

<b>Title:</b>	Investigational New Drugs (IND), Biologics and Investigational Device Exemptions (IDE)
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	<i>Signature/date</i>
<b>Effective Date:</b>	January 14, 2008
<b>Policy:</b>	1.13

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## **POLICY STATEMENT**

The Institutional Review Board (IRB) is responsible for reviewing and approving FDA regulated clinical investigations involving investigational biologics, devices or drugs in human research participants in accordance with the federal regulations which govern these test articles.

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## **DEFINITIONS**

**FDA:** United States Food and Drug Administration, an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

**Investigational Device Exemption (IDE):** Exemptions from certain regulations found in the Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations [21 CFR 812.20].

**Investigational New Drug (IND):** A drug or biologic permitted by 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.

**Investigator:** In research, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the investigator. (See also: Principal Investigator.)

**Phase 1, 2, 3, 4 Drug Trials:** Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phase 3), to post marketing studies (Phase 4).

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## **REFERENCES**

21 CFR 11  
21 CFR 50  
21 CFR 312  
21 CFR 812

Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors (FDA): *Significant Risk and Non-significant Risk Medical Device Studies*

Information Sheets Guidance for IRBs and Clinical Investigators (FDA): “Off-label” and Investigational Use of Marketed Drugs, Biologics and Medical Devices

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## PRINCIPLES/OVERVIEW

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The Institutional Review Board (IRB) is responsible for reviewing and approving FDA regulated clinical investigations involving investigational biologics, devices or drugs in human research participants in accordance with the federal regulations which govern these test articles. This policy outlines the IRB’s process and reporting criteria for studies which may involve an IND or IDE and training requirements of sponsor-investigators.

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## INDIVIDUALS AFFECTED BY THIS POLICY

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The contents of this policy apply to IRO staff, IRB members, and FHCRC and University of Washington Consortium investigators. Instructions to investigators are posted on the IRO website.

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## PROCEDURES

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### 1. New research applications submitted for IRB review

Investigators complete the *Application for Review* for IRB review and describe, where applicable, the use of an investigational biologic, device or drug as required in IRB *Policy 2.1 New Application*. The Investigator will provide the IRB with the following information via the *Application for Review Form*:

- Will a commercially available drug be used in a new way (e.g., off-label or for a new indication or population)?
- Will an investigational drug or biologic be used in this study?
- Will this study evaluate the efficacy or safety of a medical device?

If consultation is required for making the determination about the relevance of FDA regulations and oversight for the investigational product, the Research Trials Office’s Regulatory Affairs Director will provide investigators and/or the IRB assistance with that process of determination.

GCP training is required for Investigators who are holding either an IND or IDE at FHCRC to ensure they are knowledgeable about their obligations and commitments outlined in the 1572, per 21 CFR 312.53 (1)(g). The Research Trials Office (RTO) offer several courses of GCP training. Accepted courses include:

- In-person lecture at FHCRC
- CITI online course ([www.citiprogram.org](http://www.citiprogram.org)): Refresher Course in *Good Clinical Practice and ICH*.
- ClinSource Modules

Once an Investigator completes the required GCP training, they will forward the certificate of completion to the IRO to update for the training records.

### 2. Continuation review reports, modifications and adverse event reporting to IRB for approved clinical investigations

The investigator is responsible for assuring that FDA regulated clinical investigations receive continuing IRB review and approval. The IRB requests *Continuation Review Reports* as defined in *IRB Policy 2.2 Continuing Review*.

Modifications or changes to research require prior IRB review and approval and the mechanism for submitting modifications are defined in *IRB Policy 2.5 Modifications to Ongoing Activities*.

Investigators will be responsible for reporting to the IRB: a) adverse events or other unanticipated risks to research subjects or others, as described in *IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others* and b) serious or continuing noncompliance with applicable laws and regulation, the FHCRC human research protection programs or determination of the IRB as described in *IRB Policy 1.9 Noncompliance with the Office of the Director's Human Research Protection Program Policy*.

### 3. IRB review and response to investigators

The IRB will provide review of the proposed research as outlined in *IRB Policy 2.1 New Application* and will determine if the following have been met:

For studies which require an Investigational New Drug (IND) application, an IND number must be provided on the *Application for Review*. Patient accrual cannot begin until the IND documentation receives IRB review and approval.

For studies which will employ an investigational device, the IRB will determine if the device is a "Significant Risk" or "Non-Significant Risk" based on the information provided with the *Application for Review*. The IRB will also review the plan provided by the Investigator and approved by the Research Trials Office, Department of Regulatory Affairs for the management, control and use of the device. Patient accrual cannot begin until the IDE documentation receives IRB review and approval.

- *Significant risk devices are those which present a potential for serious risk to the health, safety, or welfare of subjects, and are subject to FDA review. An IDE is required for significant risk devices*
- *Non-significant risk devices include items such as crutches, elastic knee braces, medical chairs, and tongue depressors. Non-significant risk devices do not require an IDE*

The outcome of the IRB's review will be communicated to the Investigator as outlined in *IRB Policy 1.6 Meeting and Meeting Records*.

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## SUPPORTING DOCUMENTS

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IRB Policy 1.6 Meeting and Meeting Records

IRB Policy 1.9 Noncompliance with the Office of the Director's Human Research Protection Program Policy

IRB Policy 2.1 New Application

IRB Policy 2.2 Continuing Review

IRB Policy 2.5 Modifications to Ongoing Activities

IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others  
Application For Review

Continuing Review Report