



THE IRB REVIEW

The Office for the Protection for Human Research Subjects (OPHRS)

May 2006

Volume 2, Issue 5

Drugs in Research



FDA definition: (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

Researchers who employ a test article classified by the Food and Drug Administration as an investigational new drug must comply with the FDA's IND regulations ([21 CFR 312](#)). The IND number assigned to the test article must be filed with the IRB when the application for review is submitted.

If a protocol involves a drug and does not include an IND number, the IRB Chair determines whether the proposed activity is exempt from the requirement to submit an IND application to the FDA. If an IND number is required, the IRB Coordinator forwards a written request to the PI requesting documentation of a valid IND number. The proposal will not be forwarded for review until a valid IND number is present.

Research is exempt from the requirement for an IND if it meets the exemption for approved drugs, the exemption for *in vitro* diagnostic biological products, the exemption for *in vitro* or animal use, or if the FDA has granted a determination of exemption.

Devices in Research

FDA definition: A Device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Inside this issue:

<i>Drugs in Research</i>	1
<i>Devices in Research</i>	1
<i>Exemptions</i>	2
<i>Device Determinations</i>	3
<i>Acting as a Sponsor</i>	3
<i>Supplemental Forms</i>	3
<i>Calendar</i>	4

Janine Richardson
 HRPP Director
 (423) 439-6054
 richardf@etsu.edu

Kasey Boyd-Smith
 IRB Secretary
 (423) 439-6053
 boydsmit@etsu.edu

Becky Haas
 IRB Coordinator
 Medical Board
 (423) 439-6055
 haasr@etsu.edu

Aracelis Vasquez
 IRB Coordinator
 Campus Board
 (423) 439-6002
 vasqueza@etsu.edu
 Editor-in-Chief

Exemptions from Requirement for an IND

A. For research to meet the exemption for approved drugs, all of the following must be true:

- ⇒ The drug being used in the research is lawfully marketed in the United States.
- ⇒ The research 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.
- ⇒ The research is not intended to support a significant change in the advertising for the product.
- ⇒ The research 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.
- ⇒ The research is conducted in compliance with FDA requirements for IRB review and informed consent and all of the following are true:
 - ◇ The participant or the participant's representative will date the consent document.
 - ◇ Consent documents include a statement that notes the possibility that the FDA may inspect the records.
 - ◇ The requirement for informed consent will not be waived.
 - ◇ The requirement to obtain written documentation of informed consent will not be waived because the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.
- ⇒ The research is conducted in compliance with all of the following:
 - ◇ The sponsor or investigator, or any person acting on behalf of the sponsor or investigator, will not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug.

- ◇ The sponsor or investigator will not commercially distribute or test market the drug.
- ◇ The sponsor will not unduly prolong an investigation after finding that the results of the investigation appear to establish sufficient data to support a marketing application.
- ◇ The sponsor will not charge for the drug in the clinical trial without the prior written approval of FDA.
- ⇒ The research does not request a waiver from the requirement for informed consent.



B. For research to meet the exemption for *in vitro* diagnostic biological products, all of the following must be true:

- ⇒ The research involves one of the following:
 - ◇ Blood grouping serum
 - ◇ Reagent red blood cells
 - ◇ Anti-human globulin
- ⇒ The article will be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
- ⇒ The article is shipped in compliance with §312.160.

C. For research to meet the exemption for *in vitro* or animal use, all of the following must be true:

- ⇒ The drug intended solely for tests *in vitro* or in laboratory research animals.
- ⇒ The drug is shipped in compliance with §312.160.

D. For research to meet the exemption by FDA determination, the research must have been submitted to the FDA who has determined in writing that an IND is not required.

Device Determinations

Significant Risk Device: is defined [21 CFR 812.3(m)] as a study of 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 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.

An Non-Significant Risk device investigation is one that does not meet the definition for a significant risk study. NSR device studies, however, should not be confused with the concept of "minimal risk," a term utilized in the Institutional Review Board (IRB) regulations [21 CFR part 56] to identify certain studies that may be approved through an "expedited review" procedure.

For both SR and NSR device studies, IRB approval prior to conducting clinical trials and continuing review by the IRB are required. In addition, informed consent must be obtained for either type of study [21 CFR part 50].

In reviewing studies involving medical devices, the Medical Campus IRB will make two determinations:

- ⇒ Whether a device study represents a significant or non-significant risk and
- ⇒ Whether the study should be approved

Determining whether a device study poses a significant risk will be based solely on considerations of risk to subjects while IRB approval of the study is based on many factors.

If the IRB decides the study is Significant Risk,

- ⇒ The IRB Coordinator forwards a letter to notify the sponsor and investigator of the decision that the study is significant risk.



- ⇒ The IRB tables the study until an IDE is obtained by the sponsor.
- ⇒ After IDE is obtained and submitted, the convened IRB reviews the study.

If the IRB decides the study is Non-Significant Risk,

- ⇒ IRB proceeds to review study applying requisite criteria [21 CFR 56.111]

For more details on drug or device, see IRB Policy 19(device) or IRB Policy 33 (drug).



Acting as the Sponsor

If the investigator or organization is acting as the sponsor, the investigator or sponsor must follow all the additional regulatory requirements of sponsors. The IRB must evaluate whether the investigator knows how to follow the additional regulatory requirements of sponsors. In order to determine this evaluation, the IRB requires any investigator acting as the sponsor to read the FDA's "Responsibilities for Sponsors of Significant Risk Device Studies, Responsibilities for Sponsors of Non-Significant Risk Device Studies", "Responsibilities for Investigators of Significant Risk Device Studies, Responsibilities for Investigators of Non-Significant Risk Device Studies" published on-line at <http://www.fda.gov/cdrh/devadvice/ide/print/responsibilities.html>. The IRB receives a signed attestation that the investigator/sponsor has read this document prior to issuing final study approval.

Supplemental Forms

When submitting a protocol to the IRB involving drug or device, a supplemental form for device and/or drug (available on the IRB website) must be submitted with the application. These supplemental forms help the IRB determine that the PI attest to their responsibilities set forth when a drug and/or device is used in a study.

The Office for the Protection for Human Research Subjects

PO Box 70565
Johnson City, TN 37614

Phone: (423) 439-6053
Fax: (423) 439-6060

We're on the web
www.etsu.edu/irb

June 2006

Sun	Mon	Tue	Wed	Thu	Fri	Sat
				1 <i>Campus Board Meeting</i>	2	3
4	5	6 <i>Medical Board Meeting</i>	7	8	9	10
11	12 <i>Deadline for submission for July Meeting</i>	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

Coming Up Next Month

- What to do After Approval of Study



Coming Up in July

- Recruitment/Ads/Payments



IMPORTANT NOTE

IRB Forms have been updated. When submitting an initial proposal or a proposal for continuation review, please check the IRB website for new Forms. Always obtain forms from the IRB website. Do not use older forms that you or someone else have previously saved.