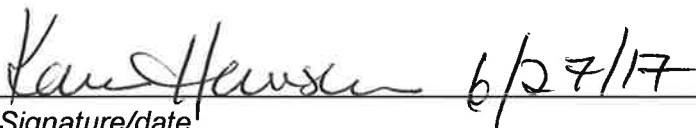




Title:	Database PIRO
Policy:	2.22
Version	3.03
Effective Date	July 3, 2017
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	
	Signature/date 6/27/17

Version History	Effective Date
3.02	08-01-14
3.01	01-31-12
3.00	09-01-09
2.00	08-01-07

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research Center (Fred Hutch) 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 Continuing 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 Fred Hutch and investigators from other institutions who submit research studies to the Fred Hutch 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 Fred Hutch 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, Fred Hutch affiliated members must have a Fred Hutch "HutchNet ID" and follow all the necessary security procedures associated with obtaining access to the Fred Hutch network.

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

- HR Non-Employee Information Form
- Fred Hutch Agreements and Understanding Related to Copyrights
- Fred Hutch Agreement Relating to Inventions
- Fred Hutch 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.
 - Continuing 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 (AAll) 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, C, or D). If there are discrepancies (e.g. there is a copy of a Research Modification Form but the modification does not appear on the agenda, the IRB AAll checks that all the information was entered correctly for that review 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, and 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. 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

Fred Hutch Clinical Research Data Systems (Systems Access Form)

Fred Hutch Confidentiality Agreement for employee or affiliate

Screeener: Meeting Minutes / Agenda Binder