Title:	Staff Structure
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official / Approved By:	Meghan Scott, IRO Director

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POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Center (Fred Hutch) 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

See *HRP-001 - SOP - Glossary of Terms and Acronyms* for full definitions of the following:

IRO Staff

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 IRO staff, Institutional Review Board (IRB) members, employees of Fred Hutch and investigators from other institutions who submit research studies to the Fred Hutch 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 IRO Director and IRO 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 staff training, see *IRB Policy 2.20 Training* (038).

3. **Staff Structure**

   Each staff member has a team of back-up individuals responsible for coverage of their assigned activities during absences.

   There are four IRB Committees that are supported by two teams of IRB Analysts and IRB Coordinators. Each team ("pod") supports two IRB Committees and consists of a Senior IRB Analyst (Team Lead) and a mix of IRB Analyst 1, IRB Analyst 2, and IRB Coordinators.

   All team members conduct pre-review and post-review tasks. The Senior IRB Analyst (Team Lead) is responsible for first tier support and assigning work in collaboration with the IRB Ops Manager as needed.

   A Senior IRB Analyst (technical track) triages the bulk of Reportable New Information submissions and drafts most IRB meeting minutes.

   All IRB staff are authorized to independently approve administrative Modifications.

   Staff at the IRB Analyst 1 level and above are authorized to independently make determinations of Not Human Research.

   Determinations of Not Research and Not Engaged are generally made by the IRB Operations Manager or IRO Assistant Director.

   For the overall organization of the IRO, see *HRP-901 - IRO Organizational Chart*.

4. **Evaluation Process**

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

SUPPORTING DOCUMENTS

IRB Policy 2.20 Training (038)

HRP-001 - SOP - Glossary of Terms and Acronyms

HRP-901 - IRO Organizational Chart

REFERENCES

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