

<b>Title:</b>	Approval Date Guidelines and Turnaround Times
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	<i>Signature/date</i>
<b>Effective Date:</b>	January 14, 2008
<b>Policy:</b>	1.8

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## **POLICY STATEMENT**

It is the policy of the Fred Hutchinson Cancer Research Center (FHCRC) Institutional Review Office (IRO) that IRB approved activities are given approval dates per the *Approval Date Guidelines*. The *Turnaround Times Guidelines* provide the turn around time for IRO staff to process and to provide the approval documents to principal investigators (PI) in a timely manner.

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## **DEFINITIONS**

None

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## **REFERENCES**

OHRP Compliance Activities: Common Findings and Guidance (July 10, 2002) - #42  
 OHRP Guidance on Continuing Review  
 OHRP Guidance on Written IRB Procedures

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## **PRINCIPLES/OVERVIEW**

The *Approval Date Guidelines* are used by the IRO staff to determine the approval dates for all activities related to IRB activities, e.g., new application and modifications made to on-going activities. The approval dates inform PIs when they can start enrollment of research participants, when they can use the approved documents, methods, etc., as well as when their studies expire.

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## **INDIVIDUALS AFFECTED BY THIS POLICY**

The contents of this policy apply to IRO staff, IRB members, principal investigators and employees of FHCRC and University of Washington (UW) consortium, study monitors, auditors or sponsors. Instructions for reporting are posted on the IRO website.

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## **PROCEDURES**

### **1. Approval Date Guidelines**

- a. *The Approval Date Guidelines* outline the approval dates given to different outcomes resulting from the IRB review and approval process.

- b. IRB documents receiving “approved from date” and “approved through date” are:
- i. *Application for Review*
  - ii. *Protocol Modification Form*
  - iii. *Continuation Review Report*
- c. IRB documents receiving “IRB Chair signature date” are:
- *Adverse Event Reporting Form*
  - Miscellaneous memos
  - *Unanticipated Problem Reporting Form*
  - *Noncompliance Reporting Form*
  - *Emergency Treatment Acknowledgement Report*
  - Closure reports
- d. Full review activities: The “approved from date” is the IRB Committee meeting (agenda) date and the “approved through date” is the last date of the IRB approval period. The “approved through date” indicates the last day when a study is active and approved. For example, if a study is approved from 10/2/07 to 10/1/08, the study may use its approved documents such as an approach letter or consent document until midnight on 10/1/08.
- e. Expedited review activities: The “approved from date” is the same date as the “documents released date” and the “approved through date” is the last date of the IRB approval period.
- f. The “documents released date” is the date the IRB Chair or designee signed the final approved documents.
- i. Full review items with minor modifications requested: When the IRB Chair or designee reviews and approves the PIs response to minor contingencies requested by the IRB Committee, the "documents released date" represents when the IRB Chair or designee reviews and approves the PI responses and revisions.  
  
The “approved from date” is the IRB Committee meeting (agenda) date. For example, if the IRB meeting date is 1/1/06 and the IRB Chair reviewed and approved the PIs response on 1/10/06, the approval period for this study is 1/1/06 to 12/31/06. The “date documents released” date is 1/10/06 which is the date the IRB Chair gave final approval and signed the approved documents.
  - ii. A full review activity that is approved as submitted will have a "documents released date" that is the IRB Committee meeting (agenda) date. For example, the IRB Committee meeting was 1/10/06 and the new application was approved as submitted, the approval period for the new application is: 1/10/06 to 1/09/07.
  - iii. For all activities that undergo expedited review and approval, the "documents released date" represents the IRB Chair's signature date. For example, if the IRB Chair reviewed and approved a PMF on 1/10/06 and the study's expiration date is 5/12/06, the approval dates for this PMF are 1/10/06 to 5/12/06.
- g. Stamping IRB approved documents:
- The "documents released date" stamp is applied to all study documents except the consent.
  - Consent Documents: The stamp "consent released date" to "consent expiration date" is applied to all consents where accrual is active. The “consent expiration date” indicates the last day when a consent form can be used. For example, if a consent form is stamped 10/2/07 to 10/1/08, the study may use the consent form until midnight on 10/1/08. The "documents released date" is the same as the "consent released date" in all scenarios where accrual is continuing.

## 2. Correcting Wrong Approval Dates:

- a. When an activity (e.g. continuation review report) is given incorrect approval dates, the *Correction Memo* is forwarded to the PI/contact person notifying them of the corrective actions taken along with the corrected documents. The IRO staff uses a black ink pen, drawing a single line through the incorrect date(s), adds the correct dates and their initials and date of correction.
- b. A copy of the *Correction Memo* is stamped with the “Expedited” stamp grid and forwarded to the appropriate IRB Chair for signature.
- c. After the IRB Chair acknowledges the *Correction Memo*, the database is updated with the correct dates in the appropriate tab. In addition, new entry is added in the MISC tab. All fields are completed, for example:
  - Type = Memo
  - Review type = Admin
  - Report date = date of memo
  - Approved by = <insert Chair’s name>
  - Comment field = Corrected approval dates on <insert type of activity>
  - Agenda date = next agenda date
- d. The signed memo is fastened in the IR file and the front of the file folder reflects the corrective action taken. A copy of the correction memo is placed in the next agenda bin.

## 3. Turnaround Times Guidelines

The *Turnaround Times Guidelines* indicate the timeframe in which approved documents should be processed and forwarded back to the PI/contact person. These guidelines also indicate the turnaround time to forward documents to appropriate IRO staff, IRB Chair, Institutional Officials, or regulatory agencies.

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## SUPPORTING DOCUMENTS

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Approval Dates Guidelines  
Turnaround Times Guidelines  
Correction Memo  
Application for Review  
Protocol Modification Form  
Continuation Review Report  
Adverse Event Reporting Form  
Unanticipated Problem Reporting Form  
Noncompliance Reporting Form  
Emergency Treatment Acknowledgement Report