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| <b>Title:</b>                | Training                          |
| <b>Responsible Office:</b>   | Institutional Review Office (IRO) |
| <b>Responsible Official:</b> | Karen Hansen, IRO Director        |
|                              | <i>Signature/date</i>             |
| <b>Effective Date:</b>       | April 29, 2008                    |
| <b>Policy:</b>               | 2.20                              |

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## **POLICY STATEMENT**

It is the policy of Fred Hutchinson Cancer Research Center (FHCRC) that all personnel involved in the design, conduct, or reporting of research awarded to or sponsored through FHCRC receive training in the protection of human subjects in research. It is also the policy of FHCRC that all Institutional Review Office (IRO) Staff and Institutional Review Board (IRB) Members receive training and ongoing education opportunities.

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## **DEFINITIONS**

**CITI:** Collaborative Institutional Training Initiative. [www.citiprogram.org](http://www.citiprogram.org).

**Human Research Protection Training:** Training that covers, at a minimum, the history of human subjects research, ethical principles, HHS and FDA regulations, IRB structure and function, and the protection of vulnerable populations of research.

**IRO website:** <http://www.fhcrc.org/intranet/IRO/> and subpages.

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## **REFERENCES**

NIH Guide Notice, June 5, 2000. <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

NIH Guide Notice, September 5, 2001. <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html>

NIH Frequently Asked Questions for the Requirement for Education on the Protection of Human Subjects. [http://grants2.nih.gov/grants/policy/hs\\_educ\\_faq.htm](http://grants2.nih.gov/grants/policy/hs_educ_faq.htm)

OHRP Compliance Activities: Common Findings and Guidance 71(p)(d). <http://www.hhs.gov/ohrp/references/findings.pdf>

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## **PRINCIPLES/OVERVIEW**

The NIH requires education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Investigators must provide a description of education completed in the protection of human subjects for each individual identified as “key personnel” in the proposed research.

FHCRCs requirements (1) exceed those of the NIH and (2) apply to all FHCRC studies, regardless of funding source. The training requirements for investigators described here reflect the FHCRCs commitment to the protection of research participants.

Training of IRO staff and IRB members in regulations, guidelines, ethics and policies applicable to human participant research is critical to the FHCRCs ability to protect the rights and welfare of research participants consistently throughout the institution.

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## INDIVIDUALS AFFECTED BY THIS POLICY

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The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

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## PROCEDURES

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### 1. Human Research Protection Training: Requirements for FHCRC personnel

Training in the protection of human research subjects is required for FHCRC investigators involved in one or more of these activities:

- Design: developing the research concept, scientific method, and objectives that involve intervention with a human subject or the use of data or tissue derived from a human subject.
  - Conduct: implementation and management of research involving human subjects. Staff conducting research include principal investigators, research staff working on a research study, and others engaged in research activity supporting the research study (e.g., conducting interviews, surveys, data collection).
  - Reporting: analyzing, summarizing, or preparing manuscripts involving data derived from a research study involving human subjects.
- A. Initial training is required for personnel who are new to FHCRC (within 3 months after beginning employment) or have not had training in human research protection before. Accepted courses include:
- In-person lecture at FHCRC
  - CITI online course ([www.citiprogram.org](http://www.citiprogram.org)): Basic Course in *Biomedical Research* or Basic Course in *Social Behavioral Research*.
  - PRIM&R Investigator 101 (CD-ROM)
- B. Other training (eg, human-subjects lectures at another institution) may fulfill the initial training requirement. IRO staff review the training's content and decide if it will serve. Good Clinical Practice (GCP) training does not fulfill the initial training requirement.
- C. Refresher training is required within 3 years after completing initial training. Accepted courses include:
- In-person lecture at FHCRC (initial or refresher lecture)
  - CITI online course ([www.citiprogram.org](http://www.citiprogram.org)). Refresher Course in *Biomedical Research*, Refresher Course in *Social Behavioral Research*, or Refresher Course in *Good Clinical Practice and ICH*. Retaking a Basic Course is also acceptable.
  - PRIM&R Investigator 101 (CD-ROM)
  - Attendance at conferences on human subjects protection or clinical trial management

- FHCRC lectures on research ethics for trainees ([www.fhcrc.org/science/education/courses/research\\_ethics/](http://www.fhcrc.org/science/education/courses/research_ethics/))
- Good Clinical Practice (GCP) training
- Testing through a book on human subjects protection
- Case studies conducted by investigators
- At least 1 year's IRB membership in the last 2 years
- NIH web-based course (accepted from Puget Sound Oncology Consortium [PSOC] investigators only)

These requirements also apply to a lead principal investigator whose primary appointment is through an organization other than FHCRC (eg, UW, CHRMC, Benaroya Research Institute, Group Health) and who is submitting a protocol through FHCRC IRB committees for review. Any staff or co-investigators working on these protocols are responsible for meeting the training requirements of their parent institution. For these protocols, the PI should append a letter to the IRB protocol application and certify that staff members and co-investigators associated with the protocol have met their relevant institutional training requirements.

- D. Additional Training Requirement for all FHCRC/UW Cancer Consortium Sponsor/Investigators, Principal Investigators and Research Staff involved in the Design, Conduct and Reporting for Clinical Trials and Prevention Trials that involve drugs, biologics and/or devices must complete Good Clinical Practice (GCP) training. GCP two days training courses are developed by the Research Trials Office (RTO). The RTO also recognizes online training courses in lieu of attendance at an in-person GCP training course. The *Good Clinical Practice Training for Clinical Investigators and Research Staff* document describes the GCP training plan.

Examples of staff required to complete GCP training are:

- FHCRC statisticians involved in the protocol design, data analysis and interpretation of the data
- FHCRC staff members involved in protocol development or conduct, including responding to operational issues such as protocol violations, conducting site training, and advising sites in data management.
- FHCRC management who may not be involved in the actual conduct of the protocol but are instead responsible for protocol design (e.g., developing and designing Case Report Forms required by the protocol).

Examples of staff exempt from GCP training requirements:

- data entry staff
- programmers
- administrative staff

## 2. Documentation of Training

Documentation of training is maintained in the IRO using the PIRO database, *Class Evaluation Form*, and one of the *Template Letters (Seminar, CITI, or CDrom)*. Names of personnel who have fulfilled their training requirements are listed on the IRO website. The IRO sends an email reminding individual personnel that their training certification will expire.

Individuals who fail to meet their training requirements may no longer be involved in human research. The IRO will notify the employee, their supervisor, and the Division Director. The employee would need to respond to the notification, confirming they would not be involved in research; they can be reinstated when they complete their training.

If the lead investigator of a study fails to meet the training requirements, the IRB will close the study. It can be reopened when the lead investigator completes the training.

### 3. Human Research Protection Training: IRO Procedures

The IRO staff is responsible for developing new training materials, improving and updating existing materials, presenting training sessions, and maintaining training-related content on the IRO website (except documentation of individuals' training). The *Training Slides*, and *Training Handout*, are presented at the initial in-person training. Similar slides and handouts are presented at the Refresher training.

The IRO documents individuals' training as follows:

- Every month after an in-house training seminar, the participants' names are entered into the IROs database (PIRO).
- The list of participants at <http://www.fhcr.org/intranet/iro/training/participants/index.html> is updated.
- A certification of completion is emailed by the IRO staff to each participant completing any of the training described above except for CITI, which is mailed directly to the participant by CITI.

#### Tracking Human Subjects Training

- New employees:

The IRO training staff receives a daily email notification of new Center employees. Once a week, the IRO training staff emails out the HST survey to new Center employees by logging onto <https://iro.fhcr.org/hstraining/> and selecting "send email". The HST survey automatically is sent to the new Center employees and assists them to determine whether HST is required for their position. The content of the HST survey is maintained by the IRO staff.

After the HST survey is sent, a tickler is automatically generated for 60 days follow-up. After the 60 days, the IRO training staff sends a second email. The tickler is automatically set for another 30 days.

If the new employee does not respond to the 2<sup>nd</sup> email after 30 days, the IRO Assistant Director will call them. The IRO Assistant Director updates tickler for another 30 days.

If the individual does not fulfill HS training after the IRO Assistant's call after 30 days, the IRO Director sends out a letter to the individual's Division Director indicating that the individual has not completed HS training per this policy.

- Refresher training:

Tracking individuals to complete the refresher training is similar to the tracking process for new individuals. The IRO training staff sends out the initial email to individuals 90 days prior to when re-certification is required following the instructions noted above. A tickler is automatically generated for 60 days follow-up.

If the individual has not completed the refresher training after 60 days, the IRO training staff sends out the second email. A tickler is updated for another 30 days.

30 days after the second email is sent and the individual has not completed the refresher requirement, the IRO Assistant Director calls the individual. The IRO Assistant Director updates the tickler for another 30 days.

If the individual fails to complete the refresher training 30 days after the IRO Assistant Director's call, the IRO Director, the IRO Director sends out a letter to the

individual's Division Director indicating that the individual has not completed HS training per this policy.

#### **4. Other Training Materials Provided to Investigators**

*IRB Investigator Guidelines.* These guidelines, available on the IRO website, are available as an orientation and reference for investigators. They summarize regulatory and institutional requirements, the IRBs role and review practices, the responsibilities of investigators, and other resources.

*IRB Dear PI Responsibility Memo.* With every approval of a new study the principal investigator receives a copy of the *Dear PI Responsibility Memo*. The memo reviews logistical details about IRB approval, modifications, adverse event reporting, deviations and violations, and closing studies, and provides contact information of IRO staff.

#### **5. Training of IRO Staff**

The IRO Assistant Director provides an 2 hour orientation on the new staff's first day.

IRO staff are required to review IRO policies relevant to their responsibilities.

Each new IRO staff member is required to take the in-person Human Research Protection Training. Staff members are also encouraged to peruse the web-based CITI modules.

IRO staff receive continuing training and education:

- The IRO Director, the Assistant Director, and one IRB analyst attend a national human subject's conference every year.
- IRO staff is given opportunities to attend local conferences, training and seminars, including the Northwest Association for Biomedical Research (NWABR) Human Subjects Research Regional Conference.
- IRO staff is provided with information regarding other training such as CITI, PRIM&R Investigator 101, etc.
- An IRO staff member monitors FDA, OHRP and other applicable federal agencies for updated guidance and regulations, and routes them to all staff and (if appropriate) IRB members.

#### **6. Training of IRB Members**

All FHCRC IRB Members are appointed by the FHCRC Institutional Official. IRB Members will be reminded that no research subject to the FHCRC HRPP can proceed without review an approval by the IRBs even if it has been approved by some other Center department or official. All new FHCRC IRB Members (including alternate members) must obtain Human Research Protection Training and an Orientation. The IRO Assistant Director provides a comprehensive orientation for new members prior to their first IRB meeting which includes:

- An explanation of the meeting process
- The IRB member reviewer responsibilities
- The IRB members conflict of interest policy
- Types of IRB review
- The IRB member's role at the first meeting
- An overview of the *FHCRC IRB Member Handbook*
- Training Resources

Each IRB member will receive a copy of the *FHCRC IRB Member Handbook*

New IRB members are encouraged to attend the in-person Human Research Protection Training. They are also encouraged to peruse the web-based CITI modules.

- IRB members receive continuing training and education:
- IRB chairpersons are provided opportunities to attend national conferences every other year.
- IRB members are provided opportunities to attend local conferences, training and seminars, including the Northwest Association for Biomedical Research (NWABR) Human Subjects Research Regional Conference.
- IRB members are provided with information regarding other training such as CITI, IRB 101 on a CDrom, etc.
- Educational materials are distributed, if applicable, with the IRB meeting materials; members are encouraged to discuss them at each IRB meeting.
- Each IRB member receives a copy of the journal *IRB*.

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## **SUPPORTING DOCUMENTS**

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Principal Investigator Responsibilities Memorandum  
Training CDrom Checkout  
Training CDrom Template Letter  
Training CITI Template Letter  
Training Class Evaluation Form  
Training Handout  
IRB New Member Orientation Outline  
Training Registration Form  
Training Seminar Template Letter  
Training Slides  
IRB Investigator Guidelines  
Refresher Training Slides and Handouts  
Good Clinical Practice Training for Clinical Investigators and Research Staff