical trials are studies in which the investigational drug is first tested in a small group of either healthy individuals or those with the target disease. These trials attempt to determine the metabolic, pharmacokinetic, and toxicological properties involved with differing dosing ranges and routes of administration in closely monitored, short-term studies. Typical sample size is 20-80 individuals and the information obtained in this phase permits the design of well-controlled, scientifically valid Phase II studies.

Phase II clinical trials, the goal is to assess the short-term side effects encountered with the use of the drug, and to attempt to determine if the drug is effective against the medical condition under investigation. These trials involve slightly larger samples (usually several hundred) of individuals with the disease and are well controlled and closely monitored.

Phase III trials involve an expanded sample of subjects, sometimes at multiple sites concurrently. These trials are conducted after preliminary evidence suggests effectiveness has been demonstrated. These trials usually include several thousand subjects and provide additional information about the safety and effectiveness (risk/benefit) of the study drug. They also provide data that serve as the basis for physician labeling.

In some cases, Phase IV clinical trials may occur once a drug has received approval from the FDA. These trials allow the sponsor to continue to gather safety data from more realistically heterogeneous groups of subjects that will use the drug on a day-to-day basis. The distinction between scientific merit and marketing promotion becomes more difficult to discern once a drug has been approved and at times there is little support from investigators for postapproval studies. This leaves safety to be determined from anecdotal occurrences.

All phases of clinical trials under an FDA investigational new drug application must adhere to the FDA regulations described in the Federal Code of Regulations (CFR) Title 21; specifically, parts 50 (Protection of Human Subjects); 54 (Financial Disclosure by Clinical Investigators); 56 (Institutional Review Boards [IRBs]), and 312 IND Applications. CFR Part 50 sets forth the regulation for conducting research along with the principles of informed consent. The role of the IRB, the federally mandated organization that oversees human subject research, and assures that patients’ rights are protected in the informed consent process, is also identified. An IRB is empowered to make the final decision as to whether a research project or clinical trial may proceed or to require modification to a submitted protocol to ensure that the underlying principles of the federal regulations are adhered. No matter the research location, sponsors of clinical trials research will be under the jurisdiction of an IRB, either through a central IRB that provides oversight for research at several institutions or sites, or through an investigator under the jurisdiction of a local IRB, such as found in an academic or hospital setting.

Any potential conflict of interest on the part of a clinical investigator, the subinvestigator, or members of the research team must be declared on the financial disclosure form which is a reporting requirement of the FDA. Conflicts of interest include not only those for the persons identified above, but also must include conflicts of interest for their spouse and dependent children. Examples of conflicts of interest include having stock or an otherwise financial interest in the pharmaceutical company or sponsor and/or receiving any type of significant payment, other than that which is required to conduct the study, such as in the form of a grant, equipment, retainer for ongoing consultation, or honoraria.

To ensure the integrity of the data collected during a clinical trial and to validate that a research site is complying with federal regulations, pharmaceutical companies (sponsors) must provide oversight. Sponsors may choose to transfer this responsibility for site compliance to a contract research organization, which is subject to the same regulatory action as a sponsor for failure to comply. A contract research organization (CRO) employs healthcare professionals to monitor the research site and review any source documents (such as medical records) or case report forms, (both electronic and paper), as well as the regulatory documents. The CRO visits the research site on an intermittent basis for this purpose but may also query data that are inconsistent or unclear between visits. The CRO prepares a report outlining its findings for the sponsor who uses this information for its reports to the FDA or sponsor agency meetings. Data analysis is accomplished independent of the CRO review process. Likewise, the FDA may choose to conduct on-site inspections to ensure
compliance with the federal regulations either as a drug nears approval or should a significant adverse event (such as patient death or significant incidence of non-compliance become) evident. Failure to comply with FDA regulations can lead to reprimand by the FDA and/or termination of the research study.

The FDA is an agency within the US Department and Health and Human Services (HHS). The FDA and HHS have separate regulations that apply to research with human subjects. The regulations are similar but not identical. The differences between the two can be found on the FDA’s Web site. Nurses need to know that new drug studies must comply with both HHS and FDA regulations. The challenge for an IRB is to validate that the clinical trials research project under review has adhered to both the HHS and FDA regulations. The FDA, like other federal agencies, adheres to the ethical principles and regulations called the “Common Rule,” Subpart A of the Code of Federal Regulations.

**It is of primary importance that the nurse involved with research patients understands that one of the underlying premises of research is voluntary participation.**

### INVESTIGATIONAL NEW DRUG APPLICATION

An IND application must be filed with the FDA when the sponsor wants to test a newly developed drug to see if its safety and efficacy merit approval for marketing. The permission granted by the FDA is limited to the specific drug, the specific uses (indications) for which licensure is to be sought, and the specific clinical trial to be performed. An IND is also required for studies of drugs that are already licensed if the intent of the clinical study is to generate data that will lead to an approval of a new treatment indication or advertising claims. The IND application contains information and evidence of laboratory findings as well as the safety and tolerability in animals. It also includes a description of the manufacturing process with assurance of the identity of the final product and specific tests for toxins or toxic ingredients, along with a well developed plan (protocol) that minimizes the risks to human subjects. Unless otherwise notified from the FDA, the IND application becomes effective 30 days after receipt by the FDA and the clinical investigation may begin as long as the clinical investigator is in compliance with regulations and the study has been submitted for review and has been approved to the IRB.

If the sponsor/investigator adds a new patient group, alters the study design, or adds a new clinical indication, an amendment must be submitted to and approved by the FDA. This change in protocol along with appropriate changes to the informed consent must also be submitted to and approved by the IRB before any changes are instituted in the research study.

If a drug is already approved by the FDA for marketing in the United States and is licensed, a clinical study does not require an IND. Provided, as indicated above, the purpose of the study is not one that is designed to change the approved indications, the advertising claims, or the labeling of the product. In addition, the clinical study must not be one that changes the dose, route of administration, or target population for the drug. The study still requires that IRB approval is received as well as approval for the informed consent to be used.

However, should in the course of a study, a significant adverse event or interim data analysis show that there has been a significant change in the risk/benefit ratio, FDA approval for the study and/or the drug could be withdrawn. This recently occurred in a clinical trial of specific long-term hormone replacement therapy undertaken by the National Institutes of Health. Interim trial results found a statistically significant increase in rates of breast cancer, heart attacks, stroke, and blood clots in women taking estrogen with progestin when compared with women taking placebo. The FDA required that these findings be released, and that research using similar drugs notify study participants. This arm of the NIH study was discontinued. Investigators in unrelated studies using a similar drug were required to immediately notify their IRB of the study findings and follow IRB recommendations for notification of study participants and validation of continued informed consent to participate.

Likewise, should a change in risk of illness or injury related to research occur the FDA may place a clinical hold on an IND. Also, if in the general prescriptive use of the drug outside of the research setting, a significant change in safety is identified, the FDA could require a change in labeling to occur, identifying this increased risk. This change in status must be reported to the IRB which will then reconsider whether to allow the study to proceed or whether to withdraw its approval and stop the research.

### SPECIAL TYPES OF INVESTIGATIONAL NEW DRUGS

There are several special categories of IND, of which nurses should be aware, although they are not very common. The treatment IND is a treatment protocol that is
added to an existing IND application, that allows physicians to treat qualifying patients according to the protocol, and which provides additional data in the drug's safety and effectiveness. Treatment INDs are available for patients with life-threatening or very serious diseases for which no satisfactory alternative drug or other therapy exists. Treatment INDs must be reviewed by the IRB committee, and must comply with all federal regulations, and also require informed consent. A treatment IND may be granted after data exist that show the drug may be effective and does not appear to have unmeasurable risks.

The “Group C” treatment IND resulted from an agreement with the FDA and National Cancer Institute (NCI). This program provides a means to distribute investigational drugs to oncologists to treat patients with cancer outside of a controlled clinical trial. Group C drugs have demonstrated some effectiveness for a specific type of cancer. Group C drugs are distributed only by NCI. Although treatment is the primary objective, data related to safety and effectiveness are still collected. The FDA usually grants a waiver from IRB review requirements, but the institution’s IRB may elect to conduct a review.

Single-patient use is another means practitioners may obtain investigational drugs for treatment. In most cases, the patient is seriously ill, unresponsive to other treatments, or no recognized treatment is available. The physician needs to provide theoretical or anecdotal evidence to support his or her request. Access to the IND for use by a single patient can be secured through the study sponsor under a treatment protocol or through the FDA. In the latter case, the physicians must first secure the drug from the sponsor and then submit a treatment IND to the FDA requesting to use the investigational drug for the identified patient.

The parallel track mechanisms make promising investigational drugs available to persons with AIDS and other HIV-related diseases. Under FDA policy, persons with AIDS and HIV-related diseases who are unable to take standard therapy or for whom standard therapy is no longer effective, or who do not have access to ongoing clinical trials have access to promising investigational drugs. Parallel track protocols follow the treatment IND process that is described above. Data about the safety and effectiveness of the drug are usually submitted to the sponsor.

**PARTICIPATION OF CHILDREN**

The FDA's Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients supports including children in clinical trials of new drugs. Proposed drugs are expected to be tested in children unless a waiver of this requirement is justified. It is anticipated that waivers, partial or full, will be granted by the FDA only in limited circumstances, such as where there is a reasonable basis to conclude that the drug has little therapeutic benefit for children and it is not likely to be used by a substantial number of children. The ultimate goal is to have more drugs labeled for children.

There is evidence encouragement was needed to include children in new drug studies. One study conducted a retrospective review of FDA archival documents and published literature related to new drugs for pediatric oncology. More than 100 drugs had been approved by the Division of Oncology Drug Products of the FDA for the treatment of malignancies. Only 15 had pediatric use information in their labeling. In the past 20 years, there were only 6 submissions to the FDA from pediatric oncology institutions.

Thus, the wholesale exclusion of children from research trials involving new drugs is no longer justified. However, 2 equally important interests must be balanced: 1) the need for children’s participation in clinical trials; and 2) the need to protect this special population from harm. Nurses need to be especially vigilant in observing for adverse effects to these new drugs in studies involving children.

**DRUG STUDY DESIGNS**

A well-controlled clinical trial permits a comparison of subjects treated with the new drug with a control population, so the effect of the new drug can be evaluated. FDA regulations cite 5 different kinds of controls that can be used:

- placebo concurrent control
- dose-comparison concurrent control
- no-treatment concurrent control
- active treatment concurrent control
- historical control.

The FDA states no preference for any design type, but indicates the study design must be adequate to address the study’s task. Placebo control, no-treatment control, and dose-comparison control are study designs that are intended to show a difference between the test drug and some control. The active-treatment control is a design intended to show no difference between the test drug and a recognized effective drug (active-control), which would be evidence of effectiveness of a new agent. Active-controls are frequently used in antibiotic trials because one is able to tell the difference between antibiotics that have the expected effect on a specific infection and those that do not. Historical control study designs are difficult to use because the investigator must demonstrate the historical control group is comparable to the treated subjects. Thus, this design is rarely used.
Many clinical trials, particularly Phase III, are implemented under protocols as above but include a double-blind component. Under this design, neither the patient nor the investigator or investigative site knows whether the patient has received the medication or a placebo. Because identical-looking drug kits are formulated, numbered, and sent to the research site, no distinction can be made as to assignment. Randomization occurs through a third party in an effort to maintain the blind control. The potential for influencing patient response through investigator bias is eliminated; however, the potential for patient enhancement or overreporting of results from a perceived increase in support received by the patient from the research team cannot be determined. Likewise, an underreporting of positive effects by patients because of the unknown assignment is also possible.

Of all of the study designs, placebo-controlled, and active control trials are most likely to raise ethical concerns for the IRB, investigator, the nurse, and the patient. The IRB will use federal regulations to determine risks and benefits of the study. If the study poses unacceptable risks, it will not be approved. For placebo-controlled studies, the IRB will examine the risk-benefit profile of the placebo intervention separately from the risk-benefit of the experimental treatment.

Greater responsibility for thorough assessment of study participants is needed by nurses associated with blinded studies, both placebo-controlled and active control designs. Although only a predetermined proportion of the patients in a blinded study will actually receive a certain study medication or placebo, it is important that the nurse assumes that the patient is actually receiving the IND. Thus, any nurse who interacts with the study patient has a responsibility to be aware of the potential side effects of the IND, so that the investigator or study coordinator can be immediately notified of changes in a subject’s condition and evaluated to determine if the patient is having an adverse reaction to the study medication. This could possibly lead to the patient being withdrawn from the study. However, in the event of a serious change in a patient’s medical condition, a predetermined process previously communicated by the sponsor to each research site to break the blind so that study drug assignment can be determined and appropriate medical treatment can be provided to the patient.

In order to obtain additional safety and/or efficacy data, a clinical trial may be extended from a blinded design to an open label design whereby all participants receive study medication in a known dosing regime. Drug packing is received from the sponsor with numerical notation and assignment still being made through an interactive voice response system.

**HUMAN SUBJECTS REVIEW**

In reviewing the proposed IND research, the IRB considers the scientific merit of the study. This includes the documentation submitted to the FDA as well as the study proposal. The submission proposal packet will include the sponsor provided clinical protocol, the informed consent that the patient will sign, the investigator’s brochure (which provides detailed information about all previous research findings with the drug both in the laboratory, with animals, or with humans), any advertisements that will be utilized, any patient appreciation programs or incentives that will be offered, as well as the Financial Disclosure Forms and the FDA 1572.

If this is a multisite industry-sponsored protocol, or an NIH-sponsored study, then the full grant proposal is also reviewed. The IRB will evaluate the risks and benefits of the drugs, data analysis, and surveillance of subjects during the study. The IRB will also carefully review the consent process. Under the new HIPAA regulations subjects currently participating in studies involving investigational drugs need to know and understand that the FDA and other federal regulatory agencies now have access to their medical records beyond information that pertains to the study. The availability of these medical records to the investigator and members of the research team on a need-to-know basis are included. This process has been practiced by many institutions prior to the HIPAA act.

**RESPONSIBILITIES OF NURSES IN INVESTIGATIONAL NEW DRUG RESEARCH**

Throughout the IND study, the distinction between therapy and research must be maintained. Careful documentation in both the patient’s medical record and study case report form validates that the patient has been counseled about his or her role, responsibilities, and expectations of participation.

Nurses play an important role in ensuring that the patient understands and remembers that the drug is experimental, and that the benefits for the condition under study are not known. If a nurse hears any comments from the patient that indicates that the patient is unclear about this issue, she or he should report this to the investigator in charge of the study, the primary physician, or the research nurse for this study. The patient should clearly understand that there may be no personal benefit for participation in the research study. The patient should be clear that no claims are being made that this IND is more reliable, safer, more effective, or in any way superior to another drug on the market.

The copy of the informed consent for the study should be in the patient’s medical record as well as doc-
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...umentation that the patient is participating in a drug study. A notation should be made in the patient's study file or medical record that he or she has received a personal copy of the informed consent. The informed consent must contain the required elements mandated by HHS and FDA regulation. Nurses who interact and are responsible for care provided to a study patient need to review the informed consent to gain familiarity with the information that has been provided to the patient as it relates to his or her participation, and the risks and benefits. Nurses should also feel confident that the informed consent process has been followed according to federal regulatory guidelines. This includes allowing the patient ample opportunity to answer questions, read the informed consent, and/or discuss the decision to participate with his or her social support network. Nurses must make sure that the patient has not been pressured to make a hurried decision to participate or that there are questions remaining regarding participation. Nurses also need to be certain the patient understands the concept of randomization. Some patients assume their treatment protocol was determined by the doctor or researcher, others assume randomization means they were randomly chosen to participate, and some have no idea what this means but are too embarrassed to ask.

The FDA human subjects' regulations allow for an IND to be used in emergency situations without prior IRB approval, provided that the emergency use is reported to the IRB within 5 working days. An emergency is defined as a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval.

Beyond nurses' responsibility for assessment and identification of adverse events to study medication, nurses need to know their hospital's guidelines for the proper labeling, storage, distribution, and control of investigational drugs. Some institutions require that all medication be received by and dispensed through a research pharmacy; however, it is possible for medication to be shipped directly to an individual at the research site. The first study medication may be received by the study site once the 30 days has expired between IND submission and review by the FDA. If the hospital's pharmacy is utilized, the pharmacy is then responsible for the labeling, distribution, and control of INDs. If the research pharmacy is not utilized, the principal investigator's pharmacy is utilized, the pharmacy is then responsible for the labeling, distribution, and control of INDs. If the research pharmacy is not utilized, the pharmacy is then responsible for the labeling, distribution, and control of INDs. The principal investigator or research nurse should be notified if a study patient no longer wishes to participate, so that the patient can be officially withdrawn from the study. Patients are never to be made to feel that the care that they are receiving or their relationship with the healthcare system will be adversely affected by their decision to withdraw. Nurses need to immediately report any occurrence of undue pressure on a patient to participate in a research study.

Nurses must also be aware of the federal guidelines related to patient compensation and incentives in research. Patient appreciation programs for participation must be consistent with the level of participation required and never should be significant enough to influence a patient's decision to participate or continue in a research study. When discussing a research study with a patient, the nurse must be careful to not infer any promise of special consideration, compensation, or advantage for participation. Likewise, the nurse should report any incidence of preferential treatment of patients for study participation.

Ethics is a hallmark of nursing practice and is an important component of the research process. Nurses involved with research patients or working as a research nurse need to maintain a similar integrity in their practice. Because investigative sites are compensated by the sponsor for study patient participation, nurses should be...
aware of any instances where a study patient was continued in a clinical trial or enrolled in a clinical trial in a manner that was inconsistent with the study protocol.

Similarly, nurses need to serve as patient advocates if there is reason to believe that study patients are not being given similar appropriate medical attention by the principal investigator; examples might include careless physical examinations, inattention to abnormal laboratory values, or inattention to inclusion/exclusion criteria. Many people who have no access to healthcare services currently volunteer for participation in a research study. Therefore, patients should never be led to believe that they are receiving free medical care; rather, a distinction is made that the care they will receive will be consistent with the study protocol and may include components of routine health screening for which there is no charge. However, if in the course of study participation, a medical health problem is identified, the principal investigator and or his or her study nurse have a responsibility to inform the patient and provide a referral for follow-up. Patients who refuse referral or do not follow through with investigator recommendations may be prematurely discontinued from the study. If the health risk does not preclude continuation in the study, then careful documentation of the principal investigator’s approval is noted in the medical record and/or made in the study file.

As a part of the study protocol, the sponsor includes to the research site, a list of occurrences that require immediate reporting to the sponsor and the FDA. The nurse involved with study patients needs to be aware of those adverse events that are considered serious or significant by the sponsor. While all changes in patient medical condition are documented in the research file, only a select few are considered important enough that their occurrence is shared with the sponsor and the FDA. Events that are reported to the sponsor and FDA are then sent to all research sites in the form of an IND Safety Report. IND Safety Reports are submitted to the appropriate IRB for review and determination if the study may continue in its current format, if modification or change in the protocol is necessary for continuation, or if approval will be withdrawn. Informing the investigator of any significant change in patient status is the first step in this process. It is the responsibility of the principal investigator to determine if the event is serious, and if its occurrence was doubtfully, probably, or definitely associated to the IND. Serious adverse drug experiences should be recorded in as much detail as possible.

- RESPONSIBILITIES OF INVESTIGATORS

The investigators in a clinical trial are responsible for seeing that the trial is conducted in an ethically responsible manner. The investigator attests to this when he or she signs the form FDA 1572* prior to the start of the study. Table 1 describes these commitments. The investigator must also obey all federal, state, and local regulations; protect the rights, safety, and welfare of study participants; and control the use of the investigational drugs. The principal investigator has ultimate responsibility for all data submitted from the research site and validates by signature, either written or electronic. The investigator must attest that oversight was provided for each study subject. Depending upon the requirements of the IRB with jurisdiction at the institution, the principal investigator may be personally responsible for obtaining written, informed consent from all subjects or may be allowed to delegate that responsibility to a

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**TABLE 1 Commitments That the Investigator Makes When Signing the Form FDA**

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients or any persons used as controls that the drugs are being used for investigational purposes, and I will ensure that the requirements relating to obtaining informed consent in 21 CFR* part 50 and institutional review board approval in 21 CFR part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64.

I have read and understand the information in the investigator's brochure, including the potential risks and adverse effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR part 312.62 and to make those records available for inspection in accordance with 21 CFR part 312.68.

I will ensure that an institutional review board that complies with the requirements of 21 CFR part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the institutional review board all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without institutional review board approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigations and all other pertinent requirements in 21 CFR part 312.

*FDA, Food and Drug Administration; CFR, Code of Federal Regulation.*
member of the research team. The principal investigator is responsible for evaluating all adverse events which occur at his or her study site and determining the relationship to the study drug. Likewise, the principal investigator must review, authorize, and determine the clinical significance of all laboratory findings obtained during the course of the study. The principal investigator has the ultimate responsibility to make the determination if a patient meets the study inclusion/exclusion criteria or if laboratory or physical examination findings will prevent a subject from participating or continuing in the study. The investigator is also responsible for compliance with the Guideline for Good Clinical Practice of the International Conference on Harmonisation as adopted by the FDA. While preparation of the documentation sent to the IRB can be delegated to a member of the research team, the principal investigator is the individual with whom the IRB communicates regarding questions, clarifications, approval, or disapproval of research studies.

INTERNATIONAL CONFERENCE ON HARMONISATION

The FDA developed a guideline entitled, “Good Clinical Practice: A Consolidated Guideline,” that was prepared under the review of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. The guidelines provide an international ethical and scientific standard for designing, conducting, data collecting, and reporting clinical trials that involve human subjects. The objective of the guidelines is to facilitate the acceptance of international clinical data in countries that recognize and use the guidelines.

SUMMARY

The Department of Health and Human Services and the FDA have separate regulations related to research involving human subjects. The purpose of this article was to review the FDA guidelines for research with investigational new drugs. Nurses should also be aware that individual states may also have regulations that must be followed. Also, each institution may have a set of rules to follow. Nurses would be well served to discuss regulatory requirements for conducting IND research with the trial’s investigator or research nurse as well as the institution’s research office.

REFERENCES


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