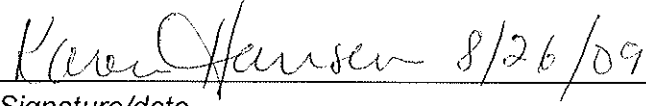


<b>Title:</b>	Staff Structure
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	
	Signature/date
<b>Effective Date:</b>	
<b>Policy:</b>	1.4

**POLICY STATEMENT**

It is the policy of the Fred Hutchinson Cancer Research Center (FHCRC) Institutional Review Office (IRO) to follow the selection and evaluation process to ensure that all the staff coordinating human subjects review activities have the skills, knowledge, and abilities to provide the appropriate level of support for their position.

**DEFINITIONS**

**IRO Staff:** Staff employed within the IRO that are responsible for the IRB operations and HRPP which includes support to three IRB committees. Includes a Director, Assistant Director, IRB Operations Manager, IRB Analysts, IRO Administrative Coordinator II, IRO Administrative Assistant II, FHCRC Administrative Assistant II (Assurance), SOP Administrator, and IRO Director's Administrative Assistant II. Copies of these job descriptions are appended as supporting documents.

**REFERENCES**

OHRP Compliance Activities: Common Findings and Guidance #52, #53

**PRINCIPLES/OVERVIEW**

The IRO staff members involved in the coordination of the review and approval processes used by the IRB committees must have a level of professionalism and competence to adequately conduct their job, as defined in their respective job descriptions.

**INDIVIDUALS AFFECTED BY THIS POLICY**

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.

## PROCEDURES

### 1. Job Descriptions and Selection Process

Each position held in the IRO has a formal description of its duties and responsibilities and qualifications to obtain the position. See individual job descriptions.

The Director and Assistant Director are responsible for the selection and hiring of staff, with input from the IRB Committee Chairs, or other administrative staff, as required.

### 2. Training of IRO Staff

For more specific details on training, please see *IRB 2.20 Policy Training*.

### 3. Staff Structure

Each staff has a back-up individual responsible for their assigned activities in their absence.

There are three (3) IRB Committees, each with its own dedicated IRB analyst.

There are two (2) IRO Administrative Assistants II (AAIL) and one (1) IRO Administrative Coordinator II, each supporting an IRB analyst. The IRB AAIL and IRO Administrative Coordinator II are responsible for most of the processing of IRB documents as well as the set-up and breakdown of the IRB meeting technology requirements.

For the overall organization of the IRO, please see the *Institutional Review Office Organizational Chart*.

### 4. Evaluation Process

The performance of the IRO staff is reviewed at least annually in accordance with FHCRC performance review process administered through FHCRC Human Resources Department.

## SUPPORTING DOCUMENTS

Institutional Review Office Organizational Chart

Job Description: Director, Institutional Review Office

Job Description: Assistant Director, Institutional Review Office

Job Description: Institutional Review Board (IRB) Analyst

Job Description: IRB Operations Manager

Job Description: SOP Administrator

Job Description: FHCRC Administrative Assistant II (Assurance)

Job Description: Administrative Coordinator II – Committees A, B, & C

Job Description: IRO Administrative Assistant II – Committees A, B, & C

Job Description: Assistant to the IRO Director, Administrative Assistant II