


<b>Title:</b>	Database PIRO
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	 8/31/09
	Signature/date
<b>Effective Date:</b>	
<b>Policy:</b>	2.22

**POLICY STATEMENT**

It is the policy of the Fred Hutchinson Cancer Research Center (FHCRC) Institutional Review Office (IRO) to use PIRO (Professional Review Institution Operations), the internally developed software solution, for the establishment and management of the Institutional Review Board (IRB) information and process.

**DEFINITIONS**

**PIRO's main feature** (the database): The administrative front-end which captures, manages and reports IRB activities and issues.

**eReview:** A secure, web-based, electronic retrieval system that IRB Committee members and IRO staff use to access relevant documents and provide comments for items listed on the full and expedited agendas.

**eSubmission:** (a future feature of PIRO), electronic submission of study data, approvals and related documents for the IRB process.

**CORE:** Clinical Oncology Research Entrance (CORE) is a secure website through which eReview is accessed. CORE is maintained by the Clinical Research Division (CRD).

**Elements:** The key, individual components in PIRO to capture essential information related to human subjects research activities (e.g., the title of a study).

**Tickler:** A reminder system allowing IRO staff responsible for the IRB process to follow up and track IRB related activities. For example, each month, tickler ensures that all Continuation Review Reports (CRR) were submitted to prevent lapse in IRB approval.

**Query:** A database function allowing IRO staff to capture or find a certain group of activities based on the given elements. For example, identifying all currently active IR files for a principal investigator (PI) based on the PI's last name.

**Reports:** Documents generated based on pre-defined queries in PIRO. For example, the electronic generation of a Full Review Agenda.

**Validation:** A process of verifying that data entered in by the IRO staff are correct and comply with applicable standards, rules, and conventions.

## REFERENCES

45 CFR §46.115

OHRP Compliance Activities: Common Findings and Guidance #20

OHRP Guidance on Written IRB Procedures: Guidance Relevant to IRB Records and Documentation.

## PRINCIPLES/OVERVIEW

PIRO is the IRO's software solution for the establishment and management of the IRB process. Secure, predefined views into PIRO are used for monitoring IRB-related information such as Conflict of Interest (COI) and Serious Adverse Events (SAE).

## 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. Access level: Who can enter information into PIRO and change elements in PIRO

As with any secured system, PIRO has different levels of access and privileges.

- Administrator: The highest level allowing individuals to change (add, delete or revise) the elements and to add or delete individuals' access to PIRO (e.g., IRO Assistant Director).
- Editor: Individuals who can enter information into PIRO (e.g., IRB analysts).
- Read Only: Individuals who can only view information but can not add or delete information into PIRO. These individuals are also identified as to which specific information they can view (e.g., the Office of the General Counsel can only view general information and specific information regarding Conflict of Interest).

### 2. Getting access to PIRO

For new IRO staff or FHCRC staff requesting access to PIRO, a PIRO Administrator adds new staff to the User tab and selects the appropriate access level. The procedures on how to add a new user are described in the How to set up a new user document.

### 3. Getting access to eReview

To access the secured website, CORE and eReview, FHCRC affiliated members must sign the following two forms maintained by the CRD:

- CORE Access Form (Clinical data Systems – Systems Access form)
- FHCRC Confidentiality Agreement for employee or affiliate

The signed forms are then authorized by the IRO Assistant Director and forwarded to the CRD computing department.

For non FHCRC affiliated IRB members, must complete and forward the following 4 documents to FHCRC Human Resources:

- HR Non-Employee Information Form
- FHCRC Agreements and Understanding Related to Copyrights
- FHCRC Agreement Relating to Inventions

- FHCRC Confidentiality Agreement for employee or affiliate

For new IRB Committee member, a PIRO Administrator adds the new IRB Committee member to the Committee tab.

#### 4. Navigating eReview

During the IRB member's orientation, the IRO Assistant Director instructs the new IRB member on how to access and navigate eReview. PIRO functions

PIRO has many unique features allowing IRO staff to coordinate IRB related activities:

- a. Queries: The ability to abstract specified information
- b. Reports: There are many different reports maintained in PIRO. For a list of reports currently maintained in PIRO, see *List of Reports*.
  - Agendas: Both the full and expedited agendas are generated by the Reports tab in PIRO. See *PIRO Staff Procedures* for specific information.
  - Continuation Review Report (CRR) Renewal Notifications. See *PIRO Staff Procedures*.
- c. Tickler: IRO staff runs a weekly tickler report for their respective activity e.g., IRB analyst for IRB Committee A runs a tickler list for IRB Committee A. This activity ensures that all pending actions are followed up and completed. See *IRB Sample Tickler List*.
- d. Validations. There are several validation activities that are followed:
  - IRB Expedited Agenda: The IRB Administrative Assistant II (AAIL) generates the expedited agenda from the Reports Tab and compares the hard copies of each approved expedited review items are in the appropriate committee basket (next agenda bin for Committee A, B or C). If there are discrepancies (e.g. there is a copy of a Protocol Disposition Form of a new Minimal Risk study but the MR study does not appear on the agenda, the IRB AAIL checks that all the information was entered correctly for that new MR study in PIRO). If not, PIRO is updated.
  - CRR Renewal Notices. See *PIRO Staff Procedures*.

#### 5. Elements entered into PIRO

The IRO staff is responsible to add, delete, update information maintained in PIRO to ensure that the information is current and accurate. IRO staff follows the instructions found in the screener form based on the type of activity as to which information needs to be entered into PIRO.

#### 6. Security and Auditing Requirements

As FHCRC IRO moves towards eSubmission the system will be developed to be 21 CFR Part 11 compliant.

- a. Unique user authentication, verification and password shall be required.
- b. Users must not be able to execute commands as another user.
- c. Passwords shall require periodic change.
- d. Audit trail must record:
  - i. User responsible for action.
  - ii. Date and time of action.
  - iii. Substance of action (e.g. change, deletion, additional information), preferably with actual values retained.

**7. Trouble-shooting**

PIRO emergency contact information:

Technical Support Analyst	Core Access	X4969*
Desktop Support Tech	Laptop Issues	X2734
Systems Analyst/Programmer	Scanning/PDFs	X4599
Systems Analyst/Programmer	PIRO	X6404
IRO Assistant Director	PIRO	X6501

**SUPPORTING DOCUMENTS**

PIRO Staff Procedures  
 IRB Sample Tickler List  
 List of Reports  
 FHCRC Clinical Research Data Systems (Systems Access Form)  
 FHCRC Confidentiality Agreement for employee or affiliate  
 Screener: Meeting Minutes / Agenda Binder