

---

# Yale University Institutional Review Boards

---

## IRB Policy 600 Use of Investigational New Drugs and Devices in Human Research

Responsible Office	Office of Research Administration	Effective Date	12/4/09
Responsible Official	IRB Director	Last Revision	5/6/10

---

<b>Policy Sections</b> .....	<b>4</b>
600.1 Investigational New Drugs (INDs).....	4
600.2 Investigational Device Exemptions (IDEs).....	6
600.3 Investigator-Held IND or IDE (Sponsor-Investigator).....	9
600.4 Treatment Use of an Investigational or Unlicensed Drug or Device.....	9
600.5 Emergency Use of an Investigational or Unlicensed Drug or Device .....	10
600.6 Compassionate Use of an Investigational or Unapproved Device.....	10

---

### Scope

This policy applies to all investigators conducting human research under an investigational new drug application or an investigational device exemption.

---

### Policy Statement

Investigators who conduct human research regulated by the Food and Drug Administration (FDA) are required to know and comply with all relevant FDA regulations governing the use of investigational drugs, devices or other test articles. Under FDA regulations (21CFR 312), research that involves the use of a drug other than the use of a marketed drug in the course of medical practice must be conducted under an investigational new drug (IND) application, unless the protocol meets one of the five exemptions from the requirement for an IND. Research that is conducted to determine the safety or effectiveness of a device must have an Investigational Device Exemption (IDE, 21CFR 812) issued by the FDA, unless the device meets the requirements for an abbreviated IDE or the protocol meets one of the five exemptions from the requirement for an IDE.

---

### Reason for the Policy

This policy helps to ensure that the regulatory requirements for the conduct of clinical investigations of drugs and devices in human research are known and complied with when Yale investigators conduct research under an IND or IDE. It is also intended to encourage the discovery and development of useful drugs and devices intended for human use while ensuring the protection of public health and safety as well as ethical standards. An accepted IND application or approved IDE permits a drug or device that otherwise would be required to comply with a performance standard or to have premarket approval by FDA to be shipped lawfully for the purpose of conducting investigations of that drug or device.

---

### Definitions

#### Clinical Investigation

Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 312 (new drug applications) of the Federal Food, Drug, and Cosmetic Act (Act), or is not subject to requirements for prior submission to the FDA under these sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

**Compassionate Use**

For purposes of this policy, compassionate use refers to the use of an investigational device as the only option available for a patient faced with a serious, albeit not life-threatening condition. The term “compassionate use” is not recognized by the FDA when referring to investigational drugs.

**Device Categories**

FDA will place all Investigational Device Exemptions (IDEs) it approves in one of two categories:

- **Category A - Experimental**

The IDE involves innovative devices in which "absolute risk" has not been established (i.e., initial questions of safety and effectiveness have not been resolved and thus FDA is unsure whether the device type can be safe and effective)

- **Category B - Investigational; Non-experimental**

The clinical investigation involves device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved). This category includes device types that can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Nonsignificant risk studies may also be included in this category.

**Human Subject or Human Participant**

A living individual (1) about whom an investigator (whether professional or student) conducting research obtains either (a) data through intervention or interaction with the individual; or (b) identifiable private information; or (2) who is or becomes a participant in research involving drugs or devices, either as a recipient of a test article or as a control. Note that both human subject and human participant are used interchangeably in IRB policies and procedures. While the term “participant” conveys the voluntary nature of an individual’s agreement to participate in the research, it also can convey a sense of partnership which is not reflected in all types of research. In some cases, the research volunteer is in fact more acted upon than truly having any sense of partnership in the research. Hence the term subject is considered more appropriate in such cases.

A subject may be either a healthy human or a patient. Specifically in regard to investigational device studies, subject means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used, or as a control. A subject may be in normal health or may have a medical condition or disease.

**Experimental Subject (for Department of Defense-sponsored research)**

Research Involving a Human Being as an Experimental Subject: An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32CFR219.102 (f), reference(c)). Examples of interventions or interactions include, but are not limited to, a physical procedure, a drug, a manipulation of the subject or subject’s environment, the withholding of an intervention that would have been undertaken if not for the research purpose.

**Immediately Life-Threatening Disease**

A stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

**Investigational New Drug (IND) application**

An exemption from the FDA premarketing requirements that are otherwise applicable which allows the drug to be shipped lawfully for the purpose of conducting clinical investigations of the drug. Current Federal law requires that a drug be the subject of an approved marketing application before it is

transported or distributed across state lines. Because a sponsor will usually 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. There are three additional IND types and two IND categories:

#### **IND Types:**

- **Investigator IND (Sponsor-Investigator)**

An Investigator IND is submitted to the FDA by an investigator who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. An investigator 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.

- **Treatment IND**

A treatment IND is submitted to the FDA to make promising new drugs available to desperately ill patients as early in the drug development process as possible. FDA will permit an investigational drug to be used under a treatment IND if there is preliminary evidence of drug efficacy and the drug is intended to treat a serious or life-threatening disease in its later stage of development or if there is no alternative drug or therapy available to treat that stage of the disease in the intended individuals.

- **Emergency Use IND**

The 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 the regulations. 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.

Emergency and Treatment INDs are sometimes referred to as "Compassionate Use" INDs, but the term "Compassionate Use" is not in the IND regulations.

#### **IND categories:**

- Commercial. These are applications that are submitted primarily by companies whose ultimate goal is to obtain marketing approval for a new product.
- Research (non-commercial)

#### **Significant Risk (SR) Device**

A device that 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 a 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.

#### **Sponsor-Investigator**

Sponsor-investigator is an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the investigational drug or device is administered, dispensed, or used. The term does not, for example, include a corporation or agency. The obligations of a sponsor-investigator include those of an investigator and those of a sponsor.

#### **Test Article**

Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Act or under sections 351 and 354-360F of the Public Health Service Act (42 U.S.C. 262 and 263b-263n).

---

## Policy Sections

---

### 600.1 Investigational New Drugs (INDs)

An investigational new drug (IND) application is required for investigational or experimental drugs if the drugs are being used for the purpose of developing information about their safety or efficacy. Approved, marketed drugs may also require an IND if the proposed use in research is different from the previously FDA-approved use, or administered by an unapproved route or method of delivery or an altered dosage. The intended use of an approved drug may be exempt from IND application requirements under certain conditions, below.

#### Exemption from IND Requirements

The clinical investigation of a marketed drug or biologic does not require submission of an IND if all six of the following conditions are met:

- (1) it is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;
- (2) it is not intended to support a significant change in the advertising for the product;
- (3) it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- (4) it is conducted in compliance with the requirements for IRB review and informed consent [21 *CFR* parts 56 and 50, respectively];
- (5) it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 *CFR* 312.7]; and
- (6) it does not intend to invoke 21 *CFR* 50.24 for the exception from informed consent requirements for emergency research.

In addition, exemption from IND requirements exists if the following conditions are met:

- (1) The clinical investigation is for an *in vitro* diagnostic biological product that involves one or more of the following:
  - Blood grouping serum.
  - Reagent red blood cells. .
  - 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.
- (3) The diagnostic test is shipped in compliance with 21 *CFR* §312.160.

Or, if the following condition is met:

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

## IRB Determinations

The fully convened IRB reviews human research protocols conducted under an IND in accordance with Policy 100 IRB Review. Investigators are required to produce documentation from the FDA indicating the IND number, which the IRB will match with information provided in the protocol submitted for review to ensure consistency. In the case of studies involving investigational drugs for which an IND has not been obtained, the investigator should justify to the IRB why exemption is appropriate. In this case, the IRB will make an exemption determination based on reviewing the proposed use of the drug in light of the exemption criteria, the investigator's statements, and its knowledge of relevant scientific information. The IRB's determination may be concurrence that an IND is not required, or requirement that the investigator file an IND with the FDA, or requirement that the investigator obtain an exemption determination from the FDA. The IRB's determination is generally driven by consideration of item (3) above. That is, if it is determined that the research involves some new aspect that may significantly increase risks over what is already known about the use of the drug, it is likely that an IND will be required.

## Investigator Responsibilities

An investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs under investigation. If the investigational drug is subject to the Controlled Substances Act (<http://www.deadiversion.usdoj.gov/21cfr/21usc/index.html>), the investigator shall take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution. An investigator shall obtain the informed consent of each human subject to whom the drug is administered, except when an exception to the requirements for informed consent is met.

Investigators are also responsible for the following (21 CFR 312 Subchapter D):

- administering the drug only to subjects under the investigator's personal supervision or under the supervision of a co-investigator responsible to the investigator;
- supplying the drug only to persons authorized to receive it;
- maintaining adequate records for the disposition of the drug (dates, quantity, and use by subjects);
- returning unused supplies to the sponsor (agency, industry or investigator) or otherwise providing for the disposition in accordance with the direction of the sponsor;
- maintaining adequate and accurate case histories on each individual receiving the drug or employed as a control (all observations and other data pertinent to the investigation including case report forms and supporting data (source documents, e.g., signed and dated consent forms, medical records including progress notes, hospital charts and nurses notes);
- retaining records for 2 years after either the date a marketing application is approved for the drug for the indication under investigation, or, if no application is to be filed or if the application is not approved, until 2 years after the investigation is discontinued and FDA is notified;
- submitting progress reports and safety reports to the sponsor and IRB;
- providing financial disclosures to the sponsor and the IRB;
- storing drugs properly and securely;

- obtaining IRB and FDA review and approval prior to initiating the research (including the consent process) and prior to initiating any changes to the approved research; and
- permitting authorized individuals (e.g., IRB personnel, University auditing personnel, FDA personnel, federal Drug Enforcement Agency (DEA) personnel) to have access to and to copy relevant records.

*Additional requirements include a commitment by the investigator that he or she:*

- Will conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after securing IRB approval and notifying the sponsor, except when necessary to protect the safety, the rights, or welfare of subjects;
- Will comply with all requirements regarding the obligations of clinical investigators and all other pertinent regulatory requirements ;
- Will personally conduct or supervise the described investigation(s);
- Will inform any potential subjects that the drugs are being used for investigational purposes and will ensure that the requirements relating to obtaining informed consent and IRB review and approval are met;
- Will report to the IRB and the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with Yale University Policy 720 on Adverse Event Reporting, and 21 CFR 312.64;
- Has read and understands the information in the investigator's brochure, including the potential risks and side effects of the drug;
- Will 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; and
- Will promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others, and will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to the human subjects.

In the event that a Yale PI is also the sponsor of the IND, the PI must comply with requirements of sponsor-investigators as described below and at <http://info.med.yale.edu/hrpp/sponsorinvest.html> (IND Sponsor-Investigator Guidance 600 GD. 1.)

---

### **600.2 Investigational Device Exemptions (IDEs)**

Under FDA regulations (21 CFR 812), research that is conducted to determine the safety or effectiveness of a device must have an IDE issued by the FDA, unless the device meets the requirements for an abbreviated investigational device exemption (IDE) or the protocol meets one of the five exemptions from the requirement for an IDE that relate to use in humans (see 21 CFR 812.2). The clinical study of a *new indication* for an already marketed, FDA-approved device falls under the IDE regulations as well.

### **Significant Risk or Non-Significant Risk Devices**

The FDA established three regulatory classes for medical devices based upon the degree of control necessary to assure that the various types of devices are safe and effective. Devices are classified depending upon their intended use as well as the risk the device presents to humans. FDA guidance for determination of classification of devices and regulatory control is located at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm#introduction>. The sponsor of the device will make the initial determination of whether

the device presents a significant risk (SR) or non-significant risk (NSR). A NSR device study is one that does not meet the definition of a SR study. NSR device studies are not necessarily minimal risk studies. For a list of NSR devices, see <http://www.fda.gov/oc/ohrt/irbs/devices.html#risk>.

For SR device studies, the FDA must approve an IDE application submitted by the sponsor, and the IRB must approve the study before it may commence. SR device studies require review of the full board. In the event that a Yale PI is also the sponsor of the IDE, the PI must comply with requirements of sponsor-investigators as described below.

NSR device studies do not require submission to the FDA. These studies must comply with the abbreviated regulations set forth in [21 CFR 812.2\(b\)](#). Unless otherwise notified these NSR devices are considered to have an approved Investigational Device Exemption (IDE) if the sponsor fulfills the regulatory requirements of 21 CFR 812.2(b). While exempt from FDA approval, **NSR studies must receive IRB approval prior to commencing**. NSR studies generally will require full board review but may be approved through the expedited review procedure if the study falls within a designated approvable category and is minimal risk.

### Device Categories

To assist Medicare (CMS) in determining coverage for such devices, and thereby assisting IRBs in understanding subject economic responsibilities for such devices, the FDA further assigns each device with an FDA-approved IDE into one of two categories: Category A – Experimental (safety and efficacy not yet established), and Category B – Investigational; Non-experimental (underlying questions on safety and efficacy have been resolved). See Definitions for complete descriptions of device categories.

### IRB Determinations

The IRB will make the final determination for NSR devices. If the IRB disagrees with the sponsor and designates the device as SR, the IRB will require that the sponsor submit to the FDA for an IDE. The study will not be approved by the IRB until the IDE is obtained or official communication from the FDA indicating its determination of NSR is obtained. The investigator will be informed of the IRB's determination in writing and the investigator must inform the sponsor.

In assessing the risk level of a device, the IRB will consider information contained within the protocol application or investigator's brochure, such as a description of the device and its proposed use, nature of the harm that may result from the use of the device or from procedures required for use of the device (e.g., surgical implants), reports of prior investigations conducted with the device, the proposed investigational plan, a description of subject selection criteria and monitoring procedures. The IRB should be provided with the sponsor's risk assessment and rationale for its determination as NSR. The sponsor must provide the IRB with the FDA's assessment of the device's risk if such an assessment has been made. The IRB may also choose to consult directly with the FDA.

### Investigator Responsibilities

The principal investigator of a device study is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable FDA regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with regulatory requirements.

If any investigational devices are used, or investigational procedures performed, in a YNHH Operating Room, then investigators are required to complete a YNHH OR New Product/Trial Request Form. The OR Materials Manager, Chris Baillargeon, should be contacted at 203-688-8912 for more information on this requirement. Furthermore, per YNHH policy, the request must

be reviewed and approved by the Operating Room New Technology Committee before patients may be scheduled. The notice of approval from the OR New Technology Committee must be submitted to the IRB for the protocol file.

Investigators are also responsible for ensuring the following (21 CFR 812.110, Subparts E and G):

- obtain appropriate approvals (IRB, YNHH, FDA) prior to obtaining consent and enrolling any subjects;
- make financial disclosures to the sponsor and the IRB;
- supervise the device use, and ensure that the device is used only with subjects under the investigator's supervision;
- supply the device to only individuals authorized under the regulations;
- upon completion or termination of a clinical investigation, or the investigator's part of an investigation, or at the sponsor's request, return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs;
- permit authorized persons (e.g., IRB staff, FDA staff) to inspect and copy records relating to the investigation;
- if authorized, permit authorized persons (e.g., IRB staff, FDA staff) to enter and inspect any establishment where devices are held (manufactured, processed, packed, installed, used, or implanted, or where records of results from use of devices are kept);
- maintain adequate records including:
  - correspondence with another investigator, an IRB, the sponsor, a monitor, or the FDA;
  - records of receipt, use or disposition of a device that relate to the type and quantity of the device, the dates of its receipt, and the batch number or code mark, the names of all persons who received, used, or disposed of each device, why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of;
  - each subject's case history and exposure to the device (include the case report forms and supporting data including, for example, the signed and dated consent forms, medical records including progress notes, adverse event reports);
  - the protocol and records of any deviations from the protocol; and
  - any other records required by the FDA or IRB or relevant to the study;
- submit reports of unanticipated adverse device effects to the IRB within 48 hours of discovery, in accordance with Adverse Event Reporting Policy 720, and to the sponsor as soon as possible but within 10 days of becoming aware of the event;
- submit a report to the sponsor within 5 days of any withdrawal of IRB approval;
- submit progress reports to the IRB, sponsor, and monitor at least annually.

Investigators should refer to

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049864.htm> for additional information on responsibilities in conducting significant risk device investigations.

---

**600.3 Investigator-Held IND or IDE (Sponsor-Investigator)**

Investigators who hold an investigational new drug application (IND) or investigational device exemption (IDE) are required to follow the FDA's requirements for sponsors in addition to those for investigators.

**Additional general requirements for IND holders:**

Sponsors are responsible for selecting qualified investigators, providing them with the information they need to conduct an investigation properly, ensuring proper monitoring of the investigation(s), ensuring that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND, maintaining an effective IND with respect to the investigations, and ensuring that FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug. Additional specific responsibilities of sponsors are described in 21 CFR 12 Subpart D--Responsibilities of Sponsors and Investigators. (See also <http://info.med.yale.edu/hrpp/sponsorinvest.html>, or IND Sponsor-Investigator Guidance 600 GD. 1.)

**Additional general requirements for IDE holders:**

Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to FDA, and ensuring that any reviewing IRB and FDA are promptly informed of significant new information about an investigation. Additional responsibilities of sponsors are described in 21 CFR 812 Subparts B (Application and Administrative Action) and G (Records and Reports).

Sponsor-Investigators should refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm049859.htm> for additional information on responsibilities as holders of an IDE.

---

**600.4 Treatment Use of an Investigational or Unlicensed Drug or Device**

An investigational drug or device may be used in a research study (clinical investigation) for the treatment (or diagnosis) of a serious or immediately life-threatening disease or condition in patients for whom no comparable or satisfactory alternative drug, device, or other therapy is available. During the course of the research study, it may be appropriate to use the drug or device in the treatment of a patient not able to enroll in the research, in accordance with a specially developed treatment protocol or treatment IND or IDE (21 CFR 312.34 and 812.36).

The provider in this case is regarded as a treating clinician for the patient, and not an investigator for a research participant. The clinician is required to develop and submit a specific protocol application and associated consent document for full IRB review and approval **prior to** the specifically intended single-patient treatment use of an IND or IDE. The clinician should seek FDA approval for the treatment use of an IND or IDE before requesting IRB review. Treatment may begin 30 days after FDA receives the treatment IND or IDE submission, or on earlier notification by FDA that the treatment use described in the protocol may begin, unless FDA notifies the sponsor in writing earlier than the 30 days that the treatment use may not begin.

**Criteria for Treatment IND or Treatment IDE**

FDA will permit an investigational drug or device to be used for a treatment use under a treatment protocol or treatment IND (or IDE) if the clinician/investigator provides sufficient evidence of safety and effectiveness to support such use, or provides reasonable basis that the drug or device may be effective for its intended use in its intended patient population; or would not expose the patients to whom the drug is to be administered to an unreasonable and significant additional risk of illness or injury. The clinician/investigator must demonstrate that:

- (i) The drug (or device) is intended to treat (or diagnose) a serious or immediately life-threatening disease (or condition);
- (ii) There is no comparable or satisfactory alternative drug (or device) or other therapy available to treat (or diagnose) that stage of the disease (or condition) in the intended patient population;
- (iii) The drug (or device) is under investigation in a clinical trial under an IND in effect for the trial (or for the same use under an approved IDE), or all clinical trials have been completed; and
- (iv) The sponsor of the clinical trial (or investigation) is actively pursuing marketing approval (or clearance) of the investigational drug (or device) with due diligence.

To ensure that appropriate safeguards are in place, treatment use of an investigational drug (or device) is conditioned on the sponsor and clinician/investigator complying with the safeguards of the IND (or IDE) process, including the regulations governing informed consent and prior review and approval by the IRB, and the provisions of 21 CFR 312 (or 21 CFR 812) that include distribution of the drug (or device) through qualified experts, maintenance of adequate manufacturing facilities, and submission of IND (or IDE) safety reports.

---

#### **600.5 Emergency Use of an Investigational or Unlicensed Drug or Device**

When a clinician conducts an emergency use of a test article (e.g., investigational drug or device) in a life-threatening situation without prior IRB review, the activity is still regarded as research under FDA regulations and the patient is regarded as a research subject, and the FDA may require data from an emergency use of a test article in a life-threatening situation to be reported in a marketing application. FDA regulations permit the emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days after it is used. (See 21 CFR 56.104(c).) The IRB will determine that the circumstances of the emergency use met FDA regulations. (*Note that any subsequent use of the test article for this purpose at the institution is subject to prior IRB review.*) Whenever possible, the treating clinician should notify one of the Chairs of the IRB of his/her intent to utilize an investigational drug or device for an emergency therapeutic or diagnostic reason at least 24 hours prior to the planned date of the first administration of the drug or use of the device. Review by the IRB Chair for such use is specific and limited to the individual patient. (For more information on procedures to follow, see Procedure 600 PR.1 Emergency Use of an Investigational New Drug (IND) or Device (IDE)).

---

#### **600.6 Compassionate Use of an Investigational or Unapproved Device**

For devices only, FDA recognizes that there are circumstances in which an investigational device is the only option available for a patient faced with a serious, albeit not life-threatening condition (referred to as "compassionate use"). In these circumstances, FDA uses its regulatory discretion in determining whether such use of an investigational device should occur. Unlike emergency use of an unapproved device, **prior FDA approval IS needed** before compassionate use occurs. In order to obtain FDA approval, the sponsor should submit an IDE supplement requesting approval for a protocol deviation under section 812.35(a) in order to treat the patient. (See Procedure 600 PR.2 Compassionate Use of an Investigational or Unapproved Device.)

---

## **Related Information**

IRB Policy 100: IRB Review of Research Proposals

IRB Policy 200: Informed Consent for Research Involving Human Participants

Yale University Policy on the Use of Controlled Substances in Research:  
<http://www.yale.edu/ehs/consub.htm#>

Connecticut Mental Health Center Department of Pharmacy Policy and Procedure Manual: Drug Distribution and Control, Section C-IX

Yale-New Haven Hospital Department of Pharmacy Services Investigational Drug Service Policy

Yale-New Haven Hospital Operating Room New Technology Committee

600 PR 1: Emergency Use of an Investigational New Drug (IND) or Device (IDE)

600 PR 2: Compassionate Use of an Investigational or Unapproved Device

600 GD 1: Guidance on Data and Document Use for the IND Sponsor Investigator

---

## Contacts

Subject	Contact	Phone
Investigational New Drugs or Devices	Human Investigation Committee	203-785-4688

---

## Roles and Responsibilities

### Human Investigation Committee

The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human subjects research conducted by Yale University.

---

## References

FDA Device Advice: Investigational Device Exemption (IDE)  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm>

FDA IRB Information Sheets – Medical Devices (Updated 9/98)  
<http://www.fda.gov/oc/ohrt/irbs/devices.html#emergency>

---

## Revision History:

12/4/2009, 5/5/2010, 5/6/2010